Medtronic

Statistical Analysis Plan

Clinical Investigation Plan Title	AF Septal pacing
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Confidentiality Statement

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2. Version History

Version	Summary of Changes	Author(s)/Title
1.0	• 'Not Applicable, New Document'	Berthold Stegemann, Sr Prin Scientist

3. List of Abbreviations and Definitions of Terms

Abbreviation	Term
AEAC	Adverse Event Advisory Committee
AE	Adverse Event
AF	Atrial fibrillation
AFCL	AF cycle length
AT	Atrial tachy arrhythmia
BRC	Bakken Research Center
CIP	Clinical Investigation Plan
CS	Coronary sinus
DD	Device Deficiency
EC	Ethics Committee
ECG	Electrocardiogram
EP	Electrophysiology
IB	Investigator Brochure
ICF	Informed consent form

Abbreviation	Term
LBBB	Left Bundle Branch Block
LV	Left Ventricle
LVEDV	Left Ventricular End Diastolic Volume
LVEF	Left Ventricular Ejection Fraction
LVESV	Left Ventricular End Systolic Volume
LVEF	Left Ventricular Ejection Fraction
LVESV	Left Ventricular End Systolic Volume
MEC	Medical Ethics Committee
PIC	Patient Informed Consent
RA	Right Atrium
RBBB	Right Bundle Branch Block
RV	Right Ventricle
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan

4. Introduction

Pacemaker-based therapy for atrial fibrillation (AF) has been discussed as an alternative to drugs and ablation for patients with a conventional indication for pacing. (Redfearn and Yee 2006) (Ellenbogen 2007) Today, many pacemakers and implantable defibrillators include pacing algorithms developed for the prevention or the termination of AF. (Redfearn and Yee 2006) Most existing pacing algorithms have a preventive nature, designed to suppress AF triggers and to reduce the dispersion of atrial refractoriness that predisposes to re-entry (Ellenbogen 2007). Preventive pacing algorithms are primarily designed to decrease premature atrial contractions and prevent pauses, but results of clinical trials with these algorithms have been mixed, probably because of the differences in study design, pacing algorithms and patient populations. (Knight, Gersh et al. 2005) (Carlson, Ip et al. 2003) (LUIGI, HELMUT et al. 2003) (Gold, Adler et al. 2009) Anti-tachycardia pacing (ATP) algorithms designed to terminate atrial tachycardia's deliver pacing bursts at a cycle length shorter than that of the detected arrhythmia. (Redfearn and Yee

2006), (Ellenbogen 2007) While successful ATP could be observed in terminating atrial flutter or organized atrial tachycardia's, it has proved difficult to interpret the results from clinical studies evaluating ATP for AF. (Redfearn and Yee 2006), (Gillis, Koehler et al. 2005), (Gulizia, Mangiameli et al. 2006) Therefore, the evidence of treating AF by pacing is limited, although these algorithms are of interest, since they appear to be safe and usually add little additional cost. (Knight, Gersh et al. 2005) (Gold, Adler et al. 2009).

Animal and human mapping experiments showed that although termination of AF by rapid pacing was not observed, the possibility of creating an area of local capture of the atrial tissue by rapid pacing of AF has been demonstrated. (Allessie, Kirchhof et al. 1991) (Kirchhof, Chorro et al. 1993) (Daoud, Pariseau et al. 1996) (Pandozi, Bianconi et al. 1997)For this reason, a computer model of AF has been used to systematically simulate all existing ATP algorithms on AF and test all pacing locations. (Fukuta, Goto et al. 2017). As a result, the septum has proven to be the only pacing site yielding to sporadic AF capture episodes in both atria, even if not resulting in AF termination or permanent changes in AF patterns. Based on these findings, a new dual-stage septal pacing has been developed in the computer model to suppress AF reentries: rapid pacing was applied from the septal area following a dual-stage scheme: 1) rapid pacing for 10-30 s at pacing intervals 62-70% of AF cycle length (AFCL), 2) slow pacing for 1.5 s at 180% AFCL, initiated by a single stimulus at 130% AFCL. (Spencer, Zhu et al. 1997 The AF septal pacing algorithm concept, from a ring of stimulation electrodes on the interatrial septum, is described in Figure 1 and in the publication by Uldry et al (Spencer, Zhu et al. 1997. The septal pacing concept had been developed and tested in a computer model of AF and in a pig model. Uldry, Virag et al. 2012) Experimental studies are now needed to determine whether similar termination mechanisms and efficacies can be observed in humans.

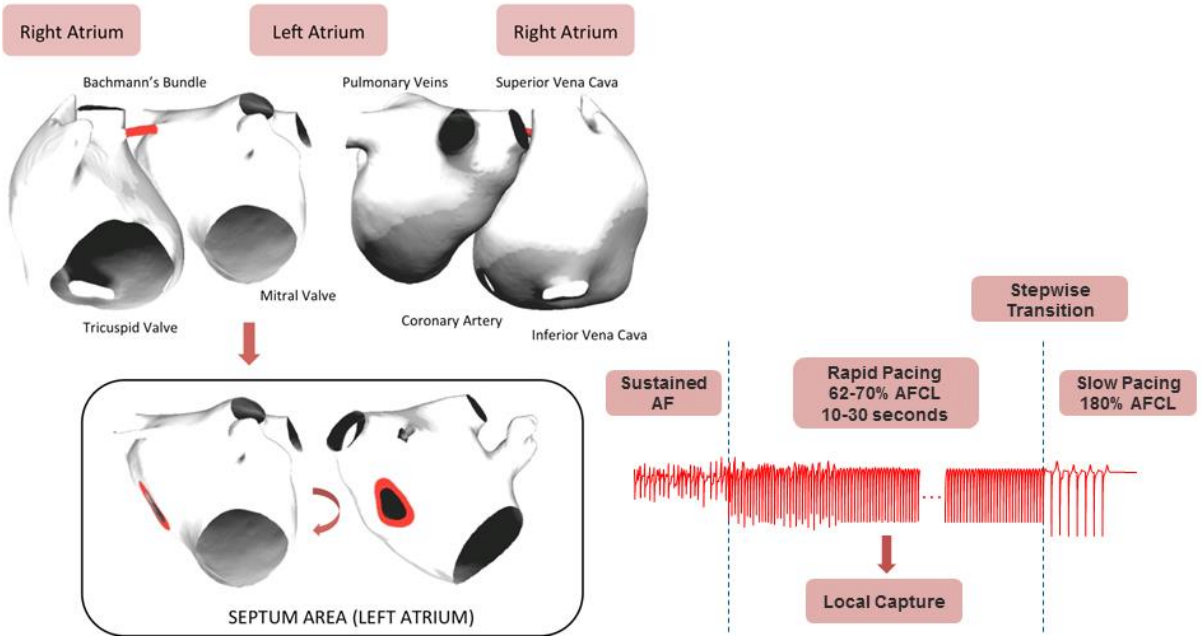


Figure 1: Septal-pacing dual-stage pacing scheme: rapid pacing until local capture is achieved, followed by slow pacing, with a step-wise transitions from 130% AFCL (one cycle) to 180% AFCL. Electrodes on the septum should be placed in the area indicated in red (as found in the computer model Luca et al[24]).

5. Study Objectives

5.1 Primary Objective

The primary objective of the study is to evaluate the feasibility to obtain a stable position of a ring of stimulation electrodes on the interatrial septum.

5.2 Secondary Objectives

The secondary objectives of this study are:

- Localized Atrial Capture: evaluate if during the rapid pacing phase of the two-stage septal pacing scheme (rapid pacing followed by a step-wise transition to slow-pacing) from multiple electrodes on the interatrial septum, local atrial capture can be observed during atrial fibrillation.
- AF Termination Scheme: evaluate if AF termination can be obtained using a dual-stage septal pacing scheme (rapid pacing followed by a step-wise transition to slow-pacing) from multiple electrodes on the interatrial septum.

6. Investigation Plan

The AF Septal Pacing study is a non-randomized, non-controlled, acute, single-arm research study that will be conducted in up to three European centers.

Approximately 15 subjects with AF indicated for ablation of the pulmonary vein will be enrolled in the study. Participants will attend the Baseline visit and the Procedure visit that can occur on the same day. Since it is an acute study, no follow-up visit will occur. The research procedure will be performed during an already scheduled ablation procedure.

The point of enrollment is the time when subject signs and dates the Informed Consent Form (ICF). At that point, the subject is considered included in the study.

Selection of subjects, treatment of subjects, and evaluation of study data are potential sources of bias. Methods incorporated in the study design to minimize potential bias include (but are not limited to):

- Patients will be screened to confirm eligibility for enrollment in accordance to the inclusion/exclusion criteria.
- Subject demographics will be collected at baseline on possible differences that may affect the primary objective.
- All study clinicians, participating site personnel, and Medtronic personnel will be trained on their respective pertinent role of the study using standardized training materials.

No control group, no randomization and no blinding will be used in this Study.

Clinical Study Flowchart is summarized in Figure 2:

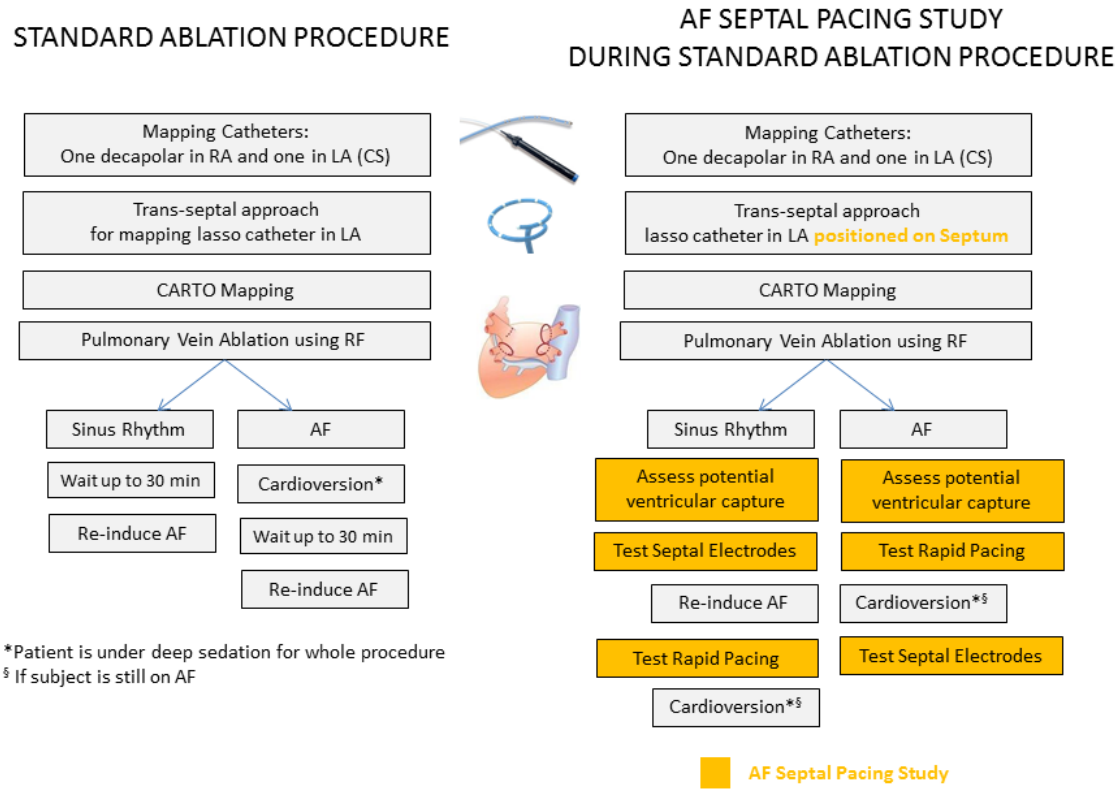


Figure2: Standard ablation procedure (left side) and experimental procedure (right side, yellow boxes) performed during standard procedures.

6.1 Inclusion Criteria

All below inclusion criteria must be met:

- Patient referred to the center to undergo ablation of the pulmonary vein using radiofrequency (initial AF ablation or redo procedure).
- In case of paroxysmal AF, the right atrium should be dilated as indicated by > 29 ml mm^2 or the left atrium should be dilated as indicated by > 34 ml mm^2.
- Patient is willing and able to cooperate with the study procedure.
- Patient is willing to provide the Informed Consent for their participation in the study.

6.2 Exclusion Criteria

None of the below exclusion criteria must be met:

- Patients under 18 years or over 80 years old.
- Women who are currently pregnant or have a positive pregnancy test.
- Patients with an implantable cardiac device
- Patients who already underwent an AF septal ablation procedure.

7. Determination of Sample Size

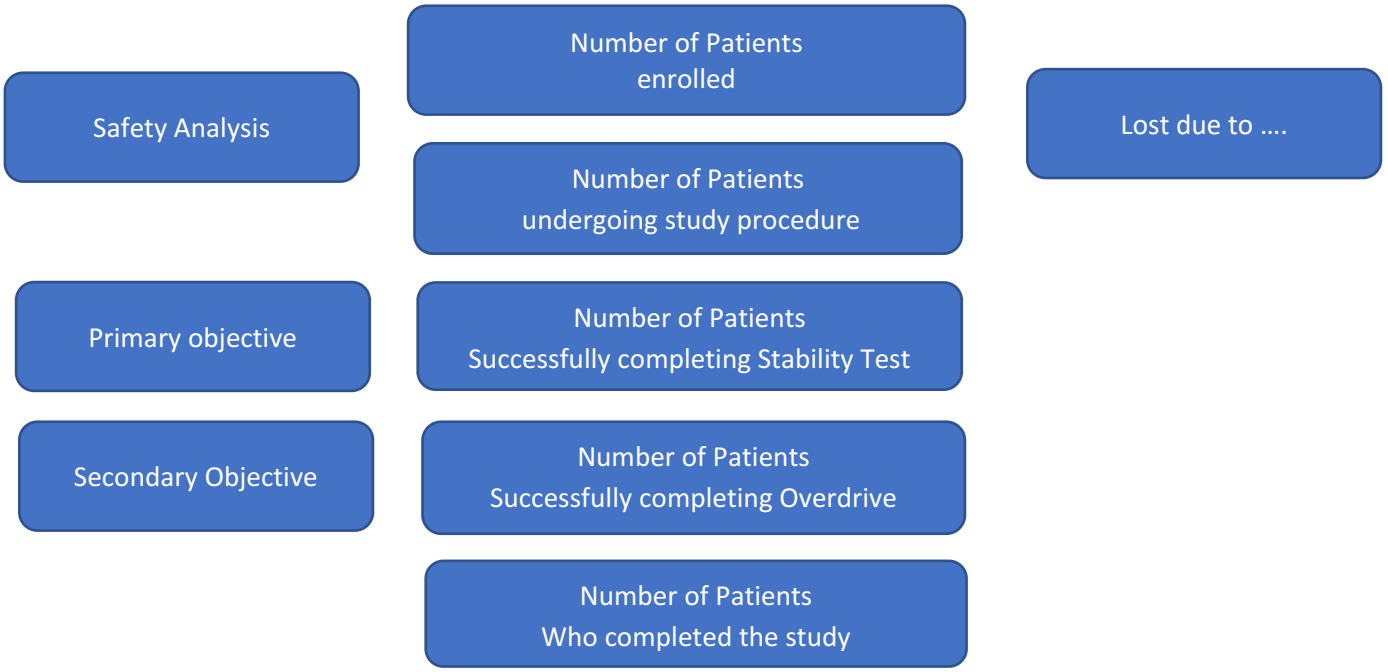
As this is a feasibility study, no formal statistical hypotheses are being tested and no sample size calculation was performed.

8. Statistical Methods

8.1 Study Subjects

8.1.1 Disposition of Subjects

The subject disposition will be described in terms of: number of patients enrolled, number of patients undergoing the study stability test, number of patients undergoing the overdrive stimulation test, patients completing the study.



8.1.2 Clinical Investigation Plan (CIP) Deviations

Any deviation(s) from the original statistical plan will be described and justified in the final report.

8.1.3 Intention to Treat Dataset

The “intention to treat” (ITT) dataset will be the primary dataset for patient baseline and safety related reporting. All patients that meet the study inclusion and exclusion criteria, that signed the informed consent, and underwent the clinically indicated ablation procedure are part of the intention to treat dataset. Patients that did not undergo the ablation procedure are not part of the intention to treat dataset.

8.1.4 Per Protocol Dataset

The “per protocol” (PP) dataset will be the primary dataset for the analysis of the primary and secondary study objective. All patients where the septal lead was placed, and the septal pacing threshold test was performed are part of the per protocol dataset. Patients remain in the per protocol dataset if no high rate overdrive pacing was performed.

8.1.5 Clinical Investigation Plan (CIP) Deviations

8.2 General Methodology

Data analysis will be performed on the final frozen set of data. Data will be read only for the analysis, and data will not be modified during analysis. Analysis code will be written, appropriately documented, and version controlled. Analysis code will be kept together with the data analysis. Analysis code will be validated before final analysis. Missing data will be included in the analysis. No imputation of missing data will be done.

Data will be displayed graphically as single or multiple (for subgroups) box plots.

All statistical analyses will be performed using R – language and environment for statistical programming and graphics (version 3.X) or alternatively other accepted statistical software.

Subject data listings and tabular and graphical presentations of analysis results will be provided.

Analysis of all safety related data, including study deviations and adverse events will be based on the “intent to treat” (ITT) principle and dataset.

Analysis of all primary, secondary objectives will be done on the per protocol data set; patient data will be summarized for the per protocol data set as well.

8.2.1 Analysis of Baseline Data

All clinically relevant baseline variables will be tabulated and reported. Categorical variables will be reported using counts and percentages, and continuous variables will be reported by giving the number of known values, the mean, standard deviation, median, minimum and maximum values. Number of missing data for continuous variables will be reported as well.

8.3 Handling of Missing, Unused, and Spurious Data and Dropouts

Missing data will be excluded from the statistical analysis. Missing data will be reported for each variable. No imputation method for missing data is planned.

8.4 Adjustments for Multiple Comparisons

The study is descriptive in nature, and statistical reporting will be descriptive. There are several groups of interest to look at, such as unipolar / bipolar stimulation, different leads, different centers, …, etc. No statistical comparison is planned between groups, and thus no adjustment for multiple comparison is required.

8.5 Demographic and Other Baseline Characteristics

Demographic and baseline characteristics are divided in continuous and categorical data that will be summarized in table format.

- Age, Gender, Weight, Height, right and left atrial volume index are considered continuous data for which count of data, count of missing data, mean, median, standard deviation, minimal and maximal values will be computed.
- Atrial arrhythmia, Sinus node dysfunction, Ventricular Arrhythmia, and AV-junctional arrhythmia and blocks are instead categorical variables for which count of data and count of missing data, number and percentage per category will be calculated..

8.6 Treatment Characteristics

Procedure data will be summarized in table format as count of data, count of missing data, mean, median, standard deviation, minimal and maximal values for continuous variables, and count of data and count of missing data, number and percentage per category, for categorical data.

The following continuous data will be summarized and reported as described above:

- Current Medication at the start of the procedure
- Medication given during procedure

The following categorical variables will be summarized and described as above:

- Type of Anesthesia
  - General
  - Sedation
- Type of AF treated:
  - Paroxysmal
  - Persistent
  - Permanent
- Type of AF procedure
  - Initial
  - Redo
- Outcome of PVI ablation
- Tabulation of devices used for atrial septal pacing.

8.7 Evaluation of Objectives

The primary objective is purely descriptive. The per protocol dataset will be used for evaluation of the primary and secondary objective. Reporting on primary and secondary objective will be initially done for the full protocol dataset. Pre-defined subgroups will be described including the following: Per Center analysis, per initial arrhythmia, per septal lead, per patient mode (unipolar vs. bipolar).

8.7.1 Primary Objective

The primary objective of the study is to evaluate the feasibility to obtain a stable position of a ring of stimulation electrodes on the interatrial septum (stability performance).

Specifically, this primary objective of stable position of a ring of stimulation electrodes on the atrial septum also includes pacing threshold, pacing impedance, stability criterion and safety criterion variables. These data will be summarized in table format as count of data, count of missing data, mean, median, standard deviation, minimal and maximal values for continuous variables, and count of data and count of missing data, number and percentage per category, for categorical data.

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Description of stability performance assessed on *per patient basis* includes:

- Description of overall stability criterion (pacing threshold < 10 mA) (categorical variable)
- Description of the number of electrode pairs reaching the stability criterion;
- Description of safety criterion (no ventricular capture) (categorical variable)
- Description of the number of electrode pairs reaching the safety criterion

Description of stability performance assessed on *electrode pair basis*:

- Description of the pacing threshold (continuous variable)
- Description of the pacing impedance (continuous variable)
- Description of stability criterion (pacing threshold < 10 mA) (categorical variable)
- Description of safety criterion (ventricular capture) (categorical variable)
    - ○

8.7.2 Secondary Objectives

The secondary objectives of this study are:

Localized Atrial Capture: evaluate if during the rapid pacing phase at a given coupling from multiple electrodes on the interatrial septum, local atrial capture can be observed during AF. Atrial capture is obtained from the electrocardiogram recordings from the interatrial septal catheter, the coronary sinus catheter and the right atrial catheter. Capture is defined as a consistent temporal association of an electrocardiogram signal and the pacing stimulus.

Initially interatrial septal pacing electrodes will be identified by it's electrode number. The electrode number will be translated by the project scientist with support of a clinician trained and experienced in the AF Ablation procedure into an anatomic location. This translation process will be done by the scientist and the clinician based on fluoroscopy recordings collected during the procedure. The data will be entered into the analysis database. The position will be consistently assigned into a clockwise scheme starting e.g. from cranial/superior at 12:00.

Atrial capture analysis will be based on the electrocardiograms recorded from the interatrial septal electrodes, the coronary sinus electrodes and the right atrial electrodes. The analysis will be performed automatically using Matlab and the results will be entered into the analysis database by the project scientist.

Capture will be classified as:

1) any atrial capture on a specific electrode during the atrial septal pacing period
2) % temporal atrial capture as an estimate of how many of the delivered interatrial pulses lead to an atrial capture on any sensing electrode
3) % spatial atrial capture as an estimate of on how many of the monitoring electrodes will be able to detect atrial capture

The anatomical distance will between any CS and RA electrode and the interatrial septum will be estimated by a clinician trained and experienced in the AF ablation procedure. The distance estimate will be obtained based on the fluoroscopic recordings. The inter-electrode distance of the diagnostic catheters will be used to help quantifying the distance in cm.

AF Termination Scheme: evaluate if AF termination was observed during the experimental atrial septal pacing scheme from multiple electrodes on the interatrial septum. Acute procedural AF termination was defined as termination of AF to SR or a regular atrial tachycardia/flutter during the experimental pacing procedure without re-initiation of atrial fibrillation during the experimental pacing scheme.

AF termination will be described as the count and frequency of any AF termination

Subgroup descriptions and summary of atrial capture and AF termination will be done for:

- Atrial fibrillation group (SR vs AF group)
- Catheter type (Achieve vs. Lasso or other)
- Anatomical electrode position
- Atrial Cycle Length

8.8 Safety Evaluation

All adverse events (AE) will be reported. Summary description of all adverse event will be provided for each reported AE.

For serious adverse events (SAE), device related adverse events, and unanticipated adverse device effects (UADE) a detailed description will be provided.

8.9 Health Outcomes Analyses

No Health Outcome Analysis will be performed. This is an acute study, and no health outcome data were recorded.

8.10 Changes to Planned Analysis

Changes to the Planned Analysis need to be reviewed and agreed by the project statistician and the project scientist.

9. Validation Requirements

Matlab analysis validation. Results from Matlab code will be validated before use for the final analysis. A random subset of datasets will be both analyzed manually and automatically. Appropriate agreement between the manual reading and the automatic reading needs to be confirmed for validation. Alternatively, sample datasets with a known performance may be used for validation.

Statistical analysis validation. Results from the statistical analysis code will be validated before use for internal and external reporting. The analysis code will be reviewed for correctness before running the final analysis. A validation dataset will be created with known results. The analysis code is validated comparing consistency between the results of the know results and the results from the statistical analysis code. Results obtained from running the analysis code will be reviewed by the project statistician and the project scientist prior to use.

10. References

Allessie, M., C. Kirchhof, et al. (1991). "Regional control of atrial fibrillation by rapid pacing in conscious dogs." Circulation **84**(4): 1689-1697.

Carlson, M. D., J. Ip, et al. (2003). "A new pacemaker algorithm for the treatment of atrial fibrillation: Results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT)." Journal of the American College of Cardiology **42**(4): 627-633.

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Ellenbogen, K. (2007). "Pacing therapy for prevention of atrial fibrillation." Heart Rhythm **4**(S84-87).

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Gold, M. R., S. Adler, et al. (2009). "Impact of atrial prevention pacing on atrial fibrillation burden: Primary results of the Study of Atrial Fibrillation Reduction (SAFARI) trial." Heart Rhythm **6**(3): 295-301.

Gulizia, M., S. Mangiameli, et al. (2006). "Randomized comparison between Ramp and Burst+ atrial antitachycardia pacing therapies in patients suffering from sinus node disease and atrial fibrillation and implanted with a DDDRP device." EP Europace **8**(7): 465-473.

Kirchhof, C., F. Chorro, et al. (1993). "Regional entrainment of atrial fibrillation studied by high-resolution mapping in open-chest dogs." Circulation **88**(2): 736-749.

Knight, B. P., B. J. Gersh, et al. (2005). "Role of Permanent Pacing to Prevent Atrial Fibrillation." Science Advisory From the American Heart Association Council on Clinical Cardiology (Subcommittee on Electrocardiography and Arrhythmias) and the Quality of Care and Outcomes Research Interdisciplinary Working Group, in Collaboration With the Heart Rhythm Society **111**(2): 240-243.

Luigi, P., P. Helmut, et al. (2003). "Combined Efficacy of Atrial Septal Lead Placement and Atrial Pacing Algorithms for Prevention of Paroxysmal Atrial Tachyarrhythmia." Journal of Cardiovascular Electrophysiology **14**(11): 1189-1195.

Pandozi, C., L. Bianconi, et al. (1997). "Local Capture by Atrial Pacing in Spontaneous Chronic Atrial Fibrillation." Circulation **95**(10): 2416-2422.

Redfearn, D. and R. Yee (2006). "Pacing delivered rate and rhythm control for atrial fibrillation." Curr Opin Cardiol. **21**(2): 83-87.

Statistical Appendices

Result table of Baseline variables for continuous variables. Data will be reported in the text for all patients, and for each analyzed subgroup.

Result table of baseline descriptive for categorical baseline variables. Data will be reported in the format of the table 1 below or text for all patients, and for each analyzed subgroup.

Table 1: baseline descriptives

Variable	Data Count	Data missing	Yes Count	Yes %	No Count	No %
Male Gender [Yes, No]						
Atrial Arrhythmia [Yes, No]						
Sinus Node Dysfunction [Yes, No]						
Ventricular Arrhythmia [Yes, No]						
AV junctional arrhythmia & blocks [Yes, No]						
Catheter [Model 1]						
Catheter [Model 2]						
Catheter [Model 3]						

Result table of stability performance assessment of the atrial septal ring electrodes. Data will be reported in the format of the table 2 or text below for all patients, and for each analyzed subgroup.

Table 2: stability performance

Variable	Data Count	Data missing	Median	Mean	Standard deviation	Minimum	Maximum
Pacing Threshold [mA]							
Pacing Pulse width [ms]							
Pacing Impedance [Ohm]							

Variable	Data Count	Data missing	Yes Count	Yes %	No Count	No %
Any capture [Yes, No]						
Stability capture [Yes, No]						
Ventricular capture [Yes, No]						

Result table of atrial septal pacing capture. Data will be reported in the format of the table 3 below or text for all patients, and for each analyzed subgroup.

Table 3: atrial septal pacing capture

Variable	Data Count	Data missing	Median	Mean	Standard deviation	Minimum	Maximum
Percentage Atrial Capture []							
AF cycle length [ms]							
AF coupling interval [ms]							

Data table description for baseline data (Table 1B).

Key Fields	Form	Field	Value
Key1	StudyBaseline	Ctr	[ctrcode]
Key2	StudyBaseline	PatID	[yes, no, na]
	StudyBaseline	Age	[18...100]
	StudyBaseline	Date	[DD-MMM-YYYY]
	StudyBaseline	Gender	[male, female, na]
	StudyBaseline	Weight	[40 ...150]
	StudyBaseline	Height	[100 ... 200]
	StudyBaseline	IC-signed	[yes, no, na]
	StudyBaseline	Inclusion_1	[yes, no, na]
	StudyBaseline	Inclusion_2	[yes, no, na]
	StudyBaseline	Inclusion_3	[yes, no, na]
	StudyBaseline	Inclusion_4	[yes, no, na]
	StudyBaseline	Exclusion_1	[yes, no, na]
	StudyBaseline	Exclusion_2	[yes, no, na]
	StudyBaseline	Exclusion_3	[yes, no, na]
	StudyBaseline	Exclusion_4	[yes, no, na]
	StudyBaseline	AA	[yes, no, na]
	StudyBaseline	SND	[yes, no, na]
	StudyBaseline	VA	[yes, no, na]
	StudyBaseline	AVJ	[yes, no, na]
	StudyBaseline	AVJ1	[yes, no, na]
	StudyBaseline	AVJ2	[yes, no, na]
	StudyBaseline	AVJ3	[yes, no, na]
	StudyBaseline	RAI	[5 ... 50]
	StudyBaseline	LAI	[5 ... 50]

Data table description for procedure data (Table 2B).

Key Fields	Key1	Key2								
Form	StudyBaseline	StudyBaseline	StudyBaseline		StudyBaseline	StudyBaseline	StudyBaseline	StudyBaseline	StudyBaseline	StudyBaseline
Field	Ctr	PatID	Date	Anesthesia	AF_treated	AF_type	AF_Ablate_AF	Catheter_name	Catheter_model	Catheter_sn
Value	[ctrcode]	[yes, no, na]	[DD-MMM-YYYY]	[General, Sedation, na]	[parox, persist, permanent, na]	[initial, redo, na]	[yes, no, na]	[text]	[text]	[text]

Data table description for pacing capture analysis (Table 3B).

Value	Field	Form	Key Fields
[ctrcode]	Ctr	StudyProc	Key1
[patcode]	PatID	StudyProc	Key2
[modelname]	Catheter	StudyProc	
[AF, SR]	Rhythmprotocol	StudyProc	
[1 … 10]	Electrode	StudyProc	
[locationcode]	Stimlocation	Scientist	
[uni, bipolar]	Stimmode	Scientist	
[0 … 25]	Pacingthreshold	StudyProc	
[mA, V]	PacingThresholdUnit	StudyProc	
[0 … 2000]	Impedance	StudyProc	
[yes, no, na]	AnyAtrialCapture	StudyProc	
[yes, no, na]	StableAtrialCapture	StudyProc	
[yes, no, na]	Ventcapture	StudyProc	
[0 … 25]	VentCaptureThreshhold	StudyProc	
[mA, V]	VentCaptureUnit	StudyProc	
[yes, no, na]	StablePosition	StudyProc	

Data table description for electrode configurations tested (Table 4).

Value	Field	Form	Key Fields
[ctrcode]	Ctr	StudyProc	Key1
[patcode]	PatID	StudyProc	Key2
[1 …]	ElecConfig	StudyProc	Key3
[modelname]	AF Septal Catheter	StudyProc	
[1 … 10]	StimElec1_1	StudyProc	
[1 … 10]	StimElec1_2	StudyProc	
[locationcode]	StimLoc1	StudyProc	
[1 … 10]	StimElec2_1	StudyProc	
[1 … 10]	StimElec2_2	StudyProc	
[locationcode]	StimLoc2	StudyProc	
[1 … 10]	StimElec3_1	StudyProc	
[1 … 10]	StimElec3_2	StudyProc	
[locationcode]	StimLoc3	StudyProc	
[1 … 10]	StimElec4_1	StudyProc	
[1 … 10]	StimElec4_2	StudyProc	
[locationcode]	StimLoc4	StudyProc	
[Uni, bipolar]	StimMode	StudyProc	

Data table description for local AF capture and AF Termination taken from the CRF (Table 5).

Value	Field	Form	Key Fields
[ctrcode]	Ctr	StudyProc	Key1
[patcode]	PatID	StudyProc	Key2
[1 … 10]	ElecConfig	StudyProc	Key3
[1 …]	Experiment	StudyProc	Key4
[100 … 400]	AFCL	StudyProc	
[100 … 400]	AFCIntervalPaced	StudyProc	
[AF, SR]	Rhythmprotocol	StudyProc	
[uni, bipolar]	Stimmode	StudyProc	
[0 … 25]	Stimoutput	StudyProc	
[mA, V]	Stimunit	StudyProc	
[yes, no, na]	Localcapture	StudyProc	
[yes, no, na]	CaptureRA	StudyProc	
[yes, no, na]	CaptureSL	StudyProc	
[yes, no, na]	CaptureCS	StudyProc	

Data table description for local AF capture and AF Termination taken from the Matlab analysis of atrial EGMs (Table 6).

Value	Field	Form	Key Fields
[ctrcode]	Ctr	StudyProc	Key1
[patcode]	PatID	StudyProc	Key2
[1 … 10]	ElecConfig	StudyProc	Key3
[1 …]	Experiment	StudyProc	Key4
[100 … 400]	AFCL	StudyProc	
[100 … 400]	AFCIntervalPaced	StudyProc	
[AF, SR]	Rhythmprotocol	StudyProc	
[uni, bipolar]	Stimmode	StudyProc	
[0 … 25]	Stimoutput	StudyProc	
[mA, V]	Stimunit	StudyProc	
[CS, RA, Septal]	SenseCatheter	Matlab	
[1 … 20]	SenseElectrode	Matlab	
[yes, no, na]	CaptureAnalysis	Matlab	
[0…100]	Capture Percentage	Matlab	