
Short Title: Remote Robotic Navigation for AF Ablation

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ABSTRACT

Background: Radiofrequency current (RFC) ablation of atrial fibrillation (AF) requires high technical skills to achieve optimal catheter stability and is associated with an individually high X-ray exposure to both the patient and the operator. In order to facilitate catheter navigation and to reduce the operator's X-ray burden remote navigation (RN) systems have been developed. Considerations for navigation of a novel remote robotic navigation system in pulmonary vein isolation (PVI) procedures are reported.

Methods and Results: In 65 patients with drug-refractory AF (43 paroxysmal, 22 persistent) complete circumferential PVI was performed using RN in conjunction with different electroanatomic mapping systems. Acute complete PVI using exclusively RN was achieved in 95%. The procedure time was 195 ± 40 min. The operator's X-ray exposure time was reduced by 6 ± 4 min (35%) using RN. In 7/14 pts with persistent AF conversion to SR was achieved by RFC ablation. During a median follow-up period of 239 days (range 184-314 days) 47/65 patients (73%) remained free of any documented atrial tachyarrhythmia recurrences following a single procedure. The relative proportion of patients remaining free of AF was 76% and 68% for paroxysmal and persistent AF, respectively.

Conclusions: PVI using the novel RN system can be performed safely and effectively. One third of the operator's fluoroscopy exposure time might be saved using RN. However, the question, whether the overall fluoroscopy exposure is reduced by RN and if RN improves PVI procedures needs to be assessed during a comparative trial between man and machine.

Keywords: Remote Robotic Navigation, Atrial Fibrillation, Pulmonary Vein Isolation, Mapping, Ablation
INTRODUCTION

Pulmonary vein isolation (PVI) has become the cornerstone procedure for patients with drug-refractory symptomatic atrial fibrillation (AF). The most commonly used ablation technique is circumferential PVI around the ipsilateral PV ostia using irrigated radiofrequency current (RFC). To establish contiguous transmural ablation lesions excellent catheter stability is an indispensable prerequisite.

Long procedure times with individually long exposure times to scattered X-ray are “side effects” that might affect the operator’s health during a long career as an interventional electrophysiologist.

In order to improve catheter stability and to reduce X-ray exposure remote navigation (RN) systems have been developed and used in pre-clinical and clinical settings.

The aim of this study was to describe the application of a novel remote robotic navigation system during PVI procedures in conjunction with different electroanatomical mapping systems with special emphasis on its ability to reduce the operator’s X-ray exposure.
PATIENTS AND METHODS

The study population consisted of 65 patients (12 female; mean age 61 ± 9 years) with drug refractory paroxysmal (n=43) or persistent (n=22) AF (Tab. 1). Patients were highly symptomatic despite the use of antiarrhythmic drugs and had suffered from AF for a median of 6 years (range 1-46 years). Arterial hypertension was present in more than half of the patients in both groups. In addition, 6 patients (11%) suffered from stable coronary artery disease and in 2 patients a pacemaker had been implanted for sick sinus syndrome. Prior to the ablation all patients underwent transesophageal echocardiography to rule out left atrial (LA) thrombus. Mean LA size was 43 ± 5 mm. No additional pre-procedural imaging was performed.

THE SENSEI™ ROBOTIC NAVIGATION SYSTEM

The Sensei™ (Hansen Medical, Mountain View, CA, USA) RN system was described in detail, previously \(^{10}\). In brief, it is an electromechanical system that facilitates catheter navigation through two steerable sheathes (Artisan™, Hansen Medical, Mountain View, CA, USA) incorporating an ablation catheter. The outer (14F) and inner sheath (10.5 F) are both manipulated via a pull-wire mechanism by a sheath carrying roboter arm that is fixed at the patient’s table. The roboter arm obeys the commands of the central workstation positioned in the control room. Catheter navigation using a three dimensional joystick (Instinctive motion controller™, Hansen Medical, USA) allows a broad range of motion in virtually any direction. In order to provide a tactile feedback the system continuously monitors the contact force (g/cm²) that is exerted by the catheter tip using a specially designed algorithm (IntelliSense™, Hansen Medical, Mountain View, CA, USA). If the contact force exceeds a preset limit an optical alarm is displayed and catheter advancement is rendered virtually impossible.

Prior to the insertion of the Artisan™ sheath both sheathes were flushed with heparinized saline and the ablation catheter was inserted into the inner sheath. Throughout the
procedure, both, the inner and the outer sheath, were continuously flushed with heparinized normal saline to prevent clot formation and air embolism.

**Electrophysiological Study and Ablation Procedure**

All EP studies were performed during deep analgo-sedation with fentanyl, midazolam and continuous infusion of propofol. Vital parameters were continuously monitored. Two standard catheters were positioned: a 6F catheter (Biosense-Webster, Inc) at the His bundle region via a femoral vein and a 6F catheter in the coronary sinus (CS) via the left subclavian vein. A single 8F SL1 sheath (SL1; St. Jude Medical, Daig Division, Minnetonka, MN, USA) was advanced to the LA by the Brockenbrough technique. Following placement of a guidewire in the left superior (LS) PV the puncture site was dilated by repeatedly advancing and retracting the sheath and dilator across the inter-atrial septum. Finally, the sheath was retracted to the right atrium (RA).

The Artisan™ sheath was advanced manually to the right atrium (RA) from the left femoral vein via a 14F sheath until the outer sheath reached the level of the CS ostium. It was then attached to the robotic arm and the inner sheath of the Artisan™ catheter was navigated remotely across the inter-atrial septum to the LSPV following the previously placed guidewire. After successful transseptal penetration of the inner sheath, the outer sheath was advanced close to the inter-atrial septum but remained in the RA to improve stability. Subsequently, the regular 8F transseptal sheath was advanced to the LA via the same hole and the guidewire removed.

Following transseptal catheterization, intravenous heparin was administered targeting an activated clotting time of 200 to 300 seconds. Additionally, continuous infusion with heparinized saline through the 8F transseptal sheath (flow rate of 10 mL/h) to prevent thrombus formation or air embolism.

In a next step selective PV angiograms of all PVs were performed using a right anterior oblique (RAO) 30° and left anterior oblique (LAO) 40° fluoroscopic view. The choice of the respective electroanatomic mapping system was left to the discretion of the physician.
3D-ELECTROANATOMIC MAPPING USING CARTO™:

The method of 3D electroanatomic mapping in the LA has been described previously in detail (3). In brief, mapping was performed with a 3.5-mm-tip catheter (ThermoCool Navi-Star™, Biosense-Webster Inc., Diamond Bar, CA, USA) during sinus rhythm or AF. After LA reconstruction, the ipsilateral PV ostia were tagged on the electroanatomic map according to fluoroscopic and electrophysiologic criteria. A decapolar spiral mapping catheter (Lasso™, Biosense Webster) was positioned at the respective PV ostium where the ablation was performed.

3D-ELECTROANATOMIC MAPPING USING NAVX™

Mapping was performed using a spiral mapping catheter. Initially, the spiral catheter was advanced to a distal position in the respective PV and data collection was started while continuously advancing and retracting the catheter inside the PV. This manoeuvre was repeated for all PVs and in a similar fashion for the left atrial appendage (LAA). The remainder of the LA was mapped by roving the spiral catheter inside the LA. In addition, distinct areas (e.g. PV ostia) were re-mapped remotely with the mapping catheter. The PV ostia were tagged using 3D-points at four locations (anterior, inferior, posterior, superior) in order to accurately delineate the PV-LA junction and to prevent RFC delivery inside the PV.

IRRIGATED RADIOFREQUENCY CURRENT ABLATION

Irrigated radiofrequency current (RFC) was delivered at target temperature of 43°C, a maximal power limit of 40 W, and an infusion rate of 17-25 ml/min. RFC ablation sites were tagged on the reconstructed 3D-LA. RFC was applied for a minimum of 30 seconds or until the maximal local electrogram amplitude decreased by 70% or double potentials were noted. Irrigated RFC ablation was performed along the posterior wall more than 1 cm and along the anterior wall more than 5 mm from the angiographically defined PV ostia. The end point for
ablation was defined as the absence of PV spikes registered on the spiral mapping catheter within the ipsilateral PVs.

**LATERAL PULMONARY VEIN ISOLATION**

The first RFC ablation was typically performed at the roof of the LPV ostium. The catheter was positioned rather parallel than perpendicular to the roof in order to prevent LA perforation (Figure 1). Wall contact was monitored by continuous registration of contact force using the IntelliSense™ algorithm. Then, RFC ablation was continued at the posterior wall by stepwise flexion and advancing the inner sheath as well as applying more distal bend to the outer sheath to increase stability. The latter was of particular importance at the anterior aspect of the LPV ostium that consists of the myocardial ridge to the LA appendage. Ablation catheter position was validated via fluoroscopic visualization and evaluation of local electrograms demonstrating a large amplitude atrial far-field potential and a small amplitude PV spike. Ablation along the anterior part of the LPV ostium was carried out from superior to inferior mainly by gradually increasing the distal bend of the outer sheath. If necessary, catheter position was adjusted by flexion of the inner sheath.

**SEPTAL PULMONARY VEIN ISOLATION**

RFC ablation was typically started at the roof of the RPVs. Similar to the LPVs, we attempted a rather parallel catheter position to avoid LA perforation (Figure 2A). The ablation line was then continued anteriorly by gradually de-inserting the outer sheath and optimizing catheter position by moving the inner sheath. This approach mimics the “pull down technique” used during conventional PVI procedures.

The ease of accessibility to the inferior border of the RIPV ostium was dependent on its anatomic position with regard to the transseptal puncture site. It was either accessible by a simple pull down manoeuvre or in some cases by applying an explicit curve to the inner sheath to eventually reach the inferior border (Figure 2B).
TRANSSEPTAL PUNCTURE SITE

The anatomic relation between the transseptal puncture site and the anterior inferior border of the inferior RPV ostium was analyzed by distance measurements during selective angiography of the inferior RPV in a standard angulation (RAO 30°) using custom software (Coroskop TOP, Siemens, Erlangen, Germany). First, we assessed the distance between the anterior inferior PV ostium and the catheter placed within the coronary sinus (dCS), the latter being an anatomical approximation of the mitral annulus (Figure 3). Second, the distance between the transseptal puncture site marked by the Artisan™ sheath and the anterior inferior PV ostium was assessed (dPS). The ratio dPS: dCS was calculated to classify the transseptal puncture site as being posterior (ratio 0 - 0.25), postero-medial (ratio 0.26 – 0.5), antero-medial (ratio 0.51 – 0.75) or anterior (ratio ≥0.75) in the fossa ovalis.

ABLATION OF COMPLEX FRACTIONATED ELECTROGRAMS

In patients with persistent AF who could not be cardioverted after PVI ablation of complex atrial fractionated electrograms (CAFE) was performed as described previously (11;12). The endpoint of CAFE ablation was either (1) conversion into atrial tachycardia that was subsequently mapped and ablated or (2) conversion into SR or (3) persistence of AF despite 60 minutes of additional RFC ablation. If AF persisted, external electrical cardioversion was performed. In all cases persistence of complete PVI was reassessed during SR and at least 30 minutes following PVI.

CATHETER STABILITY

Catheter stability was analyzed semi-quantitatively. The ipsilateral PV ostia were divided into four quadrants: superior, anterior, inferior and posterior (Figure 4). At each position the stability of the ablation catheter was assessed and classified as good (no catheter dislodgement during RF delivery), moderate (1 interrupted RF application due to catheter dislodgement) or poor (>1 interrupted RF application due to catheter dislodgement), respectively.
POST ABLATIONAL CARE

After sheath removal and pressure taping all patients were anticoagulated with unfractionated heparin targeting a PTT of 50-70 sec until an INR of 2-3 was reached. Oral anticoagulation was resumed the day after the procedure. Prior to discharge, all patients underwent transthoracic echocardiography to rule out pericardial effusion as well as a 24h-Holter-ECG and a 12-lead ECG.

Oral anticoagulation was maintained for at least 3 months following ablation and thereafter according to the individual’s risk (CHADS score ≥ 1). Previously ineffective antiarrhythmic drugs (AAD) were continued for 4 weeks.

FOLLOW-UP

Follow up was carried out according to the recently established HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation (1). All patients underwent rhythm screening in form of 12-lead ECG and 24h-Holter monitoring at 1, 3, and 6 months, respectively. In case of symptoms suggestive of arrhythmia recurrence (e.g. palpitations, heart racing etc.) patients transmitted a 30 s rhythm strip via an event recorder.

In addition telephonic interviews were carried out to assess the patient’s clinical symptoms and current medication. The success rate was calculated without using a blanking period.

PROCEDURAL ANALYSIS

In order to analyse the contribution of the different steps to the total procedure and fluoroscopy times we divided the procedure into three phases (A-C). Phase A included the time for preparation of the Artisan™ sheath, insertion of diagnostic catheters, transseptal puncture and ended when navigation of the Artisan™ sheath to the LA was completed.

Phase B comprised the time for mapping (including PV ostial tagging) and angiographies and phase C incorporated the time from first RFC application to removal of all sheathes including a 30 minutes waiting period after the last ablation.
In addition, fluoroscopy times were analyzed according to operator presence at the table or in the control room.

**STATISTICAL ANALYSIS**

All continuous variables are expressed as means ± SD or median and range where appropriate. For between group comparisons the unpaired, two-tailed Student's t-test with $\alpha = .05$ was applied, assuming that the data was approximately normally distributed. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.
RESULTS

ACUTE PULMONARY VEIN ISOLATION

In 62/65 (95%) patients the endpoint of complete PVI of all PVs exclusively using RN was achieved. In one patient access to the LA could not be achieved by RN due to a technical malfunction of the Artisan™ sheath (as post hoc technical analysis confirmed). In two patients electrical isolation of the LPVs was finalized manually at a posterior inferior gap and an anterior inferior gap in the circumferential ablation line, respectively. Both patients were among the first 12 patients treated. Afterwards, all PVs were isolated using RN.

CATHETER STABILITY

Catheter stability at the septal PV roof was good and moderate in 63 and 2 patients, respectively (Figure 4). Similarly, catheter stability was good and/or moderate at the inferior part of the RPV ostium. In contrast, catheter dislodgement was more often observed at the posterior wall (48, 14 and 3 patients with good, moderate or poor stability, respectively). Along the anterior part of the RPV ostium good, moderate or poor catheter stability was observed in 53, 11 and 1 patient, respectively.

At the lateral PVs catheter stability, both superior and inferior was good or moderate in almost all cases. Posteriorly, catheter dislodgement was more often observed (46, 15 and 4 patients with good, moderate or poor stability). In almost half of the cases (22 patients with moderate and 8 with poor catheter stability) RF delivery at the anterior aspect of the LPV ostium, e.g. the ridge to the LA appendage, had to be interrupted due to catheter dislodgement.

CATHETER NAVIGATION AND TRANSSEPTAL PUNCTURE SITE

The mean distance between the anterior RPV border and the CS catheter (dCS) was $123 \pm 8$ mm, whereas the mean distance between the RPV ostium and the transseptal puncture site (dTS) was $55 \pm 17$ mm (Figure 3). In 5 patients the transseptal puncture site was in the posterior quarter (ratio dTS : dCS = 0 - 0.25), in 41, 18 and 1 patients the transseptal
puncture 12 sites were in the two medial (ratio dTS : dCS = 0.26 – 0.5 and 0.51-0.75) or in the anterior quarter (ratio dTS : dCS = 0.76 – 1), respectively.

It was observed that the “pull down manoeuvre” was impossible, if the fossa ovalis had been punctured in the posterior quarter. In all other patients the ablation along the anterior border of the RPV ostium was carried out by the “pull down manoeuvre”.

**TERMINATION OF AF IN PATIENTS WITH PERSISTENT AF**

This study incorporated 22 patients with persistent AF. Eight patients were successfully cardioverted after PVI. In 7/14 (50%) patients, who could not be cardioverted electrically, AF was converted by ablation to a LA macro-reentrant tachycardia involving the mitral isthmus (LAMRT; n=4), typical RA flutter (n=2) or SR (n=1), respectively. The LAMRT and RA flutter were subsequently mapped and successfully ablated using RN.

**PROCEDURAL PARAMETERS**

The total procedure time (skin-to skin) was 195 ± 40 min including a 30 min waiting time (Tab. 2). This consisted of 93 ± 77 min for phase A, followed by 29 ± 11 min and 73 ± 19 min for phase B and C, respectively.

The total fluoroscopy time was 17 ± 7 min consisting of 8 ± 4 min, 4 ± 2 min and 5 ± 3 min for phase A, B and C, respectively. The major fraction of the total fluoroscopy time was used when the operator was positioned at the table rather than in the control room (11 ± 6 min and 6 ± 4 min, respectively).

The amount of radiofrequency current delivery time was 1480 ± 490 sec for the septal PVs and 1495 ± 502 sec for the lateral PVs, respectively.

**COMPARISON OF MAPPING SYSTEMS**

In 42/65 patients PVI was performed utilizing the CARTO™-system and in 23/65 patients the NavX™-system, respectively. The total procedure and fluoroscopy times were not significantly different (Tab. 3). However, it became evident that using NavX the fluoroscopy
time used manually tended to be longer (p=0.08) because LA mapping was performed with a spiral catheter and not using RN.

**LEARNING CURVE USING RN**

Figure 5 shows the progressive shortening of procedural parameters using RN. A relatively steep learning curve was observed that led to stable procedural parameters after only 12 patients.

**COMPLICATIONS**

In one patient transient ST segment elevation in all ECG leads occurred during RFC ablation at the lateral PVs. Immediate coronary angiography ruled out the presence of significant coronary artery disease. Thus, air embolism was deemed the most likely etiology for the observed ECG changes. Fortunately, the ECG changes resolved within 7 minutes and subsequent echocardiography did not demonstrate regional wall motion abnormalities. In addition, no neurological deficits were observed.

One patient developed cardiac tamponade following RA perforation caused by the outer sheath. This occurred during remote transseptal access and became clinically evident by a drop in blood pressure after completion of the remote LA map. Interestingly, following immediate pericardiocentesis only saline used for continuous flushing of the outer sheath was aspirated from the pericardial space. The patient experienced complete recovery with conservative management.

In one patient with severe odynophagia following ablation an esophageal ulcer was discovered by endoscopy and resolved within two weeks of treatment with proton pump inhibitors.

**FOLLOW-UP**

During a median follow-up period of 239 days (range 184-314 days) 47/65 patients (73%) remained free of any documented atrial tachyarrhythmia recurrences following a single
procedure. The relative proportion of patients remaining free of AF was 76% and 68% for paroxysmal and persistent AF, respectively. At 6 months follow-up 10/65 patients (15%) were still on previously ineffective antiarrhythmic drugs.

Eleven patients underwent a second procedure due to documented recurrences of atrial tachyarrhythmias. Electrical reconnection of the PVs was found during 9 repeat procedures and re-isolation was achieved at single conduction gaps along the previously circumferential ablation line. In two patients all PVs were isolated at the repeat procedure.

In 4 patients the RPVs showed reconduction and the gaps were located superior (n=2) and posterior (n=2). In the remaining 7 patients the RPVs were isolated. In 6 patients the LPVs were reconnected and the gaps were located superior (n=4) or anterior-inferior (n=2).

Both patients with isolated PVs during the repeat procedures presented with perimital atrial flutter that was successfully treated by an ablation line between the inferior LPV and the lateral mitral annulus. No PV stenosis was detected during the repeat procedures.

There was no difference in chronic success rates with regard to the mapping system used.
DISCUSSION

The present study describes the application of a novel robotic navigation system for catheter ablation of paroxysmal and persistent AF using different 3D-mapping systems. It was demonstrated that 1) in this initial study PVI using RN could be performed as safe and as efficient as using manual techniques, 2) RN can be used in conjunction with any of the two major 3D mapping systems, 3) the fluoroscopy exposure to the operator is reduced by approximately one third and 4) the chronic success rate is similar to previously reported data using manual ablation techniques (13). However, the sample size of this study is rather small, the study design is non-randomized and the results reflect the outcomes of a single high volume AF ablation (>1000 patients per year) centre. If the results can be reproduced by a less experienced EP laboratory remains an unanswered question. A randomized prospective trial to compare RN to conventional manual PVI is necessary to truly compare success rates and potential reduction in the operator’s fluoroscopy exposure.

Current ablation concepts for AF aim at PVI. When RFC is used a wide circumferential ablation line has been proven superior to a segmental approach (14). However, achieving contiguous linear ablation lesions is technically challenging and requires high navigation skills as well as excellent catheter stability.

NAVIGATION PROPERTIES

In this series it became evident that the major advantage of RN with respect to stability as compared to manual navigation was along the LA roof (Figure 4). However, at the anterior inferior portion along the lateral circumferential ablation line catheter stability is suboptimal in almost 50 % of the cases despite RN. This might be explained by the fact that this is the most distant location from the transseptal puncture site, thus decreasing stability. This can be partially compensated by a rather LA position of the outer sheath and distal bend application. Navigation to the anterior inferior aspect of the septal PVs proved challenging in those 5 patients where the transseptal puncture site was very posterior (Figure 3). As previously
described, the distance between the fossa ovalis and anterior inferior border of the RPVs is short \(^{(15)}\). In order to allow RN to this region a rather anterior transseptal puncture site (medial quarter of the fossa ovalis) is advisable.

In order to perform a predominantly remote procedure the transseptal navigation with the inner sheath was performed remotely during this study. Since the technology does not provide fully automated catheter control yet and one of the major complications was associated with this manoeuvre, it might be safer to perform this step manually. However, in the future non-steerable ablation catheters will be engaged in the Artisan sheath rendering manual navigation virtually impossible.

Due to the large outer diameter of the sheath, RN to the distal coronary sinus is discouraged. This might limit its use in ablation procedures for long-lasting persistent AF or perimital LA macroreentrant tachycardias which frequently require epicardial ablation via the coronary sinus \(^{(16)}\). However, temporary occlusion of the CS using a balloon catheter showed promising results and may allow for transmural lesion creation by endocardial RFC ablation along the LA isthmus \(^{(17)}\). A further systematic evaluation is needed with special regard to the LA isthmus line.

**X-RAY EXPOSURE**

One major argument in favor of RN is the reduction of fluoroscopy time for the operator. In this series the relative fraction of fluoroscopy time used from the control room was 35 % (6 ± 4 min). This time comprised navigating the Artisan™ sheath to the LA, ostial tagging as well as confirmation of catheter position during ablation. The total amount of fluoroscopy time was much lower as compared to other studies using RN \(^{(9)}\). However, the majority of the fluoroscopy time was required for the conventional part of the study (insertion of catheters, selective PV angiographies and transseptal puncture). Thus, the amount of potentially “saved” fluoroscopy exposure time was limited. Future developments (e.g. incorporation of a transseptal needle for direct transseptal puncture with the Artisan™ sheath) may further reduce the conventional procedure time and the operator’s X-ray exposure. Lastly, imaging
such as intracardiac echocardiography may reduce X-ray use. However, this potential benefit may be offset by additional cost.

**LESION QUALITY**

Animal experiments demonstrated that increased stability and well controlled contact force contribute to a better lesion quality (18). During this study a systematic evaluation of stability and contact force was not performed. Although the RFC energy settings were not changed as compared to manual procedures immediate and delayed re-conduction of previously isolated PVs was observed. In addition, during repeat procedures electrical reconnection of the PVs was the major finding. Therefore, it is still mandatory to ascertain optimal catheter position in order to achieve permanent transmural lesions. The optimal power settings and contact forces remain to be determined in future studies. Notably, no cardiac tamponade following a steam pop occurred.

**COMPLICATIONS**

The overall complication rate in our series of RN for PVI was low. The air embolism is a complication that may be related to any PVI procedure, whereas, development of cardiac tamponade and esophageal ulceration, deserve further exploration with regard to the safety of RN.

Since the contact force along the posterior wall is high, one may hypothesize that the LA wall is pushed towards the esophagus during RFC ablation, thereby increasing the risk for thermal damage within the esophagus. Temperature monitoring was not performed but may be helpful to avoid esophageal complications in the future as suggested by other groups (19). Whether the incidence of esophageal complications is higher than in conventionally treated patients, remains to be determined.

The RA perforation by the outer sheath underlines the importance of continuous registration of and attention to the contact force as the operator is deprived of tactile feedback. At present, the Intellisense™ algorithm provides an approximate value of contact force.
However, it remains unknown whether this algorithm is fully reliable, especially with regard to automatic catheter control. To date, it seems prudent not to rely solely on a software algorithm but to add electrophysiologic and fluoroscopic information to guide a safe remote procedure.

No LA perforation was observed during mapping and ablation in this series. The only reported LA perforation associated with RFC ablation occurred at very high power settings (50W; 30 ml/min irrigation flow) (9). We limit our setting to a maximum of 40W at the anterior wall and only 30W at the posterior wall and LA roof which has proven sufficient to create transmural lesions.

**LIMITATIONS**

Previous studies used intracardiac echocardiography to determine catheter to tissue contact (18). However, the semi-quantitative algorithm used in this study might be an easy and inexpensive clinical tool to assess catheter stability.

**CONCLUSION**

PVI using the novel RN system can be performed effectively. One third of the operator’s fluoroscopy exposure time might be saved using RN. However, the question, whether the overall fluoroscopy exposure is reduced by RN and if RN improves PVI procedures needs to be assessed during a comparative trial between man and machine.
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Table 1: Patient Characteristics. AF: Atrial fibrillation, CAD: Coronary artery disease, LA: Left atrium. Numbers in parenthesis are %.

Table 2: Procedural Parameters. Fluoroscopy time for both manual and robotic navigation. The study was divided into 3 phases (A-C; see text for details).

Table 3: Comparison of electroanatomical mapping systems.

Figure 1: Catheter ablation at the lateral pulmonary veins. Screenshots from the Sensei™ workstation are displayed containing the fluoroscopic view (right, LAO 40°) and the NavX™ map (left; PA-projection). The ablation catheter is moved caudally by continuously bending the outer sheath (from upper to lower panel; see distal bend value in the middle column). The small inserted picture demonstrates the left lateral view in order to visualize the anterior position of the mapping catheter.

Figure 2A: Catheter ablation at the septal pulmonary veins. Screenshots from the Sensei™ workstation are displayed containing the fluoroscopic view (left) and the NavX™ map (right) both in RAO 30°. The ablation catheter is moved caudally by continuously deinserting the outer sheath (upper to lower panel; see insertion value in the middle of the screen). A spiral mapping catheter is positioned in the right superior PV (red) and a multipolar catheter is advanced to the distal coronary sinus. A blue virtual catheter displays the calculated bend of the mapping catheter. In the 3D map the LAA (green), LSPV (blue), LIPV (yellow), RSPV (red) and RIPV (light green) are visible.

Figure 2B: Screenshots from the Sensei™ workstation are displayed containing the fluoroscopic view (right) and the NavX™ map (left) both in RAO 30°. The inferior aspect of the RIPV ostium was caudal to the transseptal puncture site in this patient.
Therefore, the “pulldown technique” was not sufficient to reach the inferior border of the RIPV ostium and the catheter had to be deflected maximally.

Figure 3: Selective angiographies of the right inferior PV (RAO 30°). The distance between the anterior border of the RPV ostium and the coronary sinus catheter (dCS, dotted line) and the transseptal puncture site (dTS; full line) were measured. Left panel in a patient with a posterior transseptal puncture (ratio dCS : dTS = 0.12). Right panel in a patient with an antero-medial transseptal puncture (ratio dCS : dTS = 0.68). CS: coronary sinus catheter, His: multipolar catheter at the His bundle, Ref: Reference catheter on the back of the patient, MP: multi-purpose catheter for angiography.

Figure 4: Schematic drawing of the pulmonary veins and the circumferential ablation lines. The latter was divided into 4 quadrants (superior, anterior, posterior inferior). For each quadrant catheter stability was assessed and classified as good, moderate and poor, respectively. The relative numbers are given in % for each quadrant. For the absolute numbers see text. RPVs: right pulmonary veins, LPVs: left pulmonary veins.

Figure 5: Learning curve for robotic navigation. Dotted lines indicate first (lower) and third (upper) quartile. After 12 patients the procedure times were relatively stable.
### Tables and Figures

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<th>Persistent AF (n=22)</th>
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### Concomitant Heart Disease

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<th>Persistent AF (n=22)</th>
<th>Total (n=65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAD</td>
<td>4 (9)</td>
<td>2 (9)</td>
<td>6 (9)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24 (56)</td>
<td>12 (54)</td>
<td>36 (55)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2)</td>
<td>1 (5)</td>
<td>2 (3)</td>
</tr>
<tr>
<td></td>
<td>Manual Navigation</td>
<td>Robotic Navigation</td>
<td>Phase A</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------</td>
<td>--------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Fluoroscopy Time [min]</td>
<td>11 ± 6</td>
<td>6 ± 4</td>
<td>8 ± 4</td>
</tr>
<tr>
<td>Procedure Time [min]</td>
<td></td>
<td></td>
<td>93 ± 77</td>
</tr>
</tbody>
</table>

Table 2
Table 3.

<table>
<thead>
<tr>
<th>Fluoroscopy Time [min]</th>
<th>CARTO</th>
<th>NavX</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=42</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual</td>
<td>11 ± 4</td>
<td>13 ± 0</td>
<td>0.06</td>
</tr>
<tr>
<td>Robotic</td>
<td>6 ± 4</td>
<td>5 ± 2</td>
<td>0.22</td>
</tr>
<tr>
<td>Phase A</td>
<td>8 ± 3</td>
<td>8 ± 3</td>
<td>0.28</td>
</tr>
<tr>
<td>Phase B</td>
<td>5 ± 3</td>
<td>4 ± 4</td>
<td>0.23</td>
</tr>
<tr>
<td>Phase C</td>
<td>4 ± 3</td>
<td>6 ± 5</td>
<td>0.25</td>
</tr>
<tr>
<td>Total</td>
<td>17 ± 7</td>
<td>18 ± 9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

| Procedure Time         |         |        |      |
| n=23                   |         |        |      |
| Phase A                | 93 ± 48 | 84 ± 25| 0.28 |
| Phase B                | 29 ± 10 | 30 ± 12| 0.35 |
| Phase C                | 72 ± 18 | 83 ± 22| 0.11 |
| Total                  | 194 ± 40| 197 ± 43| 0.42 |
Figure 2A.
Figure 2B.
Figure 4.
Figure 5.
Boris Schmidt, Roland R. Tilz, Kars Neven, Julian K.R. Chun, Alexander Fuernkranz and Feifan Ouyang

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