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Remotely controlled steerable sheath improves result and procedural parameters of atrial fibrillation ablation with magnetic navigation

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Aims The magnetic navigation (MN) system may be coupled with a new advancement system that fully controls both the catheter and a robotic deflectable sheath (RSh) or with a fixed-curve sheath and a catheter-only advancement system (CAS). We aimed to compare these approaches for atrial fibrillation (AF) ablation.

Methods and results Atrial fibrillation ablation patients (45, 23 paroxysmal and 22 persistent) performed with MN–RSh (RSh group) were compared with a control group (37, 18 paroxysmal and19 persistent) performed with MN–CAS (CAS group). Setup duration was measured from the procedure's start to operator transfer to control room. Ablation step duration was defined as the time from the beginning of the first radiofrequency (RF) pulse to the end of the last one and was separately acquired for the left and the right pulmonary vein (PV) pairs. Clinical characteristics, left atrial size, and AF-type distribution were similar between the groups. Setup duration as well as mapping times was also similar. Ablation step duration for the left PVs was similar, but was shorter for the right PVs in RSh group (46 $\pm$ 9 vs. 63 $\pm$ 12 min, $P < 0.0001$). Radiofrequency delivery time (34 $\pm$ 9 vs. 40 $\pm$ 11 min, $P = 0.007$) and procedure duration (227 $\pm$ 36 vs. 254 $\pm$ 62 min, $P = 0.01$) were shorter in RSh group. No complication occurred in RSh group. During follow-up, there were five recurrences (11%) in RSh group and 11 (29%) in CAS group ($P = 0.027$).

Conclusion The use of the RSh for AF ablation with MN is safe and improves outcome. Right PV isolation is faster, RF delivery time and procedure time are reduced.

Keywords Magnetic navigation • Robotic sheath • Catheter ablation • Atrial fibrillation

Introduction

Remote magnetic navigation (MN) for atrial fibrillation (AF) catheter ablation is efficient and provides increased comfort for the operators.[1] Despite the lack of randomized trials, MN seems to be associated with less peri-procedural complications compared with manual technique.[2] The latest generation of MN system (Niobe ES, Stereotaxis; Stx) allows faster remote manipulation of a soft catheter by means of a steerable magnetic field. It may be coupled with two types of catheter advancement systems: one that fully controls both the catheter and a robotic deflectable sheath (RSh) or one which is a catheter-only advancement system (CAS) using a standard fixed-curve sheath. We aimed to evaluate the two approaches for AF ablation.

Methods

Inclusion criteria

Between January 2012 and December 2013 consecutive patients who underwent AF ablation using MN coupled with the RSh (RSh group), were prospectively included. The control group consisted of consecutive AF ablation cases with MN combined with a fixed-curve sheath and a CAS in our centre before the availability of RSh (CAS group). This study was

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What's new?

- This is the first reported experience on a new remotely controlled steerable sheath coupled with magnetic navigation in the setting of atrial fibrillation ablation.
- This new device fastens right pulmonary vein isolation with significant reduction of the procedure duration and radiofrequency delivery time compared to standard magnetic navigation (catheter-only advancement).
- The use of the robotic sheath is safe and was associated with an improved outcome after AF ablation.

approved by the institutional committee on human research. According to institutional guidelines all patients gave written informed consent.

Ablation procedure

All patients received anticoagulation therapy with vitamin K antagonists (VKA) for at least 1 month before the procedure (target international normalized ratio, INR, 2–3). Anticoagulation therapy with VKA was not interrupted at the time of the procedure. Transoesophageal echocardiography was performed within the procedure to exclude left atrium (LA) thrombus and to guide transseptal puncture.

Ablation procedures were performed in the fasting state under general anaesthesia or mild sedation. Venous punctures were performed under ultrasound guidance. Through the right femoral vein were introduced (i) a deflectable decapolar catheter positioned within the coronary sinus with the distal electrode positioned at 4–5 o'clock along the mitral annulus in the 30° left anterior oblique radiographic projection; (ii) a 20 pole, variable diameter circumferential mapping catheter to guide pulmonary vein isolation (PVI) (Lasso 2550, Biosense Webster Inc.) introduced within a long sheath (Preface Multipurpose, Biosense Webster Inc. or Fast-Cath SL1); and (iii) a 3.5 mm tip externally irrigated magnetic catheter (ThermoCool RMT, Biosense Webster Inc.) within a second long sheath. The second long sheath was the robotic deflectable sheath (RSh group, *Figure 1*) or a standard fixed-curve long sheath (Fast-Cath SL1) in the CAS group.

Two separate transseptal punctures were performed under combined fluoroscopic and real-time transoesophageal echocardiography guidance. Immediately before the first transseptal puncture, a bolus of 50 IU/kg heparin was administered. Activated clotting time (ACT) was rechecked every 30 min during the procedure. Additional heparin boluses were given if necessary to maintain the ACT between 300 and 350 s.

Ablation strategy was circumferential antral PVI (CPVI) in paroxysmal AF (PAF) with lasso-proven PVI as an endpoint. Radiofrequency (RF) was delivered in a point-by-point manner with minimum 30 s burns (aiming electrograms (EGMs) modification favouring transmural lesion) at each ablation site.[3] Robotic deflectable sheath loop in the LA was systematically used for targeting the ostia of the right PV (*Figure 2*). A stepwise approach was used for persistent AF patients, with additional lesions targeting fractionated EGMs in the LA, inside the coronary sinus and in the right atrium (RA), as well as LA roof and in some cases left isthmus lines. In case of AF termination by transformation into an atrial tachycardia, the critical isthmus of conduction was localized and targeted with the endpoint of sinus rhythm restoration; if AF persisted after ablation of all suitable sites, an electrical cardioversion was performed within 48 h after the procedure. An electroanatomical mapping system was used for all procedures (Carto 3, Biosense Webster Inc.). Circumferential antral PVI was performed in all patients, as widely in the antrum as possible, with the endpoint of abolition or dissociation of activities in the PVs (entrance block). Pulmonary vein potentials were distinguished from eventual far-field potentials with pacing techniques from the left atrial appendage, or RA.

In patients under general anaesthesia, oesophageal temperature was continuously monitored, and RF delivery was immediately stopped whenever oesophageal temperature increased by $>0.5^{\circ}C$.

Procedural parameters

The procedure duration was defined as the time from the start of the first venous puncture until sheaths withdrawal at the end of the procedure. Radiofrequency application duration was defined as the cumulative length of all RF applications necessary to achieve the endpoint. Setup time was defined as the time from the start of the procedure to operator transfer into the control room. Right and left CPVI step duration was defined as the time from the first RF delivery to the total abolition or dissociation of PV potentials for each of the PV pairs.

Magnetic navigation

The MN system was described elsewhere.[2] In brief, the MN consists of two permanent giant magnets, positioned on both sides of the fluoroscopy table (Axiom Artis, Siemens, Germany), and creating a steerable computer-controlled magnetic field of an intensity of 0.08 or 0.1 tesla (T). The soft magnetic catheters equipped with three magnets near its distal tip tend to be aligned to the direction of the magnetic field. A catheter advancement system allows remote push and pull movements of the catheter and its sheath. Two versions of this system were compared in this study: a CAS (Quick-CAS, Stx; *Figure 3*), and a catheter advancement system that fully controls both the catheter and a robotic deflectable sheath (V-CAS Deflect, Stx). Full remote control is also available for the variable diameter steerable circular catheter by means of another disposable (V-Loop, Stx). V-CAS Deflect and the V-Loop are connected to one/two robotic arms (V-Drive or V-Drive Duo, *Figure 4A*). Complete

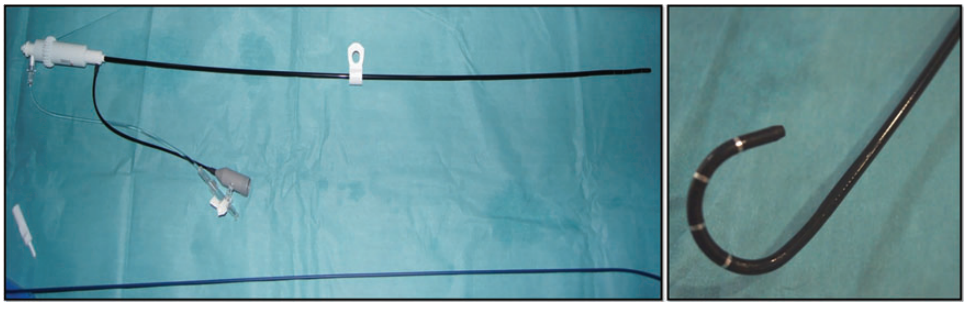

Figure 1 The robotic deflectable sheath (V-CAS Deflect) fully undeflected (left panel) and fully deflected (right panel).

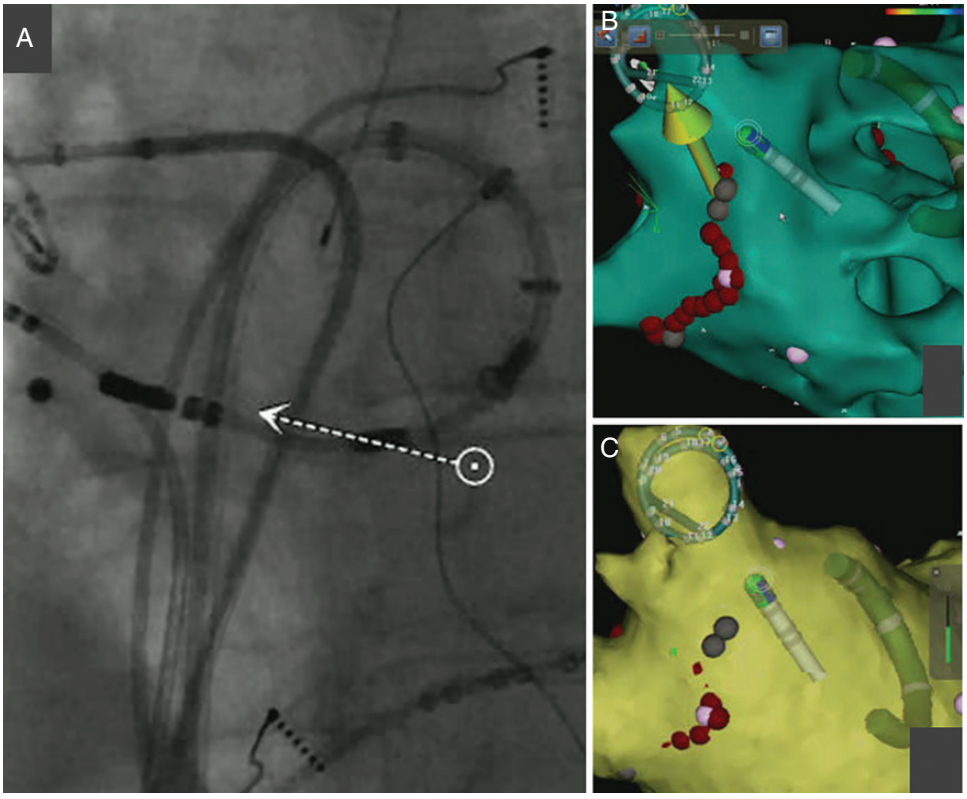

Figure 2 A loop with the robotic sheath in the LA was systematically used for targeting the ostia of the right PVs: (*A*) antero-posterior fluoroscopic image; (*B*) map of the LA; and (*C*) merge with the computed tomographic scan reconstruction of the LA.

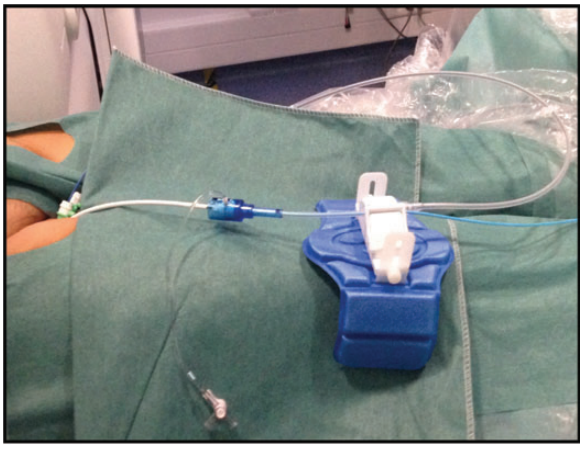

Figure 3 Final setup of the catheter-only advancement system with a fixed curve sheath.

remote manoeuvring of all the components is performed via a controller (V-Drive Controller, *Figure 4B*).

Single operators, sitting in the control room, via a computer interface (Navigant, Stereotaxis, integrated into Carto system), control the orientation of the magnetic field and advancement and retraction of catheters and sheaths. Software automation tools are available for simplifying navigation.

Robotic deflectable sheath

The V-Cas deflect is a remote navigation platform that allows the operator to manoeuvre a robotic deflectable sheath from a remote interface. The system consists of a robotic drive unit, a remote controller, and a catheter-specific disposable set that interfaces the drive unit with both the robotic sheath and the magnetic catheter (*Figure 4*).

Robotic deflectable sheath is a 79 cm length, 12.8 Fr diameter deflectable irrigated magnetic sheath with four 1.3 cm spaced platinum electrodes that allow location and identification in the mapping system. The operator controls both RSh and catheter motion by manipulating the remote controller (*Figure 4B*) from the remote workstation. The drive unit then transmits these commands directly to the catheter handle. Operations governed by the remote controller include advancement, retraction, rotation, deflection, looping, and unlooping movements.

Statistical analysis

Statistical analysis was done with Stata 9.1 (Statacorp 2005). All continuous variables are expressed as mean $\pm$ SD. Two-tailed Wilcoxon *t*-test was used to compare numerical variables. Nominal variables were compared by use of the χ^2 test (or Fisher's exact test if χ^2 test was inappropriate).The log-rank test was used to compare ablation results in the two groups. A two-tailed P value < 0.05 was considered statistically significant.

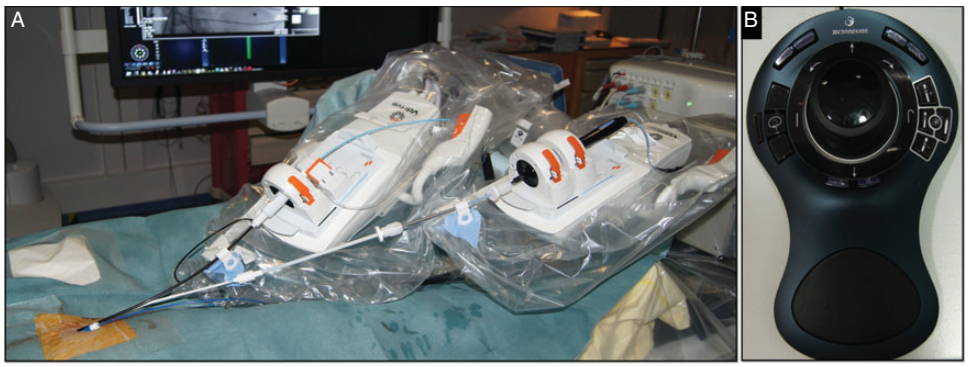

Figure 4 (*A*) Final setup of the arms of the V-Drive Duo (with V-CAS Deflect and V-Loop) at the sheath insertion site. (*B*) The V-Drive controller that allows remote manipulation of the ablation catheter, its sheath and of the lasso.

Table 1 Patients' clinical characteristics

Characteristic	RSh group ($n = 45$)	CAS group ($n = 37$)	*P*
Male sex (*n*) (%)	22 (59.46)	29 (78.38)	0.079
Age (years)	57.8 ± 11	58.8 ± 9	0.34
BMI (kg/m^2)	25.8 ± 4	26.5 ± 4	0.25
AF type (paroxysmal/ persistent)	23/22	18/19	0.81
CHA_2DS_2-Vasc score	1.54 ± 1.46	1.40 ± 1.36	0.65
LA diameter (antero-posterior; ultrasound; mm)	43.0 ± 9.1	45.8 ± 6.5	0.09
LA volume (CT Scan; mL)	117 ± 53	124 ± 53	0.30
LVEF (%)	66.1 ± 9.1	62.4 ± 11.2	0.93
Common left PV trunck	5	5	0.77

BMI, indicates body mass index; AF, atrial fibrillation; LA, left atrium; LVEF, left ventricular ejection fraction; PV, pulmonary vein.

Results

Study population

The study population consisted of 45 patients in the RSh group (57.8 ± 11 years, 59% male) and 37 patients in the CAS group (58.8 ± 9 years, 78% male). Patients' characteristics are detailed in *Table 1*. There was no significant difference between the two groups.

Ablation procedure

Lasso-proven PVI was obtained in all patients. No patients required crossover from the magnetic ablation catheter to a manual equivalent. Looping of the robotic sheath in the LA was successfully performed in all patients allowing a direct approach (from left to right) for right PVI.

Procedural parameters are shown in *Table 2*. Setup duration and LA mapping time were similar between the two groups. Right CPVI step was significantly shorter in the RSh group (46 ± 9 vs. 63 ± 12 min, $P < 0.0001$). Radiofrequency was delivered for a shorter time in the RSh group (34.15 ± 9.34 vs. 40.08 ± 11.09, $P = 0.007$). Procedure duration was shorter in the RSh group (227 ± 36 vs. 254 ± 62 min, $P = 0.014$). Total fluoroscopy time was similar between the groups but the operator exposure time was shorter in the RSh group (5.16 ± 95.71 vs. 7.53 ± 4.63 min, $P = 0.002$).

In patients with documented typical atrial flutter, cavotricuspid isthmus ablation was successfully performed with documented persistent bidirectional isthmus block in all patients without crossover to a manual catheter.

Follow-up

Patients were followed for clinical and asymptomatic recurrences for 9 ± 5 months after the procedure in the RSh group and for 10.5 ± 9 months in the CAS group. Follow-up was performed in a 'real-life' setting by regular visits to the treating cardiologist with repeated 24 h Holter monitoring in all cases (every 3 months during the first year post-ablation, every 6 months afterwards). Any recurring, sustained, symptomatic AF or atrial flutter was considered for a repeat procedure.

An arrhythmia recurrence was documented in 5 patients (11%) in the RSh group and in 11 patients (29%) in the CAS group ($P = 0.027$). Recurrences were AF in nine patients and atypical atrial flutter in 7 patients (*Figure 5*).

Complications

Access-site haematoma was observed in one patient in the CAS group (a case performed before the era of the ultrasound-guided venous puncture[4]). No complication occurred in the RSh group.

Discussion

We report our initial experience with the RSh coupled with MN, which improved the result of AF ablation when compared with MN alone. Right PVI was faster when RSh was used, RF was delivered for a shorter time in the RSh group and therefore procedure time was shortened.

Robotics are used for ablation of human arrhythmias from >10 years with three commercially available systems.[5–7] Widespread

Table 2 Procedural parameters

Parameter	RSh group (n = 45)	CAS group (n = 37)	P
Setup duration (min)	48.43 ± 7.28	49.94 ± 6.07	0.22
Mapping and image fusion duration (min)	31.84 ± 6	32.97 ± 6.	0.170
Left PV circumferential isolation step duration (min)	44 ± 11	46 ± 12	0.09
Right PV circumferential isolation step duration (min)	46 ± 9	63 ± 12	<0.0001
Procedure duration (min)	227 ± 36	254 ± 62	0.014
Total RF time (min)	34.15 ± 9.34	40.08 ± 11.09	0.007
Total fluoroscopy time (min)	12.81 ± 4.2	12.75 ± 4.97	0.794
Operator fluoroscopy exposure time (min)	5.16 ± 3.71	7.53 ± 4.63	0.002
Associated CTI ablation (n)	5	2	0.233

PV, pulmonary vein; RF, radiofrequency; CTI, cavotricuspid isthmus.

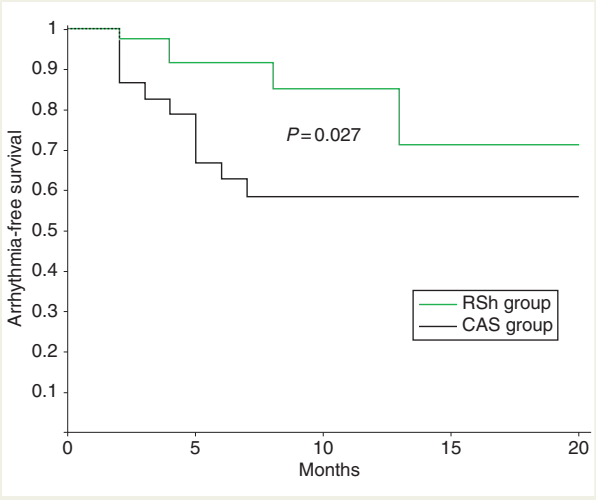

Figure 5 Kaplan–Meier curves of arrhythmia-free survival during the follow-up after the initial procedure. Robotic sheath use was associated with significant reduction of atrial fibrillation recurrence.

use of MN for AF ablation began in 2008 with the availability of irrigated magnetic catheters. When compared with manual technique, MN shows similar results for AF ablation. Longer MN procedure times have been reported, but these seem compensated by shorter fluoroscopy exposure and increased safety.[8–10] For the operator, the advantage of remotely performing lengthy procedure while seating is undeniable. For repeat AF ablation procedures, MN has been related to fewer recurrences when compared with manual conventional technique.[11]

All the above data concern the second-generation MN system (Niobe II, Stx) which used a fixed-curve sheath and the CAS, representing for us the control group. Since 2012, the third generation MN (Niobe ES), provides faster magnetic field direction changes and can be coupled with one or two robotic arms allowing remote control of the circular mapping catheter[12] and of the ablation catheter sheath.

The non-magnetic robotic systems for ablation are based on robotic steerable sheaths.[6,7] These systems provide robotic assistance for conventional stiff catheters by means of robotic steerable sheaths;[13,14] the operator movements are transmitted to the steerable sheath which in turn directs the catheter.

Our use of the specific RSh coupled with MN is different. We use the sheath to provide an anchoring point for the magnetic catheter inside the LA, in a region opposite to the ablation target site (e.g. posteriorly in the LA for anterior ablation targets like the ridge between the left PV and the LA appendage; leftwards in the LA, pointing rightwards by means of a loop (*Figure 2*) for targeting the right PV). Thus, a longer length of the magnetic catheter is available for alignment with the magnetic field, improving navigation and tissue contact. Since the RSh is visualized on the mapping system, steering, rotation, advancement, and retraction of the sheath may be performed without fluoroscopy; for safety reasons, before each remote manipulation we ensured that a sufficient length of the magnetic catheter was outside the sheath (i.e. the most distal flexion point) to serve as a soft leader guide.

Solid data exist showing the predictive value of catheter–tissue contact for the transmurality of ablation lesions.[3] The use of steerable sheaths technology has been reported to increase catheter stability, tissue contact, and improve ablation outcome.[15] Robotic assistance for conventional stiff catheters by means of a robotic steerable sheath has also been reported to improve catheter stability.[16]

Maximal contact force provided by magnetic catheters was inferior to that obtained with conventional catheters in experimental studies (26.8 vs. 45.4 g).[17] This inferior maximum pressure is compensated by the better catheter stability provided by the MN.[18–20] Magnetic catheters deliver RF energy with a lower mean temperature and with less variability of temperature during ablation, thus enhancing tissue energy transfers.[19]

We consider the absence of contact force direct measurement for the magnetic catheters and the RSh as a safety limitation for the use of the RSh to provide a 'better' push and thus increase contact force. Nevertheless, using the semi-quantitative contact tool of the MN system (based on the angulation between the catheter and the magnetic field direction), we regularly use the RSh advancement (towards the left PV) and orientation of the RSh tip (slightly anteriorly if the body of the sheath is oriented towards the posterior wall) for ablation along the ridge between the left PV and the LA appendage.

Robotic deflectable sheath combines the advantages of both MN and remote robotic manoeuvring of a steerable sheath. By improving catheter stability, this technology improved the results of AF ablation

compared with our historical cohort of MN and decreased procedure duration.

Limitations

The major limitation of this study is its non-randomized nature. Since the new version of the MN system (Niobe ES) with its robotic arms (V-Drive Duo) replaced the previous version, only a historical cohort could serve as a control group. We voluntarily chose to use from the very beginning the new robotic deflectable sheath in order to take advantage of the full system's capabilities. Thus, no information is available concerning the improvement brought by each component of the new version (faster magnets and RSh, respectively). The two techniques (RSh and CAS) should be evaluated in a randomized trial with the same MN system version.

Conclusion

The use of the new remotely controlled steerable sheath coupled with the latest generation of MN is safe and improves result of AF ablation. Looping of the RSh inside the LA fastens right PVI, RF delivery time is shortened and procedure time is thus decreased. The proper net benefit brought respectively by the robotic sheath and the new version of MN system is difficult to assess.

Acknowledgements

Preliminary results of this study have been presented at Europace 2013 in Athens (Europace (2013) 15 (suppl 2): ii168–ii170).

Conflicts of interest: Decebal Gabriel Latcu and Nadir Saoudi have received in the past consulting honoraria from Stereotaxis, Inc., St Louis, MO, USA (none in the last year).

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