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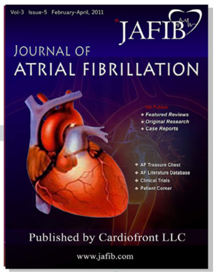

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Role of Remote Navigation Systems in AF Ablation

Boris Schmidt, MD, Britta Schulte-Hahn, MD, Bernd Nowak, MD, Verena Windhorst, MD, BN, Verena Windhorst, MD, Kyoung Ryul Julian Chun, MD

Cardioangiologisches Centrum Bethanien, Wilhelm-Epstein Str. 4, 60431 Frankfurt, Germany.

Abstract

During the past decade atrial fibrillation (AF) ablation has developed from being an experimental treatment option to an evidence based therapy implemented in current guidelines. Irrigated radiofrequency current guided ablations remain the golden standard of pulmonary vein isolation (PVI) procedures. Although practiced more frequently, it remains a demanding procedure requiring skilful operators. Novel technologies such as balloon based catheters or remote navigation (RN) systems have been developed to overcome the pitfalls of manual ablation procedures.

Introduction

During the past decade atrial fibrillation (AF) ablation has developed from being an experimental treatment option to an evidence based therapy implemented in current guidelines .[1-2] Irrigated radiofrequency current guided ablations remain the golden standard of pulmonary vein isolation (PVI) procedures. Although practiced more frequently, it remains a demanding procedure requiring skilful operators. Novel technologies such as balloon based catheters or remote navigation (RN) systems have been developed to overcome the pitfalls of manual ablation procedures.

The present literature review will report on the role of RN systems in AF ablation with particular focus on safety, efficacy and future applications.

Introduction of RN Systems

To date, two different RN systems are commercially available: 1) magnetic navigation (Niobe II™, Stereotaxis, St. Louis, USA) and 2) robotic navigation (Sensei™, Hansen Medical, Mountain View, CA, USA). Both systems and their technical specifications have been introduced in detail elsewhere but the major concepts will be described briefly. [3]

Magnetic Navigation

In brief, the MNS (Niobe II™, Stereotaxis) consists of 2 computer controlled permanent magnets located on either side of the fluoroscopy table which create a steerable, uniform magnetic field (0.08 T) approximately 15 cm inside the patient's chest. The mapping and ablation catheter is equipped with 3 permanent magnets within the distal shaft of the soft catheter and aligns parallel to the externally controlled magnetic field. The orientation of the magnetic field is manipulated by changing the orientation of the outer magnets relative to each other. All magnetic field vectors can be stored and, if necessary reapplied for automatic naviga-

Corresponding Address :Boris Schmidt, Cardioangiologisches Centrum Bethanien, Wilhelm Epstein Str. 4, 60431 Frankfurt a. M, Germany.

tion of the magnetic catheter. To enable remote controlled catheter navigation, a computer controlled catheter advancer system (Cardiodrive™, Stereotaxis, Inc.) is required. The video workstation (Navigant 3.0, Stereotaxis, Inc.) allows for precise catheter manipulations and moreover, for an integrated display of the magnetic catheter tip within the 3D electroanatomic (EA) LA map on standard fluoroscopy [Figure 1]. The second generation Niobe II™ system enables tilting both permanent magnets thus allowing increased C-arm angulations to RAO 30° and LAO 40°.

Robotic Navigation

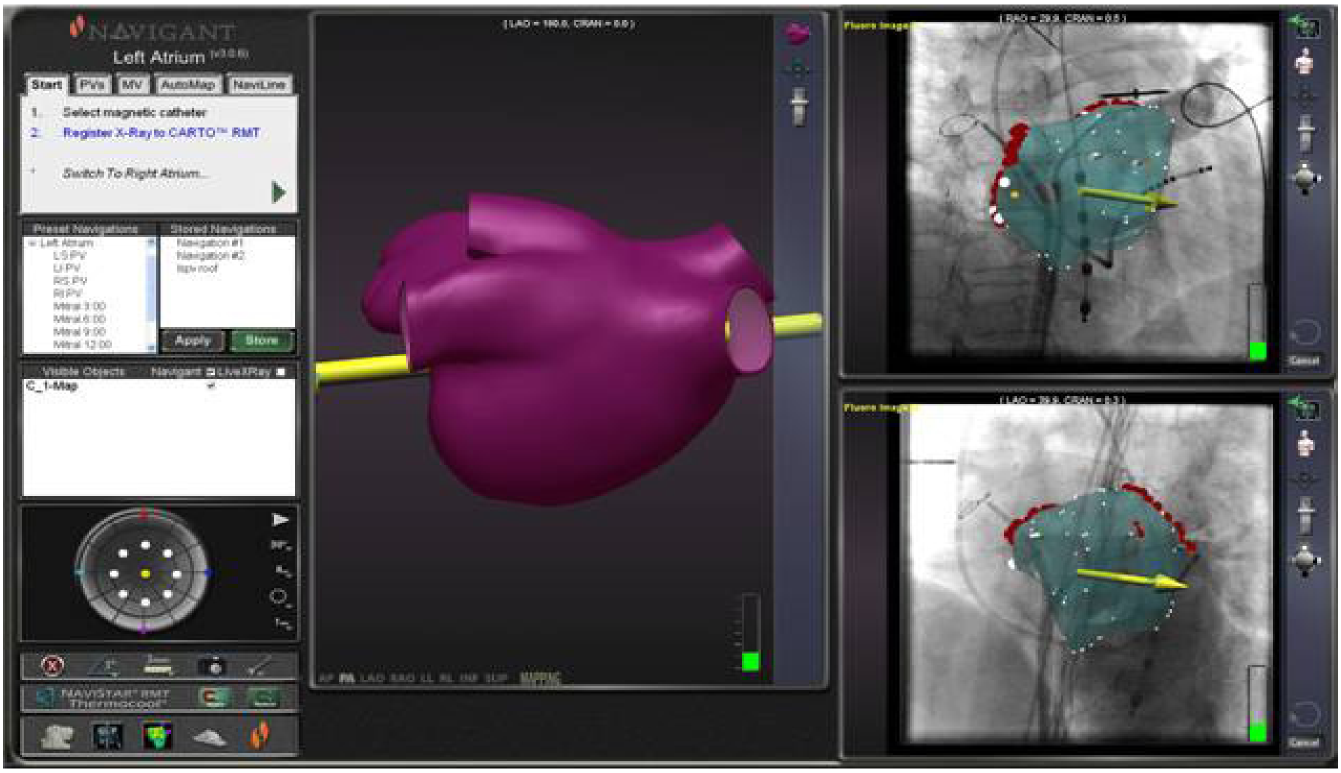
The electromechanical system achieves catheter navigation by two steerable sheathes (Artisan™, Hansen Medical, USA) incorporating an ablation catheter. Outer (14F) and inner sheath (10.5F) are both manipulated via a pull-wire mechanism by a sheath carrying roboter arm (“slave”) that is fixed at the patient’s table. The roboter arm is controlled by the commands of the central workstation (“master”) positioned in the control room. Catheter navigation is accomplished using a three dimensional joystick (Instinctive motion control™, Hansen Medical, USA) and allows a broad range of motion in virtually any direction. In general, all catheters < 8.5F and all electroanatomical mapping systems may be used. A customized software (CoHesion™) allows for integration of NavX™ (St. Jude Medical, St. Paul, MN, USA) 3D mapping data into the workstation allowing for instinctive navigation in the 3D map.

Since the operator is deprived of any tactile feedback during catheter manipulation the system is equipped with a proximal contact force sensor (IntelliSense™) for online display of calculated contact force values. An optical and a vibrant alarm can be set at an individual contact force level to increase operator’s awareness towards exaggerated forces.

Rationale to Use RN Systems for AF Ablation

The current consensus document on catheter ablation of AF states that electrical pulmonary vein isolation should be the cornerstone of any ablation procedure .[2] It was shown that circumferential PVI

Figure 1: Screenshot of the Stereotaxis workstation with the novel Navigant software (Version 3.0). It allows for integration of fluoroscopic and 3D electroanatomic reconstruction information (right upper panel RAO 30°; right lower panel LAO 40°). The yellow arrow indicates the direction of the designed magnetic field vector. All magnetic vectors can be stored and re-applied during the procedure. Moreover, the option to apply predefined vectors may allow for semi-automatic catheter navigation.



is more efficient than a segmental PVI approach .[4] However, deploying permanently transmural circumferential lesion is still a challenging task, requiring a skilled operator who is able to achieve stable catheter positions and to perform precise catheter navigation. For patients with paroxysmal AF mid-term single procedure success reported from single centre trials range between 70-80 % and decline to 50-60% over time during long-term follow-up. [5-7] The major determinant for recurrences is PV to LA reconduction across initially complete circumferential ablation lines following non-transmural ablation lesions. [8] The reasons may be multi-factorial, but recent trials suggest that insufficient contact between the catheter tip and ablated tissue may play a dominant role for incomplete ablations. [9-10] During TOCCATA multicenter study a novel contact force sensing catheter was evaluated and it was shown that 12% of all ablations during PVI procedures were carried out with a contact force of as low as 5g. Furthermore, there was a clear pattern of low-contact predilection sites namely the myocardial ridge between the lateral PVs and the LA appendage being the most critical region. In sub-analyses it was demonstrated that mean contact force during AF ablation was directly related to success during follow-up. [11]

Similarly, contact force determines the safety of an AF ablation procedure. The two most feared mechanical complications of AF ablation are pericardial tamponade and thermal esophageal injury .[12-13] The incidence as reported in a recent survey is relatively low (1% for tamponade and 0.04% for atrioesophageal fistula, respectively). Nonetheless, the low complication rate is the benchmark for novel technologies and should not be exceeded. Moreover, despite the use of 3 D mapping systems both, the patient and the physician are still exposed to scattered X-ray bearing the potential risk for adverse effects during a long professional career.

Clinical Experience of AF Ablation Using Magnetic Navigation

Published data on AF ablation using MN is scarce. This might partly be explained by the lack of an irrigated tip catheter that had been unavailable until late 2007. The initial feasibility study reported on circumferential PV ablation in 40 patients performed with a 4mm solid tip ablation catheter with the endpoint of voltage abatement >90% .[14] The endpoint could be achieved in 38/40 patients and no major complications occurred. However, the procedure times were significantly longer than in a non-randomized control group.

In contrary, in a second feasibility trial true PVI demonstrated with a spiral catheter within the PVs could not be achieved in the vast majority (92%) of patients using the non-irrigated magnetic ablation catheter. [15] Moreover, in one third of the cases significant charring on the tip of the ablation catheter was observed, underscoring the need for an irrigated ablation technology

If the PVs were disconnected at a more distal level, the solid tip catheter demonstrated efficacy in smaller patient series .[16-17] While fluoroscopy times were consistently lower using MN as compared to a manual ablation strategy, data on procedure times are controversial .[16-17] However, no data from prospective randomized trials are available yet.

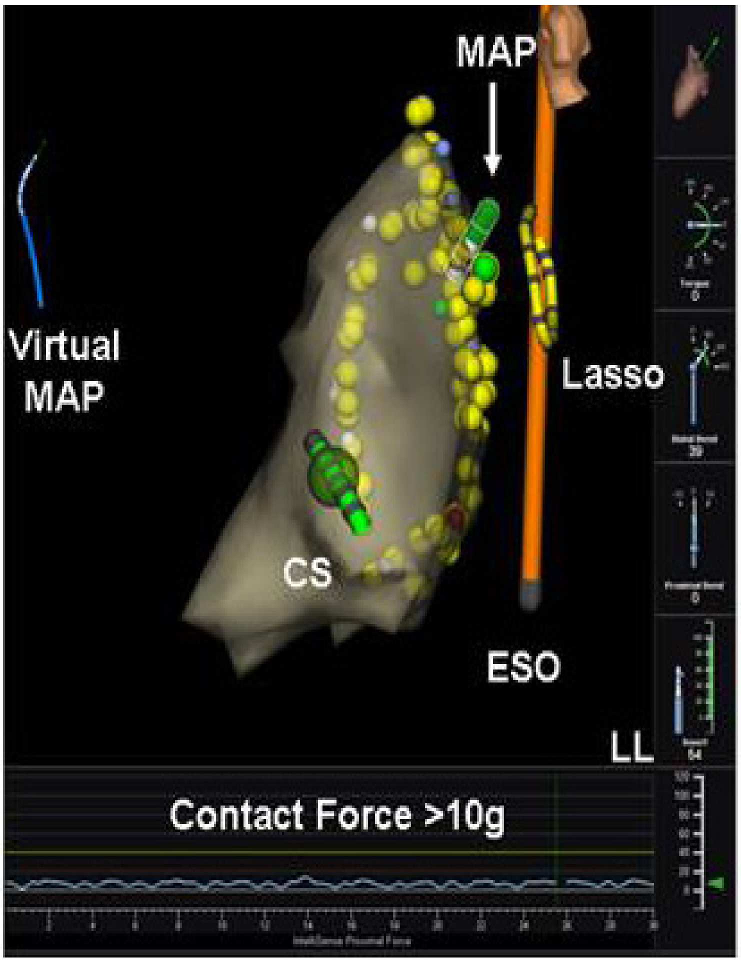
Chun and co-workers recently demonstrated the feasibility of MN based PVI using the novel irrigated tip catheter. [18] In a prospective fashion 56 patients were treated with the first (n=28; Thermocool NaviStar RMT I) or second (n=28; Thermocool NaviStar RMT II) generation irrigated tip catheter. In total the primary endpoint of complete PVI was achieved in 93% of all patients in both groups. The major improvements of the novel catheter were the higher effectiveness as documented by a significantly reduced procedure time (370 versus 243 min; $p \leq 0.0001$) and the decreased incidence of charring on the catheter tip following the ablation procedure (61% versus 0%; $p \leq 0.0001$). Notably, two patients treated with the first generation catheter and an evidence of charring experienced embolic events 7 and 14 days after the procedure. No complications occurred with the second generation irrigated tip catheter. During an average follow-up of 426 ± 213 days 70% of all patients remained in sinus rhythm after a single procedure off antiarrhythmic drugs.

Clinical Experience of AF Ablation Using Robotic Navigation

The initial results on AF ablation of a multi-centre feasibility trial using the first generation RN device were published in 2008 .[19]. In total 40 patients underwent PV antrum isolation with an irrigated tip catheter using a 3D mapping system. In all patients the acute endpoint was achieved leading to a chronic success rate of 86% at one year follow-up off antiarrhythmic drugs. However, the complication rate of 5% (2 patients developed cardiac tamponade requiring pericardiocentesis) raised safety concerns among the electrophysiologic community.

It became evident that most of the severe complications occurred during an initial learning phase and modification of procedural techniques contributed to improve safety [20]. This included the use of a long femoral sheath for introduction of the Artisan catheter to prevent mechanical venous wall stress and vascular access complications. Second, ablation power needs to be lowered and adapted to the improved wall contact in order to avoid steam popping leading to cardiac perforation. The latter also holds true for thermal esophageal complications as recently demonstrated. [21-22] The excess contact force and relative stiffness of the Artisan sheath may lead to distortion of the cardiac anatomy, [23]thereby decreasing the distance between the map catheter and the esophageal tissue [Figure 2]. The improved heat transfer may lead to an increased incidence of thermal esophageal lesions. According to our experience, ablation power at the posterior wall should therefore not exceed 20 W

Figure 2: Mechanical distortion of the posterior laeft atrial wall during an AF ablation using robotic navigation. Left panel: Screenshot from the Sensei workstation showing a NavX map in a left lateral (LL) view. The map catheter pokes out of the LA geometry at a contact force of 10-20g towards the esophageal temperature probe (ESO). Righ panel: Corresponding fluoroscopic image in LAO 40° demonstrating the map catheter is situated distant from the left PVs on top of the temperature probe (ESO). CS: multipolar catheter in the coronary sinus. Lasso: spiral catheter in the left superior PV.



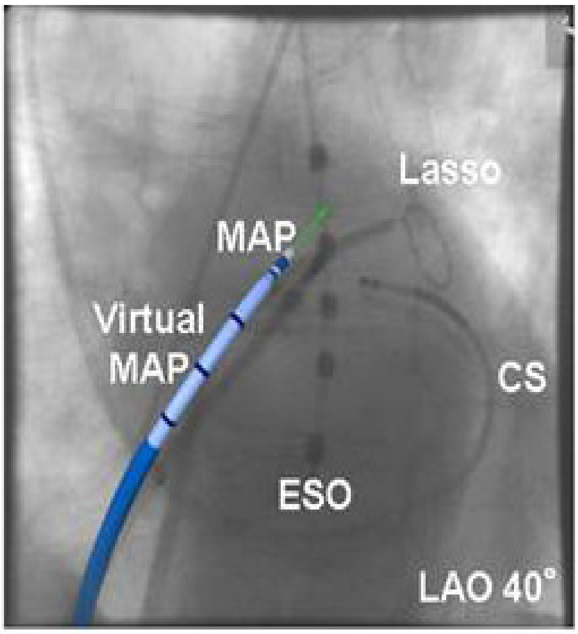


Table 1 Clinical trials on AF ablation using robotic navigation.

Author	Study cohort (n)	Success rate	Follow-up [months]	Complication rate RN (%)
Saliba et al. (19)	40	86%	12	5%
Schmidt et al. (25)	65	73%	8	4.6%
Kautzner et al. (26)	22	91%	5 ± 1	0%
Di Biase et al. (23)	193	72%	14 ± 1	1.6 %
Steven et al. (24)	30	73%	6	0%
Willems S et al. (27)	64	67%	3	0
Wazni et al. (20)	63	76%	6	12.7%

and esophageal temperature monitoring is compulsory.

To date, the largest patient series (n=390) retrospectively comparing manual navigation with RN during AF ablation did not find a significant difference in complication rate between the groups reporting 3 major complications in 193 patients (1.6%). [24]

Similarly, the only prospectively randomized trial reported a complication rate of zero. [25] However, the primary endpoint focused on procedure and fluoroscopy times with a relatively small sample size (n=60).

Data on chronic efficacy is available from numerous observational studies. The success rate lies in the range of 67-91% after a single procedure off antiarrhythmic drugs and variable follow-up intervals (Table 1) .[19;20;24-28]

In another feasibility trial, catheter stability during PVI was assessed in a semi-quantitative fashion .[26] While catheter stability was excellent at most superior and inferior PV antral sites, catheter dislodgement during ablation occurred in 46% of ablations at the anterior border of the lateral PVs. This is well in line with the aforementioned observations from the TOCCATA study.

Interestingly, the slope of the individual learning curve defined as stable procedural parameters may substantially differ between large volume centres (n=12; [26]) and low-volume community hospitals (n=75; [29]).

A major difference to manual procedures however is the relative reduction in the operator's fluoroscopy exposure by 35%.

Moreover, in a prospectively randomized trial operator's fluoroscopy exposure was significantly reduced using robotic navigation for AF ablation (7 ± 2.1 versus 22 ± 6.5 minutes; $p < 0.001$) .[25]

It is noteworthy, that despite the availability of contact force information only 22.5% of patients who had undergone a segmental PVI procedure using RN demonstrated chronic PVI at 3 months follow-up assessed by an invasive repeat EP study. [28]

Summary

In summary, feasibility of AF ablation using remote navigation systems has been demonstrated in multiple independent clinical trials. In comparison to manual ablation procedures similar acute and chronic success rates were reported, however data on safety and efficacy from prospectively randomized clinical trials ("man and machine") have not been available yet. Therefore, the question whether the use of RN translates into a better clinical outcome remains unanswered.

It became evident that the use of remote navigation systems requires modifications of the standard manual ablation approach to prevent serious complications. This includes in particular esophageal temperature monitoring and a decrease in ablation power in robotic navigation procedures.

Unfortunately, recent trials could not provide compelling data that the use of robotic navigation will overcome the problem of catheter stability at particular LA regions such as the myocardial ridge sbetween the left atrial appendage and the left PVs [26] or will improve the chronic PV isolation rate. [28]

The major demerit of MN is the extensive procedure time of approximately 4 hours.

Nonetheless, both systems help to re duce the operator's exposure to scattered X-ray by ~35% during AF ablation procedures.

Future Directions

It remains the electrophysiologist's dream to perform a completely automated AF ablation procedure from a workstation within the control room. The magnetic navigation system software contains features (NaviLine) to store vectors and to navigate the catheter to and on pre-defined lines. One day, this might enable the operator to perform a circumferential ablation just by clicking the mouse. However, there is still a long road to travel.

In times of limited economical resources novel technologies should prove at least non-inferiority to conventional treatment options. Besides the reduced X-ray burden to the operator, the theoretical advantages of RN still need to be proven in clinical trials.

References

1. Fuster V, Ryden LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Le Heuzey JY, Kay GN, Lowe JE, Olsson SB, Prystowsky EN, Tamargo JL, Wann S. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation-executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients with Atrial Fibrillation). Eur Heart J 2006; 27(16):1979-2030.

2. Calkins H, Brugada J, Packer DL, Cappato R, Chen SA, Crijns HJ, Damiano RJ, Jr., Davies DW, Haines DE, Haissaguerre M, Iesaka Y, Jackman W, Jais P, Kottkamp H, Kuck KH, Lindsay BD, Marchlinski FE, McCarthy PM, Mont JL, Morady F, Nademanee K, Natale A, Pappone C, Prystowsky E, Raviele A, Ruskin JN, Shemin RJ. HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation developed in partnership with the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society (ECAS); in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), and the Society of Thoracic Surgeons (STS). Endorsed and approved by the governing bodies of the American College of Cardiology, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society. Europace 2007; 9(6):335-379.

3. Schmidt B, Chun KR, Tilz RR, Koektuerk B, Ouyang F, Kuck KH. Remote navigation systems in electrophysiology. Europace 2008; 10 Suppl 3:iii57-iii61.

4. Arentz T, Weber R, Burkle G, Herrera C, Blum T, Stockinger J, Minners J, Neumann FJ, Kalusche D. Small or large isolation areas around the pulmonary veins for the treatment of atrial fibrillation? Results from a prospective randomized study. Circulation 2007; 115(24):3057-3063.

5. Verma A, Natale A. Should atrial fibrillation ablation be considered first-line therapy for some patients? Why atrial fibrillation ablation should be considered first-line therapy for some patients. Circulation 2005; 112(8):1214-1222.

6. Katritsis D, Wood MA, Giazitzoglou E, Shepard RK , Kourlaba G, Ellenbogen KA. Long-term follow-up after radiofrequency catheter ablation for atrial fibrillation. Europace 2008; 10(4):419-424.

7. Gaita F, Caponi D, Scaglione M, Montefusco A, Corleto A, Di Monte F, Coin D, Di Donna P, Giustetto C. Long-term clinical results of 2 different ablation strategies in patients with paroxysmal and persistent atrial fibrillation. Circ Arrhythm Electrophysiol 2008; 1(4):269-275.

8. Ouyang F, Antz M, Ernst S, Hachiya H, Mavrakis H, Deger FT, Schaumann A, Chun J, Falk P, Hennig D, Liu X, Bansch D, Kuck KH. Recovered pulmonary vein conduction as a dominant factor for recurrent atrial tachyarrhythmias after complete circular isolation of the pulmonary veins: lessons from double Lasso technique. Circulation 2005; 111(2):127-135.

9. Yokoyama K, Nakagawa H, Shah DC, Lambert H, Leo G, Aeby N, Ikeda A, Pitha JV, Sharma T, Lazzara R, Jackman WM. Novel contact force sensor incorporated in irrigated radiofrequency ablation catheter predicts lesion size and incidence of steam pop and thrombus. Circ Arrhythm Electrophysiol 2008; 1(5):354-362.

10. Schmidt B, Kuck KH, Shah D, Reddy VY, Saoudi N, Herrera C, Hindricks G, Natale A, Jais P, Lambert H. TOCCATA Multicentre clinical study using irrigated ablation catheter with integrated contact force sensor: first results. Heart Rhythm. 5S[6]. 2009. Ref Type: Abstract

11. Schmidt B, Reddy VY, Natale A, Shah D, Soudi N, Herrera C, Hindricks G, Jais P, Yulzari A, Kuck KH, Lambert H. TOCCATA Multi-Centre Clinical Study: Irrigated RF Ablation Catheter with an integrated Contact Force Sensor - Long-Term Results. Heart Rhythm. 7[5S], S152. 1-5-0010.
Ref Type: Abstract

12. Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman

J, Kim YH, Klein G, Natale A, Packer D, Skanes A, Am brogi F, Biganzoli E. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. Circ Arrhythm Electrophysiol 2010; 3(1):32-38.
13. Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J, Kim YH, Klein G, Natale A, Packer D, Skanes A. Prevalence and causes of fatal outcome in catheter ablation of atrial fibrillation. J Am Coll Cardiol 2009; 53(19):1798-1803.
14. Pappone C, Vicedomini G, Manguso F, Gugliotta F, Mazzone P, Gulletta S, Sora N, Sala S, Marzi A, Augello G, Livolsi L, Santagostino A, Santinelli V. Robotic magnetic navigation for atrial fibrillation ablation. J Am Coll Cardiol 2006; 47(7):1390-1400.
15. Di Biase L, Fahmy TS, Patel D, Bai R, Civello K, Wazni OM, Kanj M, Elayi CS, Ching CK, Khan M, Popova L, Schweikert RA, Cummings JE, Burkhardt JD, Martin DO, Bhargava M, Dresing T, Saliba W, Arruda M, Natale A. Remote magnetic navigation: human experience in pulmonary vein ablation. J Am Coll Cardiol 2007; 50(9):868-874.
16. Kim AM, Turakhia M, Lu J, Badhwar N, Lee BK, Lee RJ, Marcus GM, Tseng ZH, Scheinman M, Olgin JE. Impact of remote magnetic catheter navigation on ablation fluoroscopy and procedure time. Pacing Clin Electrophysiol 2008; 31(11):1399-1404.
17. Katsiyiannis WT, Melby DP, Matelski JL, Ervin VL , Laverence KL, Gornick CC. Feasibility and safety of remote-controlled magnetic navigation for ablation of atrial fibrillation. Am J Cardiol 2008; 102(12):1674-1676.
18. Chun KR, Wissner E, Koektuerk B, Konstantinidou M, Schmidt B, Zerm T, Metzner A, Tilz R, Boczor S, Fuernkranz A, Ouyang F, Kuck KH. Remote-Controlled Magnetic Pulmonary Vein Isolation Utilizing a New Irrigated Tip Catheter in Patients with Atrial Fibrillation. Circ Arrhythm Electrophysiol 2010.
19. Saliba W, Reddy VY, Wazni O, Cummings JE, Burkhardt JD, Haissaguerre M, Kautzner J, Peichl P, Neuzil P, Schibgilla V, Noelker G, Brachmann J, Di Biase L, Barrett C, Jais P, Natale A. Atrial fibrillation ablation using a robotic catheter remote control system: initial human experience and long-term follow-up results. J Am Coll Cardiol 2008; 51(25):2407-2411.
20. Wazni OM, Barrett C, Martin DO, Shaheen M, Tarakji K, Baranowski B, Hussein A, Callahan T, Dresing T, Bhargava M, Kanj M, Tchou P, Natale A, Saliba W. Experience with the Hansen Robotic System for Atrial Fibrillation Ablation-Lessons Learned and Techniques Modified: Hansen in the Real World. J Cardiovasc Electrophysiol 2009.
21. Tilz RR, Chun KR, Metzner A, Burchard A, Wissner E, Koektuerk B, Konstantinidou M, Nuyens D, Potter TD, Neven K, Fuernkranz A, Ouyang F, Schmidt B. Unexpected High Incidence of Esophageal Injury Following Pulmonary Vein Isolation Using Robotic Navigation. J Cardiovasc Electrophysiol 2010.
22. Rillig A, Meyerfeldt U, Birkemeyer R, Wiest S, Sauer BM, Staritz M, Jung W. Oesophageal temperature monitoring and incidence of oesophageal lesions after pulmonary vein isolation using a remote robotic navigation system. Europace 2010; 12(5):655-661.
23. Okumura Y, Johnson SB, Bunch TJ, Henz BD, O'Brien CJ, Packer DL. A systematical analysis of in vivo contact forces on virtual catheter tip/tissue surface contact during cardiac mapping and intervention. J Cardiovasc Electrophysiol 2008; 19(6):632-640.
24. Di Biase L, Wang Y, Horton R, Gallinghouse GJ, Mohanty P, Sanchez J, Patel D, Dare M, Canby R, Price LD, Zagrodzky JD, Bailey S, Burkhardt JD, Natale A. Ablation of atrial fibrillation utilizing robotic catheter navigation in comparison to manual navigation and ablation: single-center experience. J Cardiovasc Electrophysiol 2009; 20(12):1328-1335.
25. Steven D, Servatius H, Rostock T, Hoffmann B, Drewitz I, Mullerleile K, Sultan A, Aydin MA, Meinertz T, Willems S. Reduced Fluoroscopy During Atrial Fibrillation Ablation: Benefits of Robotic Guided Navigation. J Cardiovasc Electrophysiol 2009.
26. Schmidt B, Tilz RR, Neven K, Julian Chun KR, Furnkranz A, Ouyang F. Remote robotic navigation and electroanatomical mapping for ablation of atrial fibrillation: considerations for navigation and impact on procedural outcome. Circ Arrhythm Electrophysiol 2009; 2(2):120-128.
27. Kautzner J, Peichl P, Cihak R, Wichterle D, Mlcochova H. Early experience with robotic navigation for catheter ablation of paroxysmal atrial fibrillation. Pacing Clin Electrophysiol 2009; 32 Suppl 1:S163-S166.

28. Willems S, Steven D, Servatius H, Hoffmann BA, Drewitz I, Mullerleile K, Aydin MA, Wegscheider K, Salukhe TV, Meinertz T, Rostock T. Persistence of Pulmonary Vein Isolation After Robotic Remote-Navigated Ablation for Atrial Fibrillation and its Relation to Clinical Outcome. J Cardiovasc Electrophysiol 2010.
29. Rillig A, Meyerfeldt U, Birkemeyer R, Treusch F, Kunze M, Miljak T, Zvereva V, Jung W. Remote robotic catheter ablation for atrial fibrillation: how fast is it learned and what benefits can be earned? J Interv Card Electrophysiol 2010; 29(2):109-117.