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ORIGINAL ARTICLE

Cardiology Journal
2023, Vol. 30, No. 1, 36–43
DOI: 10.5603/CJ.a2022.0122
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ISSN 1897–5593
eISSN 1898–018X

First clinical experience using the DiamondTemp catheter and a novel omnipolar high-resolution mapping system for atrial fibrillation ablation

Christian Sohns*, Thomas Fink*, Leonard Bergau, Martin Braun, Mustapha El Hamriti, Vanessa Sciacca, Denise Guckel, Moneeb Khalaph, Guram Imnadze, Philipp Sommer

Clinic for Electrophysiology, Herz- und Diabeteszentrum NRW, Bad Oeynhausen, Germany

Abstract

Background: *The DiamondTemp (DT) radiofrequency ablation (RFA) catheter has been introduced as a new tool for atrial fibrillation (AF) ablation. The new technology allows for temperature-controlled irrigated ablation and real-time lesion assessment. Recently, the EnSite X mapping system became commercially available allowing for omnipolar and ultra-high-resolution mapping. We aimed to assess the feasibility of the new DT RFA catheter in performing AF ablation procedures in conjunction with the novel EnSite X system under routine clinical conditions.*

Methods: *We analyzed data from 10 consecutive patients who underwent AF ablation using the DT RFA catheter guided by EnSite X. Procedural data and short-term follow-up were assessed as well as potential technical issues.*

Results: *Nine out of 10 patients underwent de-novo pulmonary vein isolation (PVI), and 1 patient underwent repeat ablation. First-pass isolation was observed in 7/10 patients. Total procedure duration (skin-to-skin) was 88.9 ± 30.1 min, and left atrium dwell time was 70 ± 22.3 min. The mean number of RF applications needed for PVI and additional ablation was 70.52 ± 26.70. The HD Grid SE mapping catheter was utilized in 8 patients and the Advisor SE in 2 patients. Bidirectional block of the applied lines was achieved in all patients. No steam pops were observed, and no intraprocedural complications occurred.*

Conclusions: *This first clinical series demonstrated that temperature-controlled irrigated ablation in combination with the novel omnipolar and high-resolution mapping system resulted in rapid, efficient, and durable lesion formation under routine clinical conditions. Randomized controlled trials are needed to elucidate the impact on lesion formation, long-term outcomes, and reproducibility of our initial findings.* (Cardiol J 2023; 30, 1: 36–43)

Key words: atrial fibrillation, pulmonary vein isolation, DiamondTemp, EnSite X, radiofrequency ablation

Address for correspondence: Christian Sohns, MD, Clinic for Electrophysiology, Herz- und Diabeteszentrum Nordrhein-Westfalen, Ruhr-Universität Bochum, Georgstr. 11, 32545 Bad Oeynhausen, Germany, tel: 0049 5731 97 1327, fax: 0049 5731 97 2123, e-mail: csohns@hdz-nrw.de

Received: 3.06.2022 Accepted: 10.10.2022 Early publication date: 29.12.2022

**Both authors contributed equally*

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Introduction

The DiamondTemp (DT) radiofrequency (RF) ablation (RFA) catheter (Medtronic plc, Dublin, Ireland) has been introduced as a new tool for atrial fibrillation (AF) ablation. It features 6 external thermocouples at its tip, with a synthetic diamond which offers high thermal diffusivity. The new technology allows for temperature-controlled irrigated ablation, very high-resolution electrograms from the split-tip electrode, as well as real-time rapid lesion assessment [1]. Currently, higher energy outputs for shorter application duration have been investigated for RF-guided AF ablation. The rationale behind this technique is an improved impact of direct resistive heating and reduction of less effective and potentially harmful conductive heating through shorter application times [2]. With its technical specifications, the DT catheter combines high ablation power levels with a direct temperature feedback, demonstrating its efficiency in preclinical models, cavotricuspid isthmus ablation (CTI) [3] and ventricular tachycardia ablation [4]. Recently, a novel electroanatomical mapping system (EnSite X; Abbott, Abbott Park, North Chicago, Illinois, USA) became commercially available allowing for omnipolar and ultra-high-resolution mapping. Until today, no data exist about the utilization of the DT catheter to guide AF ablation under routine clinical conditions with EnSite X.

Therefore, the aim of our study was to assess feasibility of the new DT RFA catheter in performing AF ablation procedures, in conjunction with the novel EnSite X system, under routine clinical conditions.

Methods

Study design

We performed an observational analysis of consecutive patients who underwent AF ablation at the Herz- und Diabeteszentrum NRW Bad Oeynhausen (Bad Oeynhausen, Germany) with the new DT ablation catheter in conjunction with the novel EnSite X mapping system between 12/2021 and 2/2022. We included 10 patients who underwent de novo pulmonary vein isolation (PVI) as well as repeat AF ablations.

Pre-procedural preparations

Written consent was obtained at least 24 hours before the procedure. Non-warfarin oral anticoagulants were paused at least 24 hours before the procedure; in the case of warfarin use, an international normalized ratio in the therapeutic range < 2.5 was targeted.

Technical setup

To connect the 2 systems, the Medtronic Generator Connection Box and the GenConnect cable are required. In our situation the cable connection to the EnSite X system was made using the Ampere Connect cable to the Generator Connection Box. The EnSite X system was configured in NavX, mode and the DT was set-up as an ablation catheter using the "ablation type" option (Fig. 1).

Ablation procedure

In all procedures, deep sedation with midazolam, fentanyl, and propofol was used. Left atrial thrombus formation was ruled out prior to the procedure. After application of local anesthesia, the right femoral vein was accessed with three 8 F introducer sheaths. The left atrium (LA) was accessed using a transseptal approach via a steerable sheath (Agilis; Abbott, Abbott Park, North Chicago, Illinois, USA). In case of double transseptal puncture, an 8.5 F SL1 sheath (Abbott, Abbott Park, North Chicago, Illinois, USA) and a modified Brockenbrough technique were used to access the LA. Afterwards, a predefined heparin bolus was applied. Activated clotting time (ACT) was assessed every 15 min throughout the procedures, and heparin was repeatedly administered to maintain an ACT of 300–350 s. A decapolar diagnostic catheter was placed into the coronary sinus.

The DT catheter was used in all procedures and connected to the EnSite X system as demonstrated in Figures 1 and 2. In all procedures, three-dimensional (3D) electroanatomical mapping was performed using the EnSite X mapping system in NavX mode together with a multipolar mapping catheter (Advisor FL SE or Advisor HD Grid SE; Abbott Laboratories, Abbott Park, North Chicago, Illinois, USA). Procedural data were logged using the electrophysiological (EP) recording system (CardioLab, General Electric, Boston, USA). In all index PVI procedures, a paired, antral, ipsilateral PVI was performed in a point-by-point fashion (Fig. 3). Prior to ablation, each pulmonary vein (PV) ostium was carefully registered in the 3D-mapping system after selective angiography. A temperature-controlled mode was used with a maximum tolerated temperature of 60°C. Maximum output power was set to 50 W. In case of repeat procedures, ablation beyond PVI was carried out at the operator's discretion focusing on substrate modification based on bipolar low-voltage mapping in sinus rhythm (Fig. 4).

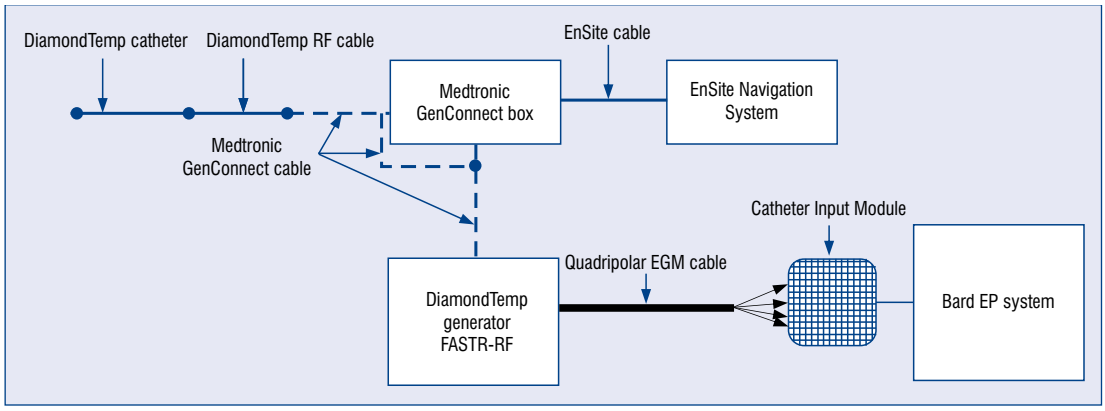

Figure 1. Schematic visualization of the utilized connections between the DiamondTemp ablation system, the EnSite X, and the electrophysiological (EP) recording system.

Figure 2. Connection template of the EnSite X mapping system and configuration of the DiamondTemp catheter.

No esophageal temperature measurement was used because this was not part of our institutional ablation protocol.

Postprocedural care

Transthoracic echocardiography was performed directly after the procedure and 1 day after to rule out pericardial effusion. Patients were monitored by telemetry until hospital discharge to detect early recurrences of AF, and a 12-lead-electrocardiogram (ECG) was performed the day after the procedure. Oral anticoagulation was continued. In the case of once-daily applied anticoagulants, a therapeutic dose of a low-molecular-weight heparin was administered on the evening of the procedure. All patients were scheduled to undergo magnetic resonance imaging (MRI) of the left atrium 6–8 weeks after ablation to rule out PV stenosis.

Ethical approval

The study was performed in compliance with the principals outlined in the Declaration of Helsinki and approved by the local Ethics Committee (No. 2019-563). All patients gave their informed consent.

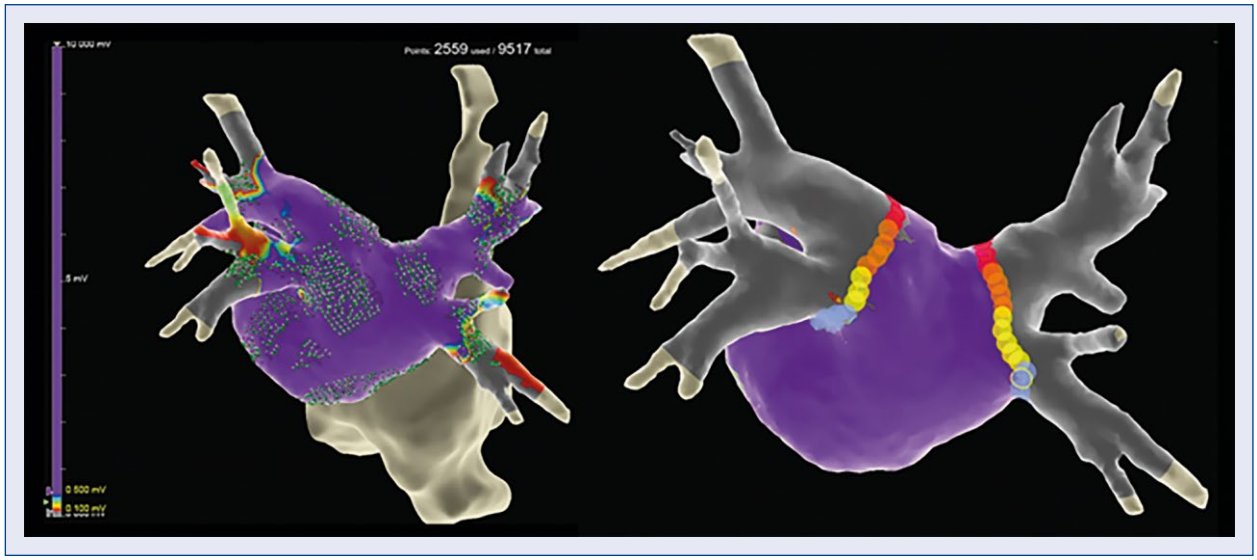

Figure 3. Typical example of a three-dimensional reconstruction using the novel high-resolution omnipolar mapping system EnSite X in conjunction the DiamondTemp ablation catheter. **Left panel:** Left atrium (LA) with bipolar voltage information from advanced mapping, using the HD Grid catheter. Posteroanterior view of the right atrium, in the back of the LA. **Right panel:** Acute procedural success in terms of pulmonary vein isolation. Bipolar voltage mapping shows isolated pulmonary veins (gray color) and normal atrial tissue (purple color) of the LA. Ablation tags are color-coded, representing different pulmonary vein segments.

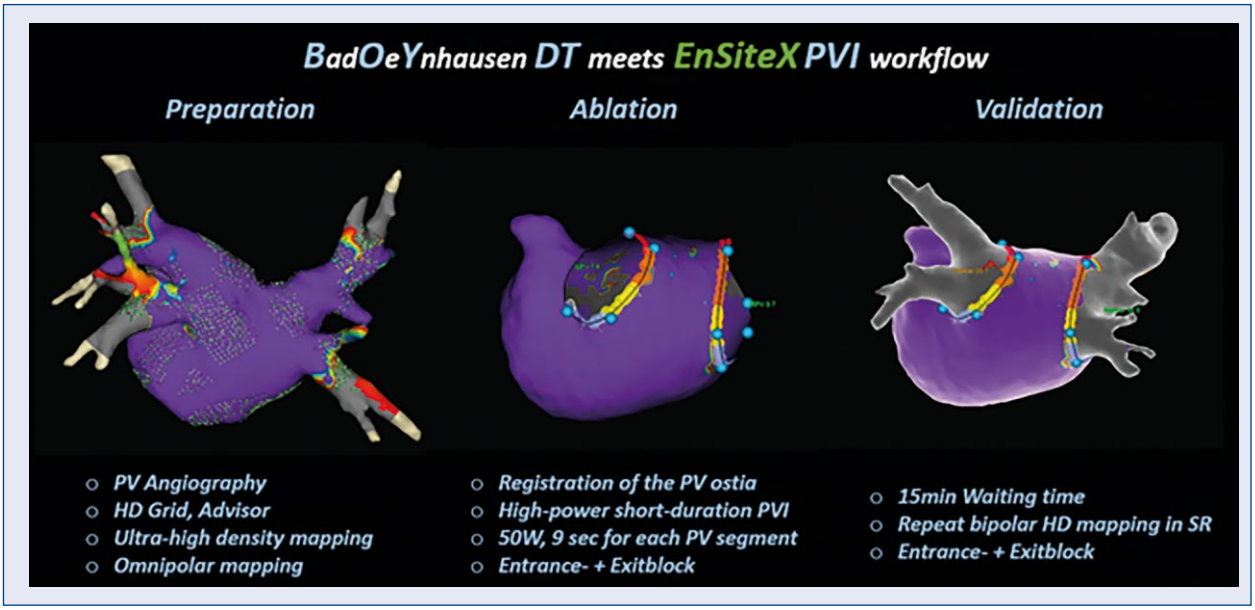

Figure 4. Institutional workflow for pulmonary vein isolation, utilizing the DiamondTemp ablation catheter guided by EnSite X.

Statistical analysis

Statistical analysis was performed using SPSS for Windows. Continuous variables are expressed as mean ± standard deviation or as median with interquartile range, as appropriate. Normally distributed data were compared using the unpaired Student's t test. A p value < 0.05 was considered as statistically significant.

Results

Study population and comorbidities

Baseline characteristics of the study population are displayed in Table 1. In total, 9 patients underwent index PVI, and 1 patient underwent repeat AF ablation. Five (50%) patients had documented paroxysmal AF, whereas persistent AF was present in 5 (50%) patients. Symptom severity was reported according to an European Heart Rhythm Association (EHRA) score of I–II in 4 (40%) patients and III–IV in 6 (60%) patients.

Procedural data

Procedural data are summarized in Table 2. First-pass isolation of the PVs was observed in 7/10 patients (70%). Total procedure time was relatively short with a skin-to-skin time of 88.9 ± 30.1 min and an LA dwell time of 70 ± 22.3 min. The number of RF applications needed for completion of PVI and additional ablation (2 patients with PVI + LA anterior line; Fig. 5, 6; 2 patients with PVI + + cavotricuspid isthmus ablation) was 70.52 ± ± 26.7 min. Mean fluid infusion was 342.2 ± ± 118.4 mL. The HD Grid SE mapping catheter was utilized in 8 (80%) patients and the Advisor SE in 2 (20%) patients. Bidirectional block of the applied lines was achieved in all patients (Fig. 6). No steam pops were observed, and no intraprocedural complications occurred. No charring at the catheter tip was observed in any patient.

Follow up and technical issues

Acute PVI was achieved in all patients (100%) and we found no electrical reconduction requiring repeat ablation after a waiting period of 15 min. This held also true for the LA anterior line and CTI. Only a very limited follow-up is currently available because ablation was performed between 12/2021 and 02/2022. One patient had AF recurrence requiring electrical cardioversion the day after ablation. In addition, rhythm control with flecainide was continued for 3 months. Another patient reported paroxysmal symptoms suggestive for AF recurrence within the blanking period. However, there was no AF/atrial tachycardia (AT) documentation from ECG until today.

Postprocedural MRI, including 4D-flow measurements of the LA and PVs, found no evidence for PV stenosis in this study cohort (n = 3 until 03/2022).

Of note, baseline noise was present in all ablation procedures predominantly on the bipolar electrogram from the distal electrode pair of the ablation catheter (Fig. 6C). The noise-level on the bipolar electrogram from the proximal electrode pair was lower but also present during mapping and ablation. It is important to note that the noise was only present on the EP recording system but not present on the EnSite X system, and there was no negative impact on the ablation procedures.

Table 1. Patient characteristics at baseline.

	DiamondTemp
Number of patients	n = 10
First procedure	9 (90%)
Age [years]	62.4 ± 8.7
Male sex	6 (60%)
Paroxysmal AF	5 (50%)
EHRA I-II	4 (40%)
EHRA III-IV	6 (60%)
History of CAD	2 (205%)
Hypertension	5 (50%)
Body mass index [kg/m^2]	31.1 ± 6.3
Hyperlipoproteinemia	3 (30%)
History of stroke	1 (10%)
Sinus rhythm at beginning of the procedure	5 (50%)
CHA_2DS_2-VASc-Score	2.5 ± 1.5
Oral anticoagulation prior to ablation	35 (87.5%)

Table 2. Procedural data.

	DiamondTemp
Patients [n]	10
Procedure duration; skin-to-skin [min]	88.9 ± 30.1
LA dwell time [min]	70 ± 22.3
RF applications applied [n]	70.52 ± 26.7
Total RF duration [s]	701 ± 292.4
Fluoroscopic time [min]	4.6 ± 2.1
PVI	n = 10; 100%
PVI + left atrial anterior line	n = 2; 20%
PVI + cavotricuspid isthmus	n = 2; 20%

LA — left atrium; PVI — pulmonary vein isolation; RF — rediofrequency

Discussion

This first clinical series demonstrated that temperature-controlled irrigated ablation in combination with the novel omnipolar and ultra-high-resolution mapping system resulted in rapid, efficient, and durable lesion formation under routine clinical conditions.

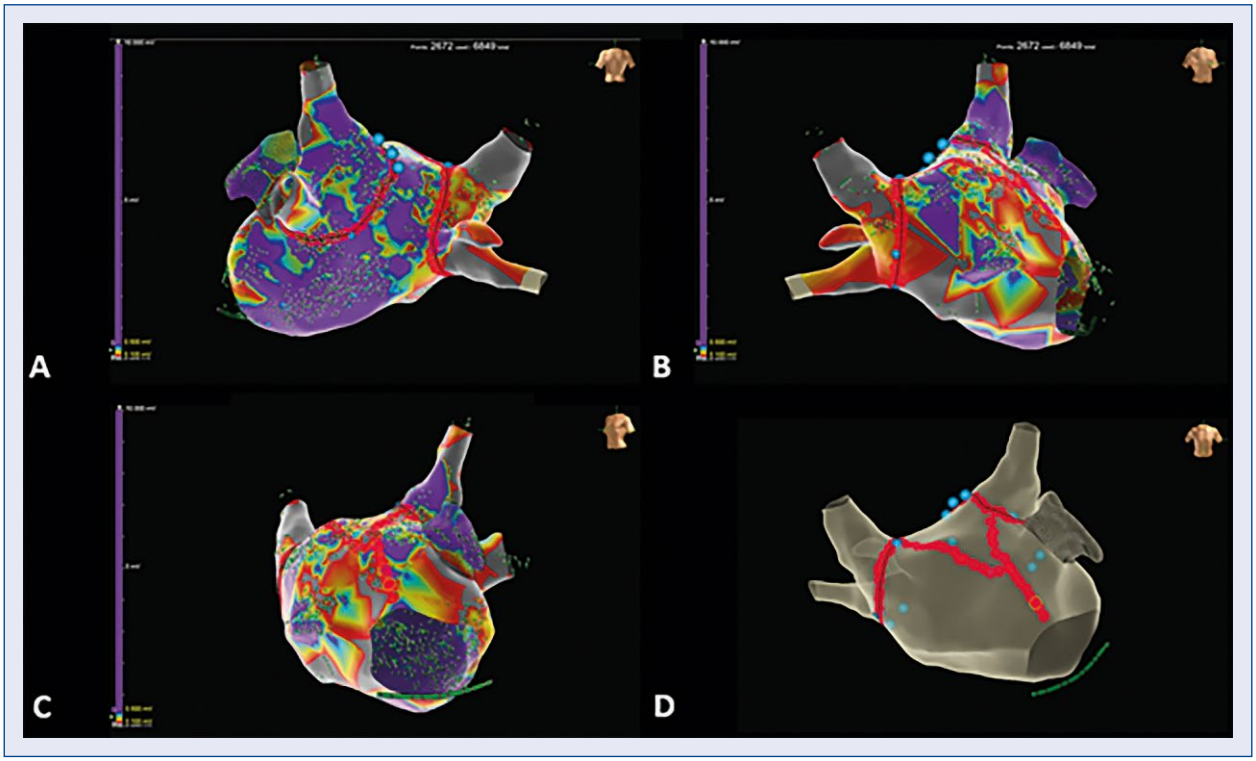

Figure 5. A. Typical example of pulmonary vein isolation from posterior view; **B, C, D.** Demonstrate left atrial substrate modification in terms of a line from the mitral valve annulus to the right superior pulmonary vein and an extension to the left superior pulmonary vein.

Strategies to ensure higher lesion quality

Radiofrequency ablation and cryoablation are regularly applied methods for the treatment of AF, and studies have demonstrated comparable success rates for both methods [5]. However, RFA is the most commonly applied method for LA lesion formation, in de novo as well as repeat procedures. However, PV reconnection and gaps in the circumferential ablation lines are still a major issue for AF recurrence after initial ablation. Rates of AF recurrence vary, and one of the challenges during RFA procedures is that durable lesions cannot be distinguished from non-durable lesions with a high probability of reconduction. In this context, real-time validation and knowledge of lesion formation are important aspects in evaluating new ablation tools as well as mapping technologies. Preclinical data demonstrated that the DT RFA catheter showed sufficient lesion quality in 55 of 64 lesions 7 days post ablation in a preclinical study in pigs [1]. Apart from a retrospective lesion validation, several steps have been undertaken to measure the quality of the applied lesion and provide a standardized value for lesion quality during the procedure. The lack of contact force measurement has been mentioned as a potential limitation of the current ablation system, but it remains questionable whether this information is valuable, taking into account the very homogeneous lesion formation observed when using this system in temperature-controlled ablation mode [6, 7]. In addition, there seems to be no negative impact on safety or long-term freedom from AF/ /atrial tachycardia recurrence, when comparing the DT RFA catheter with contact force-sensing catheters [8].

Higher-power, shorter-duration ablation in AF

Another promising approach towards improved lesion formation is the optimization of RF delivery in terms of higher than usual energy levels for shorter ablation periods (high-power, short--duration approach) [9], resulting in shorter procedure times and shorter RF duration, during AF ablation [8, 9]. Providing accurate temperature feedback is the key factor enabling operators to use higher power settings during ablation, to avoid excessive tissue temperature and thereby ensure procedural safety at the same time. Fur-

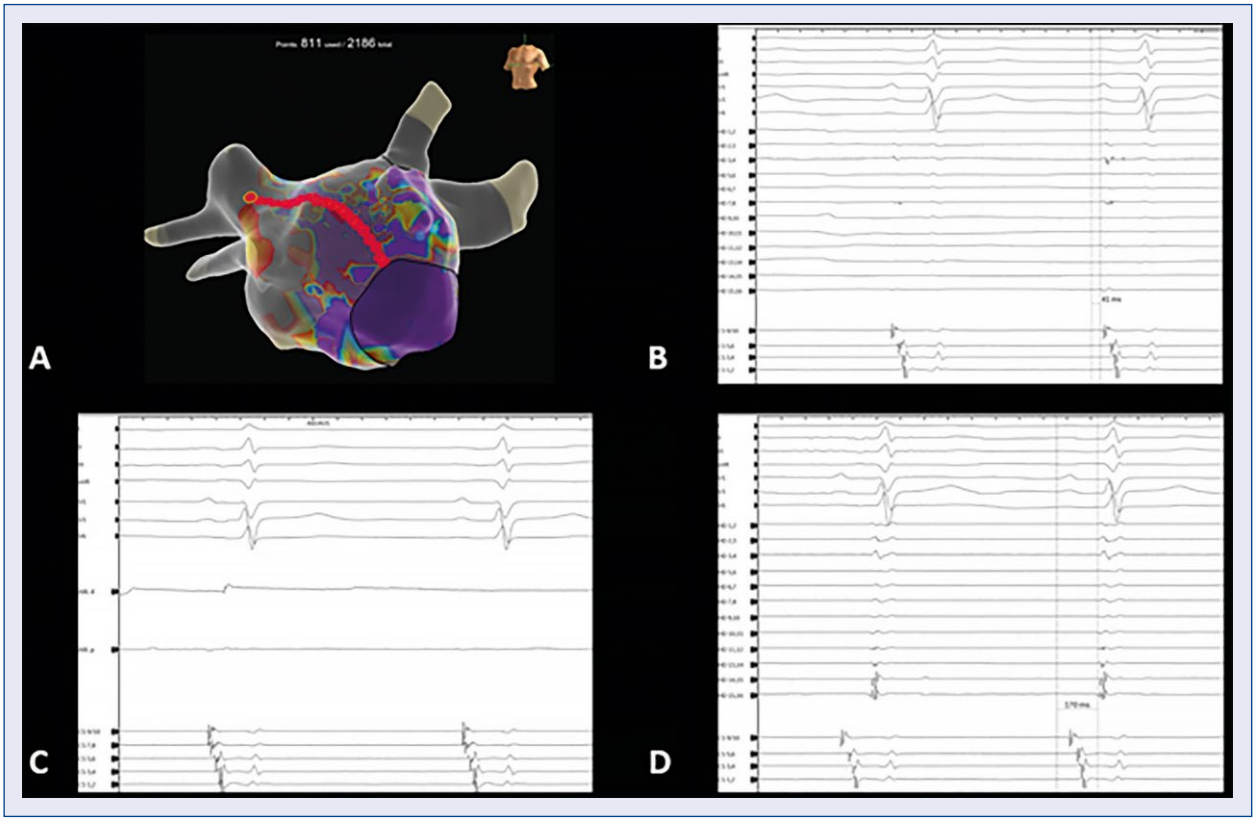

Figure 6. A. Visualization of a large scar area across the anterior and septal part of the left atrium, using high-density mapping from EnSite X. A linear lesion set was applied from the mitral valve annulus to the right superior pulmonary vein (red ablations tags); **B.** The intra-atrial activation time represented by the duration from the P-wave onset until the left atrial appendage prior to ablation. **C.** The baseline noise of the distal and proximal electrode; **D.** The confirmation of block across the ablation line, by a significant prolongation of the intra-atrial conduction time. Conduction block was also confirmed via pacing maneuvers.

thermore, the short duration of RF application requires a stable catheter position with exact knowledge of the specific patient anatomy. In our experience, an initially annotated line around the PV antrum may be helpful to reliably achieve this goal (Fig. 3).

In the present manuscript, we provide the first clinical experience performing temperature-controlled AF ablation in conjunction with EnSite X. Our data show that use of the novel catheter results in a relevant reduction of procedure times for AF ablation, including ablation strategies beyond PVI (Fig. 5). This could be achieved by a relatively low number of RF applications required for circumferential ablation lines as well as linear lesion sets across the LA and cavotricuspid isthmus. At the same time, the RF energy delivered and mean fluoroscopy times have been comparably low [6, 8, 10]. These results are in line with our general expectations for high-power, short-duration approaches for atrial tachyarrhythmia ablations.

Recently, a novel ablation catheter, the QDOT catheter, enabling ablation with up to 90 W was introduced [11]. Early studies demonstrated high procedural efficacy and procedural safety [11, 12]. A direct comparison of procedures performed with the DT catheter and the QDOT catheter is not possible across different studies. Ablation with the QDOT catheter utilizes ablation of up to 90 W over 4 s, potentially resulting in even shorter procedure times as compared to the DT catheter. Nevertheless, comparably short procedure times as well as good procedural safety were reported for both catheters in available studies. Further studies are needed to clarify the potential advantages and disadvantages of the newly developed catheter systems in clinical practice.

Safety

No steam pops or other procedure-related complications occurred. Follow-up MRI found no evidence of PV stenosis in this cohort of patients,

highlighting the beneficial effects of temperature-guided, high-power, short-duration RFA inside the LA and around the PVs.

Limitations of the study

Limitations of our study include a small sample size and the utilization of a novel electroanatomical mapping system. In addition, long-term follow-up data are missing at this point, so no statement can be made regarding long-term reconduction of ablation lines. Follow-up studies are important in this regard, for example using MRI-based approaches to visualize scar formation.

As a minor limitation using the combination of the DT RFA with EnSite X in conjunction with the CardioLab EP recording system, we observed a baseline noise predominantly on the distal electrode of the ablation catheter (Fig. 6C). The noise level on the proximal electrode was lower, but also present during mapping and ablation. The baseline noise could be due to the specific configuration being used for this initial cohort of patients or the way the equipment was connected. One may speculate that noise might have an impact on ablation procedures for which this combination of equipment might be used to search for prepotentials, Purkinje-like potentials, or abnormal electrograms (potentially representing scar tissue) as ablation targets. In this case, the operator should focus on the DT signals on EnSite X, for which no noise was observed.

Conclusions

In this study, we demonstrate that an ablation strategy with high-power and short-duration RFA using the DT catheter together with EnSite X was safe and effective for AF ablation under routine clinical conditions. More clinical data will be mandatory before final clinical conclusions can be drawn.

Conflict of interest: Christian Sohns received research support and lecture fees from Medtronic, Boston Scientific, and Biosense Webster. In addition, Christian Sohns is a consultant for Medtronic, Boston Scientific, and Biosense Webster; Philipp Sommer is an advisory board member of Abbott, Biosense Webster, Boston Scientific and Medtronic; other authors report no conflict of interest.

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