

Experience of robotic catheter ablation in humans using a novel remotely steerable catheter sheath

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Abstract

Background A novel remotely controlled steerable guide catheter has been developed to enable precise manipulation and stable positioning of any eight French (Fr) or smaller electrophysiological catheter within the heart for the purposes of mapping and ablation.

Objective To report our initial experience using this system for remotely performing catheter ablation in humans.

Methods Consecutive patients attending for routine ablation were recruited. Various conventional diagnostic catheters were inserted through the left femoral vein in preparation for treating

an accessory pathway ($n=1$), atrial flutter ($n=2$) and atrial fibrillation ($n=7$). The steerable guide catheter was inserted into the right femoral vein through which various irrigated and non-irrigated tip ablation catheters were used. Conventional endpoints of loss of pathway conduction, bidirectional cavotricuspid isthmus block and four pulmonary vein isolation were used to determine acute procedural success.

Results Ten patients underwent remote catheter ablation using conventional and/or 3D non-fluoroscopic mapping technologies. All procedural endpoints were achieved using the robotic control system without manual manipulation of the ablation catheter. There was no major complication. A radiation dosimeter positioned next to the operator 2.7 m away from the X-ray source showed negligible exposure despite a mean cumulative dose area product of 7,281.4 cGycm² for all ten ablation procedures.

Conclusions Safe and clinically effective remote navigation of ablation catheters can be achieved using a novel remotely controlled steerable guide catheter in a variety of arrhythmias. The system is compatible with current mapping and ablation technologies. Remote navigation substantially reduces radiation exposure to the operator.

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1 Introduction

Mapping and catheter ablation of cardiac arrhythmias can be technically complex and challenging. Currently the majority of such procedures are performed using manually deflectable catheters. These catheters have limited range and flexibility

and rely on operator skill to manoeuvre the catheter tip and maintain stability at target sites within the heart.

A novel electromechanical master/slave system that can remotely control a steerable guide catheter (Hansen Medical, Inc., Mountain View, CA, USA) has been developed to enable precise positioning and manipulation of any type of electrophysiological catheter within the heart for the purposes of mapping and ablation. The system comprises three linked components: the physician's workstation (Sensei™ robotic control system), remote catheter manipulator (RCM) and steerable guide catheter (Artisan™ Control Catheter) (Fig. 1).

1.1 The physician's workstation

The physician's workstation consists of display screens for contact intracardiac electrophysiology data and 3D mapping systems as well as a central fluoroscopic control view also displaying a superimposed icon of the Artisan Control Catheter (Fig. 2). Integral to the workstation and its control of the Artisan is the Instinctive Motion Controller (IMC); effectively a 3-dimensional hand operated joystick. The position of the IMC handle is calculated from internal sensors, and this position is fed to control computers in a separate electronics rack which in turn guides the remote catheter manipulator (RCM).

1.2 Remote catheter manipulator

The RCM is a robot designed to accept the Artisan catheter. The RCM receives catheter position commands from the control computers as issued by the IMC. Acting on these commands, the RCM uses servo motors to control its motions. These motions transfer to the Artisan catheter's pull wires, ultimately determining the position of the catheter tip.

1.3 Steerable guide catheter (Artisan)

The Artisan is a single use sterile guide catheter that is composed of two parts: a steerable inner guide within a steerable outer guide (Fig. 3). The outer guide catheter (outer size 14 Fr, inner size 11 Fr), controlled by two pull wires 180° apart, provides a stable base for the inner guide (11 Fr outer, 8.5 Fr inner). Four orthogonal pull wires deflect the inner guide catheter in x and y direction so it can reach anywhere within a roughly toroidal workspace defined by bend of up to 270° and 10 cm extension. Both sheath movements are controlled by the operator. Combined with the RCM's ability to insert the entire Artisan forward and rotate it, the tip has a versatile reach. Conventional 8 Fr or smaller mapping and ablation catheters are inserted through the inner guide catheter and locked in place at the proximal end of the Artisan. The deflection mechanisms of these catheters are not required and remain within the Artisan. The only part of the catheters to protrude from the tip of the Artisan control catheter are the distal bipole and occasionally the proximal bipole, as determined by the operator on insertion of the conventional catheter into the Artisan.

We report our initial experience in testing the hypothesis that robotic remote catheter ablation in humans is feasible and safe using existing catheters and mapping systems. This study was approved by St. Mary's Hospital local ethics committee.

2 Materials and methods

Consecutive patients meeting inclusion criteria and without exclusion criteria (Table 1) were recruited. As part of the

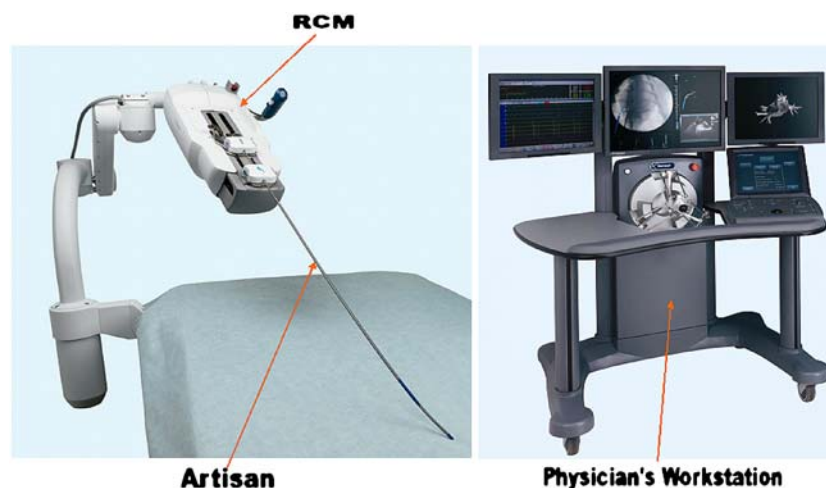


Fig. 1 The remote catheter manipulator (RCM) (*left*) is attached to the steerable guide catheter (Artisan™) through which a mapping catheter can be positioned within the heart. The physician's workstation (*right*) navigates the steerable guide catheter remotely

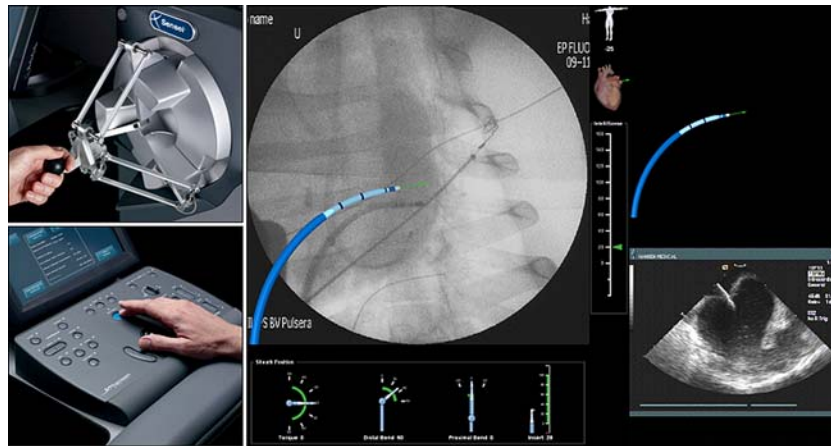


Fig. 2 The Instinctive Motion Controller (*top left*) used with a control panel on the physician’s workstation (*bottom left*) remotely guides the steerable guide catheter which can be seen on the central “control

view” display (*right*). Real-time data on catheter orientation, catheter-tip pressure, fluoroscopic views as well as intracardiac echocardiography are shown

initial safety protocol, ten patients underwent remote mapping *only* and these patients subsequently underwent conventional ablation after the steerable guide catheter was removed. A further ten patients underwent both remote mapping *and* ablation using the Artisan, the results of which are presented in this paper. Informed written consent was obtained from all patients prior to the procedure. All were studied in the fasted state with or without intravenous sedation.

Various diagnostic catheters were inserted and manipulated manually through the left femoral vein for initial arrhythmia mapping. These included Josephson™ quad-

ripolar catheters in combination with Cardima™, Halo™ and Lasso™ catheters for mapping a left lateral accessory pathway, two atrial flutter circuits and for seven atrial fibrillation ablation procedures respectively.

Transeptal access was performed to treat the patients with an accessory pathway and atrial fibrillation. In the cases of atrial fibrillation ablation, a single transeptal puncture was made from the left femoral vein, the needle was removed, the sheath withdrawn into the right atrium and an .035 J-wire left across the puncture site. The Artisan containing the ablation catheter was then guided from the right femoral vein through the puncture site into the left atrium for ablation. It is useful to note that although the outer guide is able to cross the interatrial septum, for the majority of cases, this remains on the

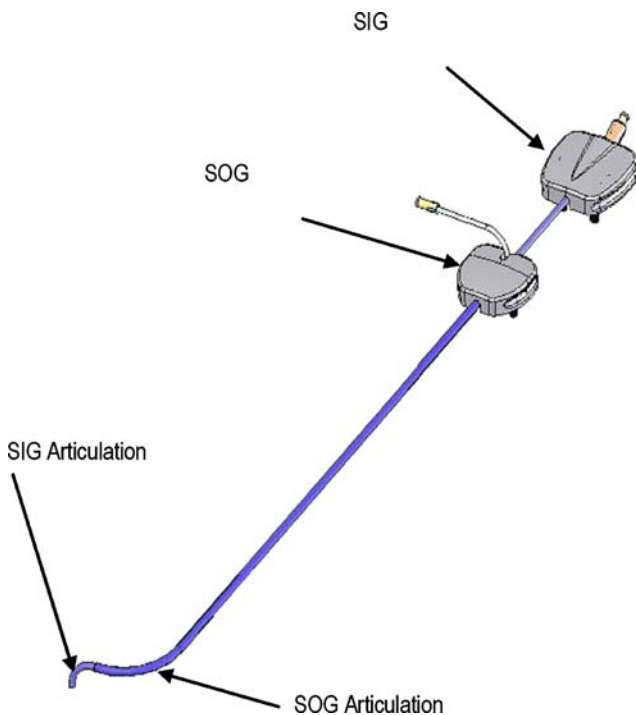


Fig. 3 The Artisan control catheter and its components. *SIG* Steerable inner guide, *SOG* steerable outer guide

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Suitable for catheter mapping/ablation	Severe cerebrovascular disease
18–85 years of age	Serum creatinine > 2.5
Body Mass Index < 40	Active gastrointestinal bleeding
Signed informed consent	Active infection or fever
	Short life expectancy <1 year
	Significant anemia
	Severe electrolyte imbalance
	Allergy to contrast
	Congestive heart failure (NYHA Class IV), ejection fraction <30%
	Unstable angina requiring emergent percutaneous intervention
	Recent myocardial infarction within 2 weeks
	Bleeding or clotting disorders
	Uncontrolled diabetes
	Inability to receive IV anticoagulants

right atrial side of the septum and catheter navigation within the left atrium was done mainly using the inner sheath. The pulmonary veins were mapped manually with a Lasso™ placed via the left femoral transeptal sheath. For left-sided procedures titrated intravenous heparin boluses of up to 10,000 units were given every 30 min to maintain an activated clotting time of at least 300 s.

The Artisan control catheter was inserted into the right femoral vein through a short non-irrigated 14 Fr sheath. Various conventional 4 and 8 mm non-irrigated tip (EPT Blazer II™) and irrigated-tip (Navistar™ Thermocool™) catheters were deployed through the lumen of the Artisan for ablation. Continuous heparinised saline flushing was maintained through the side ports of the inner and outer sheaths of the Artisan.

Conventional mapping was complemented with 3D non-fluoroscopic mapping technologies as required, including NavX™ (St. Jude Medical, St. Paul, MN, USA), CARTO™ and CARTOMERGE™ (Biosense Webster Inc., Diamond Bar, CA, USA).

All 3D maps, computed tomography scan registration, mapping and ablation were performed remotely. In the atrial fibrillation cases some ablation points were ‘drag’ lesions used to construct ablation lines.

Conventional endpoints of loss of accessory pathway function, bidirectional cavotricuspid isthmus block and four

pulmonary vein isolation were used to determine immediate procedural success.

At the end of the procedure the Artisan was removed from the 14 Fr venous sheath manually. If heparin had been given during the procedure, intravenous protamine was administered and removal of the 14 Fr sheath was done under manual pressure once the activated clotting time was less than 150 s.

3 Results

Twenty patients were studied. In ten, only mapping to specific anatomical sites was performed using the Hansen system for regulatory purposes without any procedural complication related to using the system. The other ten patients underwent remote catheter ablation and are the subjects of this report. All mapping and ablation endpoints were achieved using only the Sensei robotic control system, without manual manipulation of the ablation catheter in these ten patients.

Table 2 shows the procedures undertaken, equipment used, radiation exposure, procedural and ablation times. (Note that ablation times are taken from the first application to the last application of radiofrequency energy. All RF applications were given for up to 1 min at a time). Figures 4 and 5 show

Table 2 Robotic ablation procedural data

Patient	Sex	Age	Diagnosis	Procedure	Mapping system	Catheter tip	Number of RFs	RF time	Total procedure time	Flouro time	Patient DAP	Workstation DAP
1	F	76	Atrial flutter	CTI	conventional	4 mm irrigated	38	103	140	44.5	8,383	0
2	M	55	Permanent atrial fibrillation	PVI, left atrial maze	NavX™	4 mm irrigated	63	191	259	116	24,667	0
3	M	50	Paroxysmal atrial fibrillation	PVI	NavX™	4 mm irrigated	42	111	170	52	11,216	0
4	M	41	Accessory pathway	Pathway ablation	conventional	4 mm non-irrigated	3	31	106	13.4	779	0
5	F	71	Atrial flutter	CTI	conventional	8 mm non-irrigated	15	33	70	19.9	1,042	0
6	M	53	Persistent atrial fibrillation	PVI roof line, MI	NavX™	4 mm irrigated	39	123	165	55.2	6,577	0
7	M	73	Persistent atrial fibrillation	PVI and roof line	NavX™	4 mm irrigated	46	143	166	64.2	4,739	0
8	F	63	Paroxysmal atrial fibrillation	PVI and roof line	NavX™	4 mm irrigated	48	118	157	42.8	7,271	0
9	F	46	Atrial ectopy/paroxysmal atrial fibrillation	PVI	CARTOMERGE™	4 mm irrigated	31	143	124	41.7	2,262	0
10	M	54	Persistent atrial fibrillation	PVI and roof line	CARTO™	4 mm irrigated	68	155	223	43.4	5,878	0

[CTI cavotricuspid isthmus line, PVI pulmonary vein isolation, MI mitral isthmus, line, RF radiofrequency ablation. RF time – time from first RF to the end of the last RF. All times are in minutes. Radiation exposures are expressed as dose area product DAP (cGycm²).]

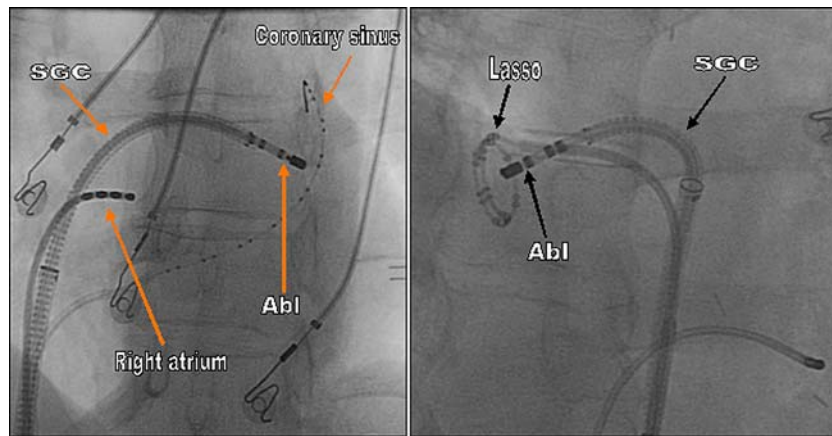


Fig. 4 Examples of the use of the remotely controlled catheter sheath in conventional electrophysiological procedures. LAO projection of a left free wall accessory pathway ablation (*left*) and PA projection of

segmental right upper pulmonary vein isolation (*right*). (SGC steerable guide catheter, Abl ablation catheter tip)

examples of the use of the steerable catheter in combination with each mapping system.

No major complication occurred. One patient (accessory pathway) had a small <1 cm pericardial effusion measured on echocardiogram 24 h post-procedure. The patient was not on post-procedural anticoagulation and was discharged without any clinical sequelae. There were no femoral haematomas associated with the use of the system.

A radiation dosimeter (Mydose Mini X, Aloka Co. Ltd., Japan) positioned at the physician’s workstation approximately 2.7 m away from the X-ray source demonstrated negligible

exposure to the operator despite a mean cumulative dose area product of 7,281.4 cGycm² for all ten ablation procedures.

4 Discussion

Complex ablation procedures to treat cardiac arrhythmias can be time consuming and technically challenging. There is always a need to improve procedural success, reduce procedure times and minimize fluoroscopy screening times. These issues are largely governed by the skill and efficiency

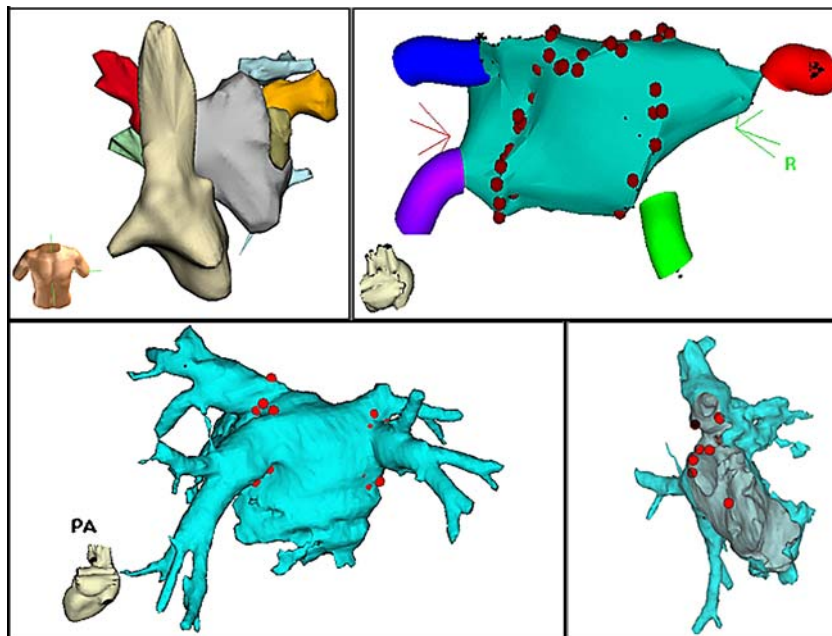


Fig. 5 Non-fluoroscopic mapping system images created using the remotely controlled steerable guide catheter. Anteroposterior view of the left and right atrial geometry using NavX™ (*top left*) and posteroanterior view of the left atrium during wide area circumferen-

tial ablation using CARTO™ (*top right*). Posteroanterior view of the left atrium (*bottom left*) and cross-sectional view of the left sided pulmonary veins (*bottom right*) during segmental pulmonary vein isolation using CARTOMERGE™. (Ablation lesions in red)

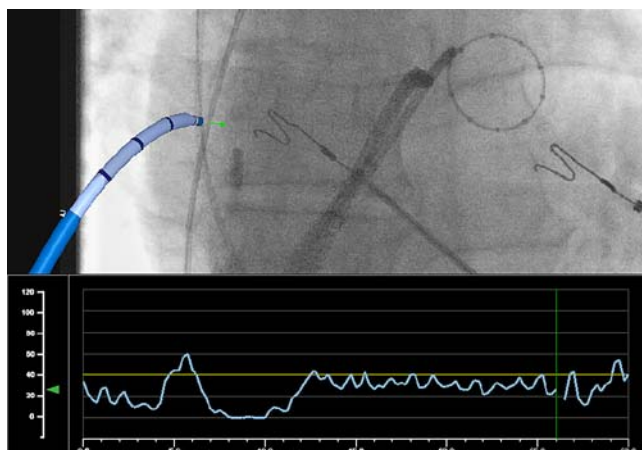


Fig. 6 The Intellisense system display (*close-up edited view*). Coaxial forces sensed at the catheter tip are displayed as a realtime waveform strip chart and gauge. On the strip chart there is a “warning level” threshold which is set by the operator. When forces exceed this level, the tip of the animated catheter changes colour (from *white* to *yellow*), and the strip chart plot line changes colour as well

of the operator using manually controlled catheters that may be limited in their flexibility and manoeuvrability. Computer assisted remote catheter ablation systems may minimize some of these difficulties by reducing the manual skill required, potentially reducing the operator’s learning curves.

The potential advantages of remote ablation include improved catheter manoeuvrability, precision and especially stability in areas within the heart which may be difficult to reach manually and the ability to reproducibly and accurately return to sites of interest during a procedure. Another remotely controlled catheter technology in current clinical use involves magnetic tipped catheters that are directed within a magnetic field. Its efficacy has already been demonstrated in mapping and ablation of accessory pathways, atrial, nodal and ventricular arrhythmias [1–5].

Electromechanical systems are an alternative means of remote catheter ablation. An in-depth comparison of the advantages and disadvantages of both systems is beyond the remit of this paper; particularly as robotic catheter navigation has only just been developed whereas magnetic navigation has already established itself in clinical trials. However, one can see the advantages of being able to use a remote navigation system that is portable; does not exclude

patients that have metal implants or devices and is compatible with other mapping systems and catheters. It remains to be seen whether robotic navigation can achieve the long-term efficacy and safety of magnetic navigation. In particular, whilst catheter-tip stability is improved, the amount of energy applied and the duration needed to achieve successful ablation without increasing the risk of “pops” and resultant perforation needs to be determined.

Robotic systems have already been used in surgical procedures, demonstrating improved precision, stability and dexterity [6]. Our study has shown that the Sensei robotic system in combination with the Artisan control catheter is safe, feasible and effective in achieving conventional endpoints in mapping and ablation within the human heart.

4.1 Safety

Previous studies with porcine models as well as a small human study have shown its safety *in vivo* [7–9]. A potential problem with a remote catheter control system is the lack of mechanical feedback that one would receive from manually controlling a catheter. This is important in assessing how much force is being applied in moving and maintaining catheter tip position. Knowledge of this force is important in avoiding damage to or perforation of cardiac and vascular structures. A system called Intellisense™ Fine Force Technology uses two force sensors that grip the shaft of the working catheter as it protrudes from the Artisan catheter. The working catheter is pulsed a short distance (<1.5 mm) in and out of the Artisan four times each second and with each pulse, coaxial force data are collected and compared. Forces applied to the working catheter tip are measured and displayed on the main screen as visual feedback of force (Fig. 6). This does not provide feedback on all the multidirectional forces applied to all parts of the catheter and, whilst it would be ideal to receive mechanical feedback through the instinctive motion controller, the visual data provided on the most important part of the catheter helps the operator to overcome this potential problem.

In the authors’ personal experience using this system, although visual representation of the forces applied at the catheter tip is better than none at all, it does not replace the tactile responses that experienced operators use to prevent

Table 3 Conventional ablation procedural data

Ablation procedure	Number RFs	RF time	Total procedure time	Flouro time	DAP
Atrial fibrillation	–	111±51 (44–171)	143±52 (45–204)	61.4±31 (24–121)	6,636±5,867 (1,776–19,489)
Atrial flutter	7±5 (2–18)	21±16 (4–56)	62±24 (25–94)	23±13.3 (7–49)	1,369±1,108 (189–3,596)
Accessory pathway	3±3 (1–11)	14±25 (1–83)	97±53 (36–186)	22.9±12.2 (9–44)	2,899±3,224 (219–11,055)

Figures represents data taken from conventional procedures ($n=10$) for each arrhythmia type. Means are given with standard deviations and ranges. Times are in minutes. RF—radiofrequency energy lesion. Dose area product (DAP) in cGycm^2 .

damage or perforation of cardiac structures. The Intellisense system allows the operator to predetermine what pressure level is deemed to be ‘excessive’ and if pressures exceed this arbitrary threshold the tip of the virtual catheter and the pressure waveform changes colour as a warning but there is no auditory alarm, requiring the operator to be constantly vigilant.

Another potential problem is the potential for thrombus to form within the Artisan’s sheaths. This was avoided by high flow continuous flushing and appropriate heparinisation. No thrombotic complication occurred in this study.

4.2 Fluoroscopy and radiation exposure

Complex ablation procedures such as for atrial fibrillation can be lengthy and radiation exposure to both patients and operators remains a concern. The present study does not fully represent the potential for a robotic system to reduce X-ray exposure to patients. For the operator, during conventional ablation procedures, despite adequate radiation protection, areas such as the face and extremities are still subject to scattered radiation exposure which impacts on cumulative dose [10, 11]. Our study has shown that negligible operator radiation exposure can already be achieved from being less than 3 m away from the radiation source whilst still being within the laboratory, potentially reducing the long-term risks to operators from radiation. Once the learning curve is overcome and procedure times improve, when used fully in combination with non-fluoroscopic mapping systems, robotic ablation could potentially reduce patient radiation exposure as well.

4.3 Versatility

This study has demonstrated the system’s compatibility with various irrigated and non-irrigated tipped ablation catheters as well as its use with existing non-fluoroscopic mapping systems such as CARTO™ and NavX™. There was no technical difficulty in setting up and performing mapping and ablation in any of the cases. In the case using a Thermocool Navistar 8 mm tip catheter, insertion into the Artisan was not problematic, though the fit prevented the Intellisense force feedback system from moving the catheter tip. Mapping and ablation was performed unhindered but with the Intellisense system switched off.

5 Limitations

This is a small feasibility study therefore conclusions with regards to overall efficacy and efficiency of the system for each type of arrhythmia cannot be made. For comparison, averaged data from conventional procedures ($n=10$ for

each) undertaken at our laboratory are shown in Table 3. It should be noted that this data represents the work of several operators of varying skill and experience. The robotic atrial fibrillation data (RF time 140 ± 27 min, procedure time 181 ± 45 min, $n=7$) show that times are longer on average compared to conventional procedures. This is not surprising as, with any new device, there is a learning curve to its use.

The operators themselves underwent an intensive two day training course to familiarise themselves with the set-up and use of the equipment in animals prior to the study being undertaken. During the animal case the physician is instructed in how to drive to certain places in the right atrium, how to cross the septum and drive to defined points in the left atrium and also how to create a 3D atrial geometry. It is understandable that great caution was employed with its use in the first human subjects. Despite this, the data are sufficient to conclude that the system can work safely and effectively in humans and can achieve conventional endpoints of ablation.

6 Conclusions

The Sensei robotic control system in combination with the Artisan control catheter is compatible with current mapping and ablation technologies, enabling clinically effective remote navigation of ablation catheters. Remotely controlled catheter ablation for cardiac arrhythmias using this system reduces operator radiation exposure.

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