Robot arm-guided ablation

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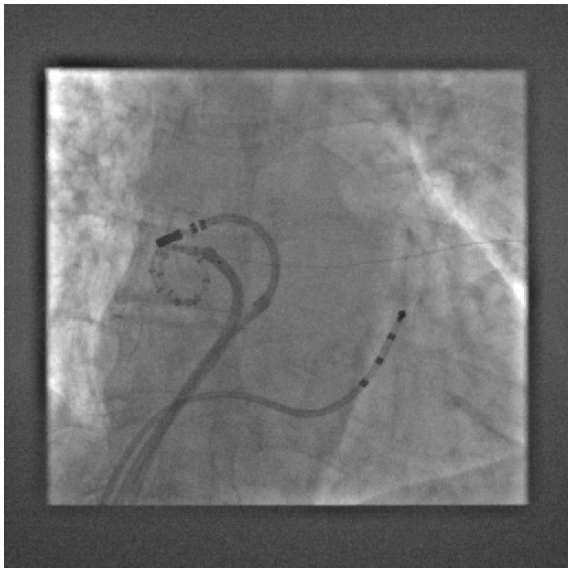
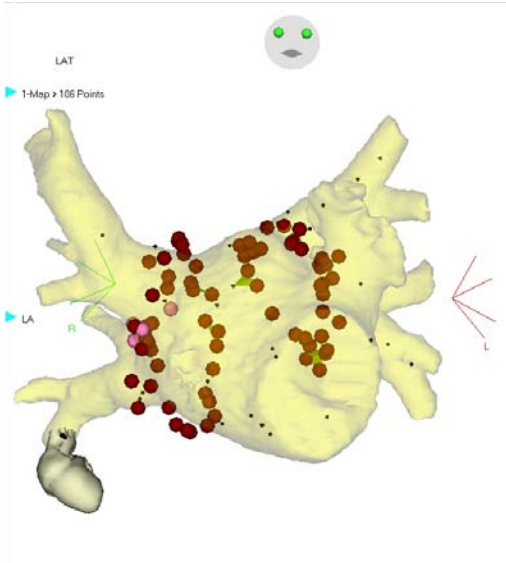
Manual catheter ablation





Aim

Contiguous, transmural, permanent lesions

Limitations

- Manoeuvrability
- Precision
- Tissue contact
- Catheter stability
- Procedure duration
- Operator fatigue
- Radiation exposure
- Operator-dependence

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Hansen robotic catheter navigation system

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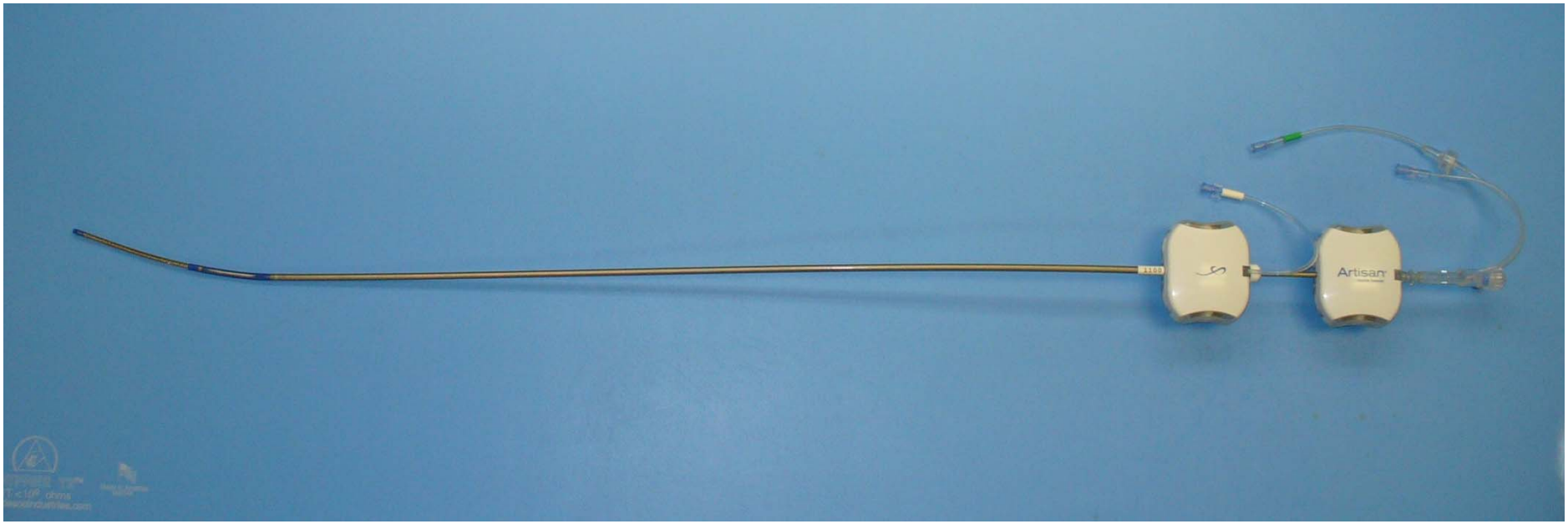
Hansen robotic catheter navigation system

Artisan steerable sheath 14Frr



+ any mapping/ablation catheter

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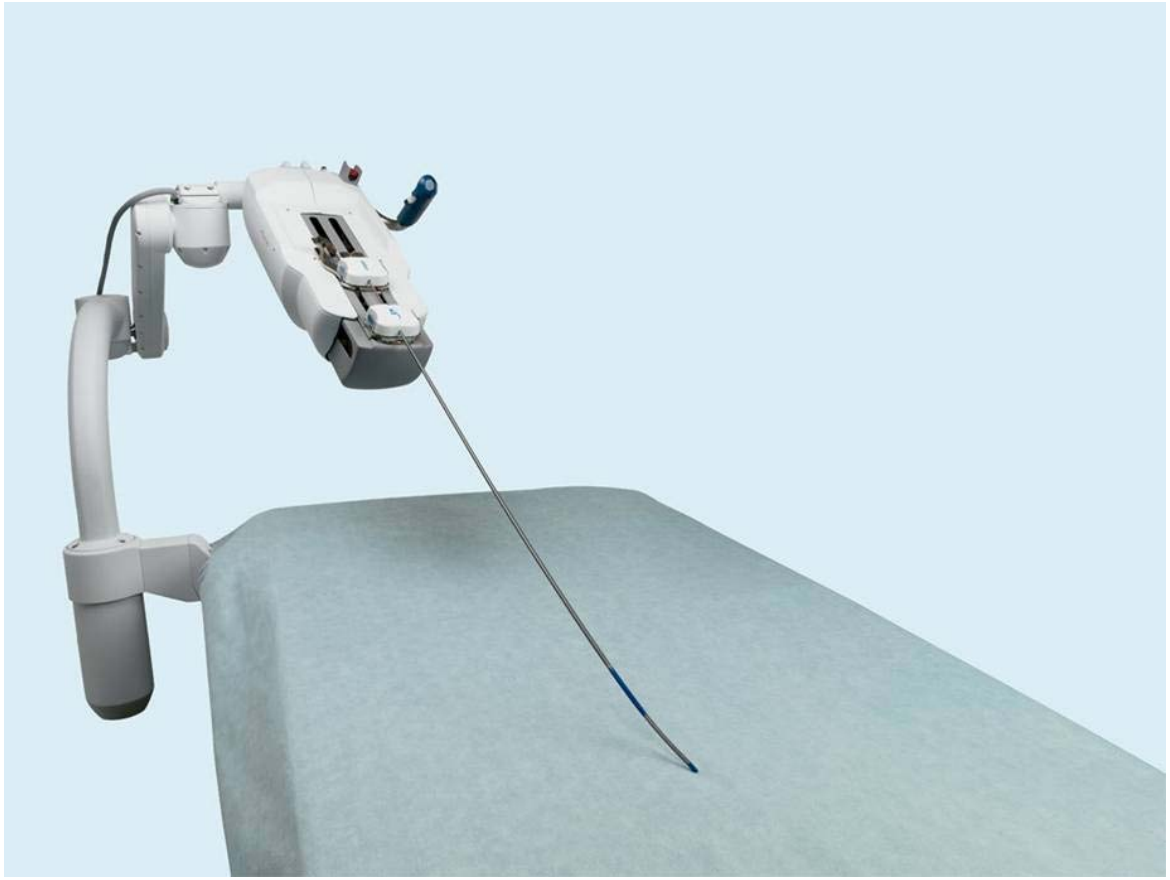
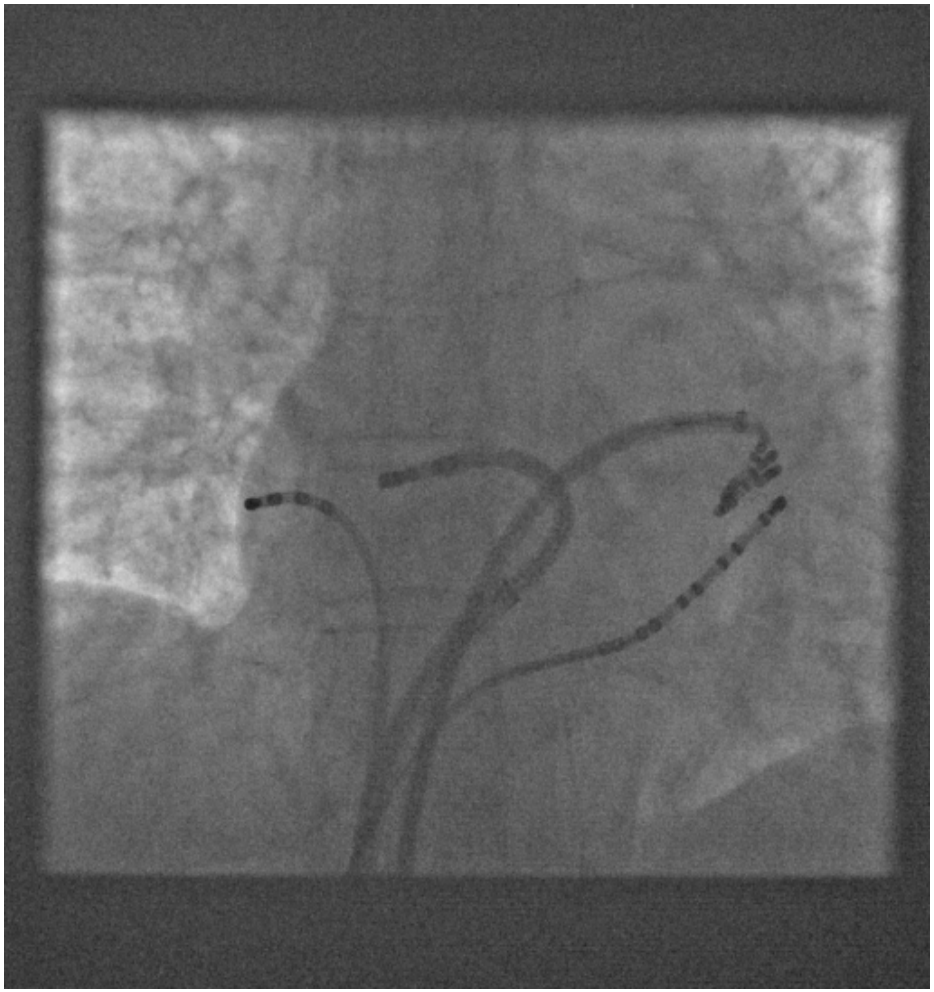
Hansen robotic catheter navigation system

RCM (remote catheter manipulator) arm and Artisan steerable sheath



Hansen robotic catheter navigation system



Catheter control
- Insertion/deinsertion
- Rotation
- Flexion/extension X and Y
- Bend up to 270°

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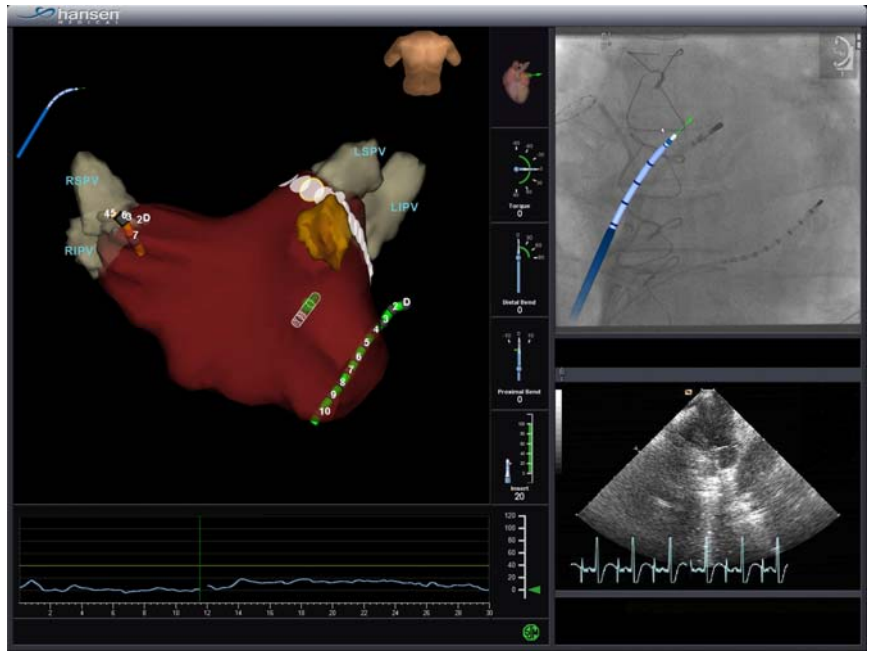
Hansen robotic catheter navigation system

Instinctive motion controller (Joystick)

‘Cohesion’ screen



‘Intellisense’ feedback

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Robot-guided ablation of AF

Evidence of efficacy and safety - 1

Saliba W et al. JACC 2008

Feasibility study of efficacy and safety of RCN for AF and AFL ablation

Method

Multicentre study

40 patients with AF (75% paroxysmal) 23 also AFL

ICE-guided TSP

Antral ablation with PVI, SVCI, CTI ablation with BDB

Irrigated RF 30W, 45°C, 30 mls/min

No intellisense

12 month follow up with event monitors

AADs 2/12 + blanking period

CT for PV stenosis

Robot-guided ablation of AF

Evidence of efficacy and safety - 1

Results

PV isolation	100%
SVC isolation	100%
CTI bidirectional block	100%
Procedure duration (AF) mins	189±88
Fluoro time (AF) mins	83±15
Radiation exposure (table) µSv	149
Radiation exposure (workstation) µSv	13
Freedom from arrhythmia off AADs at 12 months	34/40
Complications	2 tamponades (1 TSP 1 pop @50W) No PV stenosis

Robot-guided ablation of AF

Evidence of efficacy and safety - 2

Di Biase L et al. JCE 2009

390 consecutive AF ablations (67% paroxysmal)

Sequentially assigned to manual or robot-guided RF ablation

Paroxysmal: antral ablation with PVI

Persistent: antral ablation with PVI + R&L atrial ablation

2 operators

Robot-guided ablation of AF

Evidence of efficacy and safety - 2

Results

	Robot	Manual	
PVI all veins (%)	100	100	
Procedure time (hrs)	3.1±1.1	3.1±0.8	ns
Fluoro time (mins)	49±26	58±20	P<0.001
Success + AADs	85%	81%	ns
Success - AADs	72%	70%	ns
Major comps	3 (2 T 1 GH)	2 (1T 1 GH)	ns

'success' = freedom from AT/AF >1 min off AADs or previously ineffective AADs at 14±1 months

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Robot-guided ablation of AF

Evidence of efficacy and safety - 3

Duncan E et al. HRC 2009

Results of the first randomised controlled trial comparing Hansen robotic and manual catheter ablation of AF

Design

Consecutive pts, first ablation for AF → Robot-guided ablation

Consecutive pts, first ablation for AF → Manual ablation

Paroxysmal AF – WACA with PVI

Persistent AF – WACA with PVI + lines + CFEA

Irrigated RF 30 watts (25 watts posterior), 50°C, flow 2-10mls/min

Robot-guided ablation of AF

Evidence of efficacy and safety - 3

Results

100 randomised, 93 underwent procedure

4 consultant operators

	Robot	Manual
Paroxysmal	20	23
Persistent	25	25

Robot-guided ablation of AF

Evidence of efficacy and safety - 3

Results

		Robot	Manual	P
Procedure time	Paroxysmal	248±15	219±13	0.16
	Persistent	328±13	324±18	0.85
Fluoro time	Paroxysmal	47±6	50±5	0.75
	Persistent	53±14	84±6	0.0004
Cath dislodgement		2.1±3	8.5±1	<0.0001
PV reconnection (%)		22	24	0.73
Operator fatigue (1-5)		1.9	2.6	0.0005

Robot-guided ablation of AF

Evidence of efficacy and safety - 3

Results

		Robot	Manual
3 month success*	Paroxysmal	80%	71%
	Persistent	50%	60%
Major complications		4 (8.8%)	2 (4.2%)
		1 death	1 stroke
		1 rpb	1 tamponade
		2 tamponade	

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Robot-guided ablation of AF

Evidence of efficacy and safety - 3

Conclusions

- Similar procedure time
- Reduced fluoro time
- Reduced operator fatigue
- Similar short term outcome
- Complications?

Robot-guided ablation of AF

Robot vs. manual ablation – summary of evidence

	Di Biase 2009	Kautzner 2009	Duncan 2009
Procedure time	↔	↓	↔
Fluoro time	↓	↓	↓
RF time		↓	
Operator fatigue			↓
Short-term success	↔	↔	↔
Complications	↔	↔	↔

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Robot-guided ablation

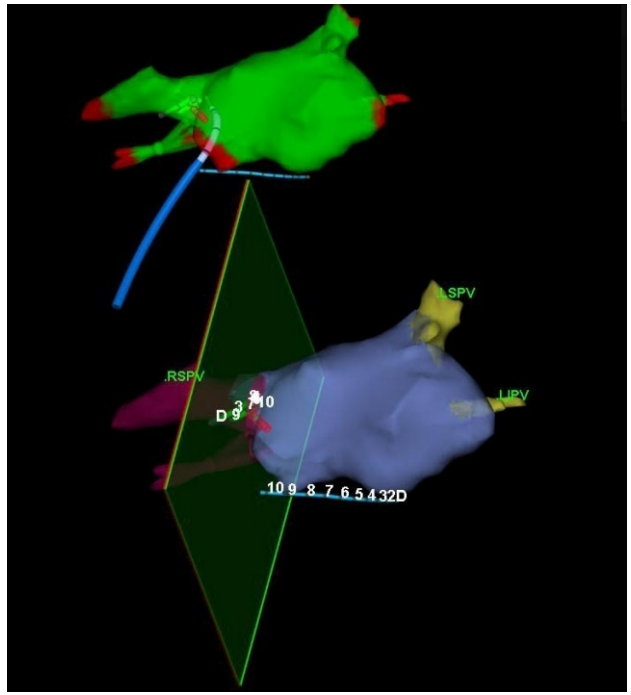
Safety issues

Vascular damage

- Long (30cm) 14 French sheath
- Lead up with ablation catheter under fluoro

Cardiac perforation

- Cross interatrial septum manually (or ICE)
- Intellisense – visual and now tactile feedback
- Constraint plane
- Optimal contact force
  - <10g 40% transmuural
  - 20-30g optimal (?)
  - >40g ↑ risk steam pops
- Optimal RF power and duration
- How to recognise steam pops?



Robot-guided ablation

Other issues

- Cost
  - System
  - Artisan sheaths – excluded devices
- No need to rebuild lab
- Integration with Carto

Robot-guided ablation of AF

Conclusions

- Manoeuvrability √
- Precision √
- Tissue contact √
- Catheter stability √
- Procedure duration X
- Operator fatigue √
- Radiation exposure √
- Operator-dependence ?
- Short-term success ?
- Complications ?