"Finestra sul cortile di Santa Maria Nuova":
Procedure elettrofisiologiche a raggi 0

Giornate Mediche di Santa Maria Nuova 2015
2-3 ottobre 2015

Dott. Marzia Giaccardi

UOS di Cardiologia ed Elettrofisiologia
Dott. M.Milli

La finestra sul cortile Alfred Hitchcock
James Stewart “Jeff” e Grace Kelly “Lisa Freemont”

……..Questo vuol intendere come una struttura antica come Santa Maria Nuova, riferimento assistenziale e scientifico per secoli, continui ad avere ancora oggi un importante ruolo sanitario all’interno della rete assistenziale fiorentina e non rinunci a confrontarsi con l’innovazione gestionale e culturale……

The 28 December 1895 by the official announcement of Roentgen's discovery of x-rays to the president of the Physical Medical Society of Wurzburg;

The 12 April 1898 Marie Sklodowska Curie announced to the Académie des Sciences in Paris the discovery of Polonium - Radium.

Two dates that mark a turning point in the history of medicine.

In recent years the capability and complexity of invasive cardiovascular procedures have increased substantially. Originally, fluoroscopically guided procedures were principally **diagnostic**. Currently, many procedures are **therapeutic** as well. As procedures have become increasingly complex, they may employ greater fluoroscopic durations leading to the potential for greater patient radiation exposure

Ionizing radiation, although a **very beneficial aid** to invasive procedures, **can be harmful**. Radiation effects fall into two classes: deterministic effects and stochastic effects.

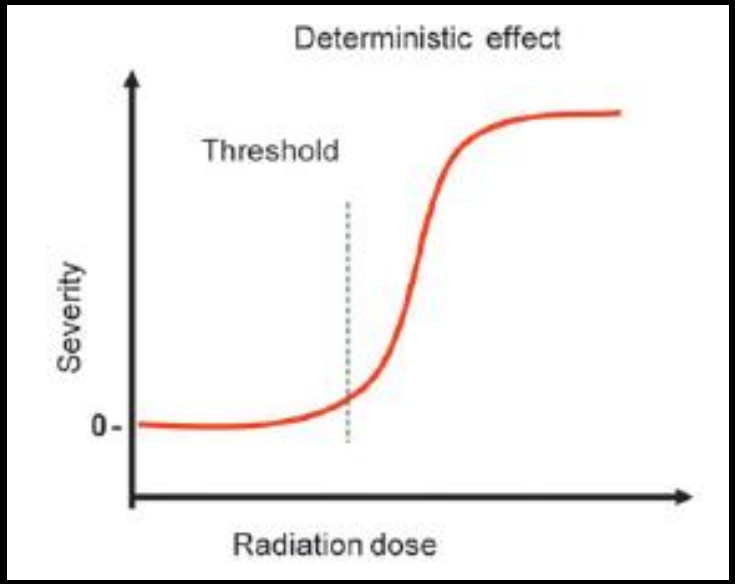
Adverse Effects of Radiation

- Deterministic Effects
  - Skin injury and hair loss
    - Thresholds
    - Dose-response relationships
    - Progression of injury
  - Eyes
    - Other organs
- Stochastic Effects
  - Neoplasm
    - Incidence and mortality risks
    - Risk models for low-dose effects
    - Latent periods
    - Heritable genetic effects

Circulation 2005;111:511-532

Deterministic effects

They are **predictable** dose-related phenomena. They have a **threshold** dose below which the effect does not occur. The **threshold is variable**, depending on the nature and condition of the exposed tissue. For doses in excess of the threshold, both the **probability and the severity** of deterministic effects increase with dose. Examples of deterministic
effects include radiation-induced epilation, erythema, and necrosis of the skin.



Picano et al. European Heart Journal 2014;35:665-672

TABLE II. Chronology and Severity of Tissue Reactions From Single-Delivery Radiation Dose

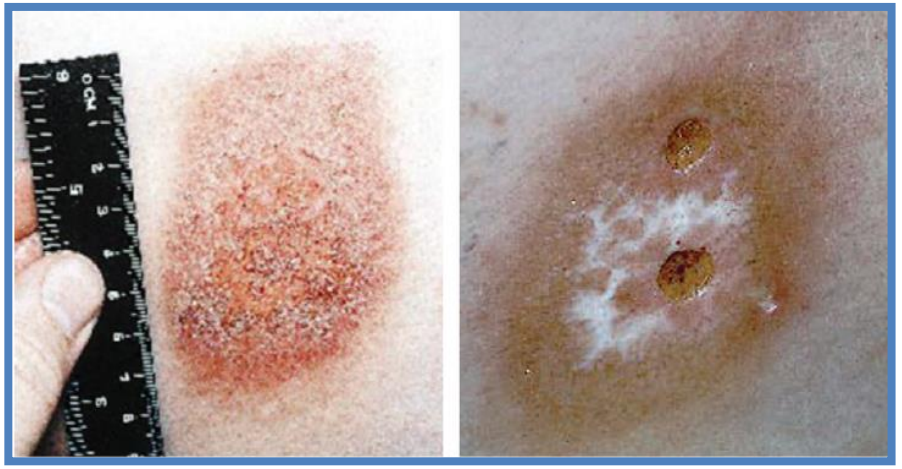
Single site (Gy) acute skin dose	Prompt (<2 weeks)	Early (2–8 weeks)	Mid term (6–52 weeks)	Long term (<40 weeks)
0–2	No observable effects expected			
2–5	Transient erythema	Epilation	Recovery from hair loss	None expected
5–10	Transient erythema	Erythema, epilation	Recovery; high doses cause prolonged erythema and permanent partial epilation	Recovery; higher dose cause dermal atrophy/induration
10–15	Transient erythema	Erythema, epilation; dry/moist desquamation	Prolonged erythema permanent epilation	Telangiectasia; dermal atrophy/induration
>15	Transient erythema; Very high dose causes moist desquamation edema/ulceration	Erythema, epilation	Dermal atrophy with secondary ulceration; atrophy/induration; High dose dermal necrosis surgical repair likely	Telangietasia; dermal Late skin breakdown

Chambers et al. Catheterization and Cardiovascular Interventions 2011;77:546–556

Fluoroscopically Guided Interventional Procedures:

A Review of Radiation Effects on Patients' Skin and Hair[1]

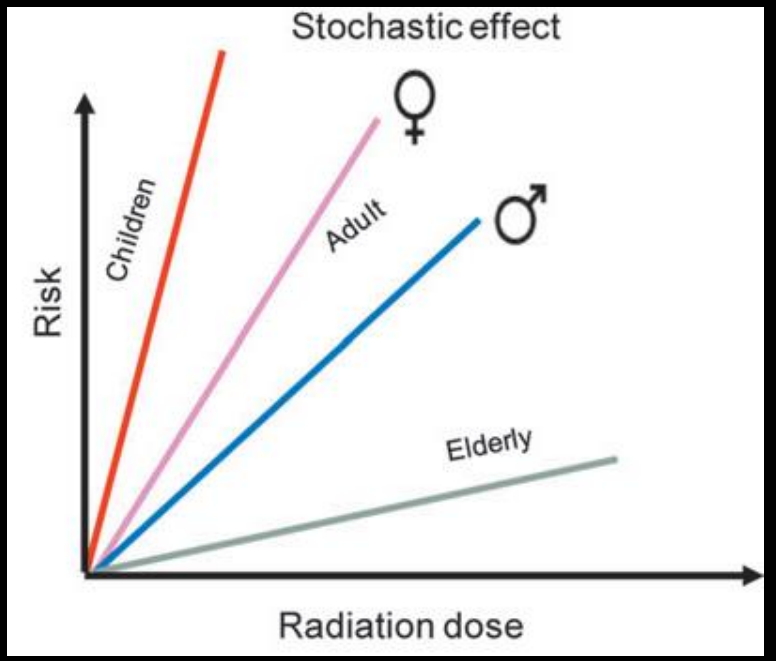
Radiology



Balter et al. Radiology 2010;254:326-341

Stochastic effects

They are **probabilistic** in nature, and their severity has no relationship to dose. The likelihood of inducing a stochastic effect increases with dose, but there is **no identifiable threshold for the effect**. The exact functional relationship with dose is **unknown**. Guidelines exist regarding the risk potential. Examples of stochastic effects include radiation-induced **neoplasm and heritable genetic defects.** This risk is cumulative and lifelong. Cancer may occur after a latency period of many years.

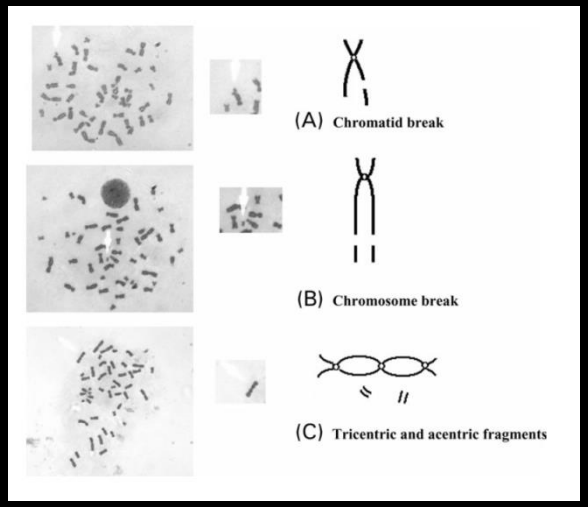


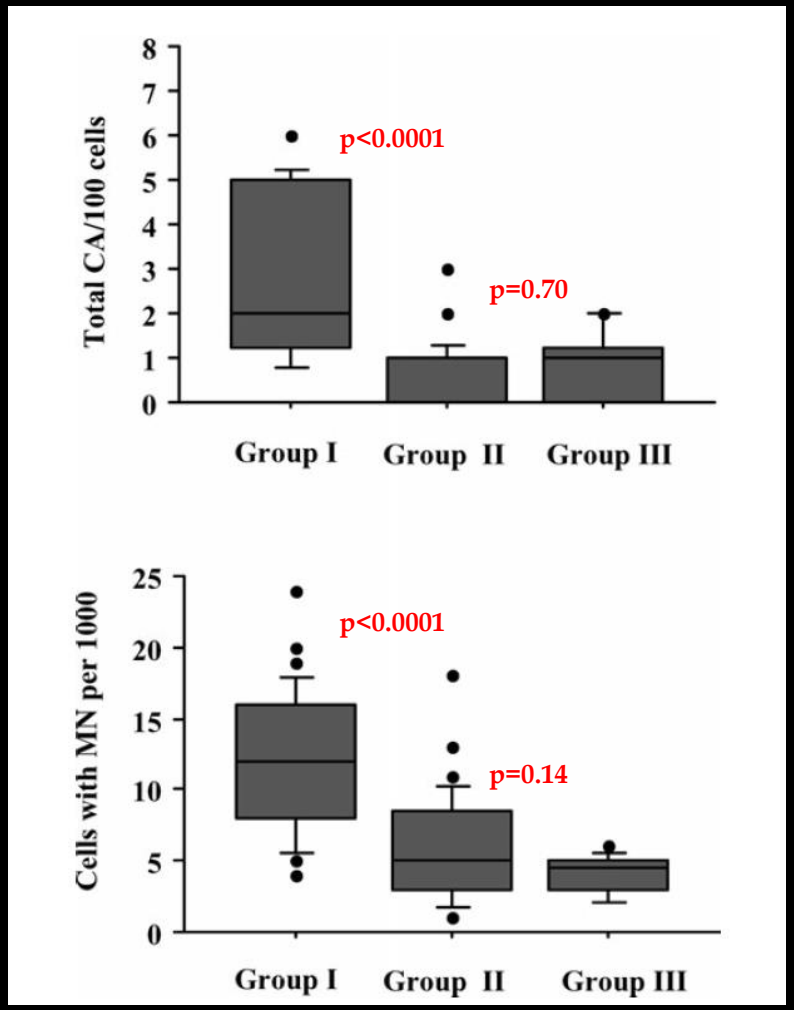
Picano et al. European Heart Journal 2014;35:665-672

Cardiac catheterization and long-term chromosomal damage in children with congenital heart disease

Risk of chromosomal damage of RX exposed children with repaired CHD.

- GROUP I children who underwent cardiac catheterization for CHD (RX exposed)
- GROUPII healthy age- and sex-mached subjects
- GROUPIII newborn non-exposed pts with CHD





CA:chromosal aberrations test MN: micronucleus assay in peripheral blood lymphocytes

Andreassi et al. European Heart Journal 2006;27:2703-2708

The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology

Cardiologists are responsible for about 40% of the entire cumulative effective dose to the US population from all medical sources excluding radiotherapy.

The majority of doctors—including cardiologists—grossly underestimate the radiation doses for most commonly requested tests. **At least one-third of all cardiac examinations are partially or totally inappropriate.**

In addition, the occupational radiation exposure of interventional cardiologists and cardiac electrophysiologists can be two to three times higher than that of diagnostic radiologists, and their exposure has increased steadily in the past few decades.

Picano et al. European Heart Journal 2014; 35:665–672

ACC/AHA Clinical Competence Statement

ACCF/AHA/HRS/SCAI Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety and Image Quality in Fluoroscopically Guided Invasive Cardiovascular Procedures

A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training

The core principle governing the use of ionizing radiation is **ALARA (As Low As Reasonably Achievable)**. The ALARA principle recognizes that there is no magnitude of radiation exposure that is known to be **completely safe**. This principle confers a responsibility on all physicians to minimize the radiation injury hazard to their patients, to their professional staff, and to themselves.

Circulation 2005;111:511-532

A new electrophysiology era: zero fluoroscopy

Matteo Anselmino, Dario Sillano, Dario Casolati, Federico Ferraris, Marco Scaglione and Fiorenzo Gaita

To help accomplish this goal (ALARA) growing interest in methods to minimize fluoroscopy during interventional procedures. This is one of the reasons why the use of 3D electroanatomic mapping systems for catheter arrhythmias ablation has grown in the past decade.

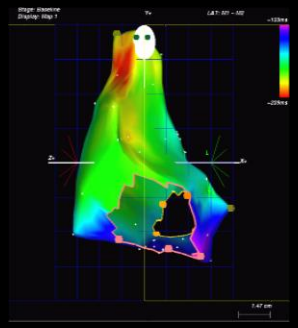
Nonfluoroscopic mapping systems may significantly reduce up to completely avoid radiological exposure. So much to define …….

Anselmino et al. J Cardiovasc Med 2013; 14:221–227

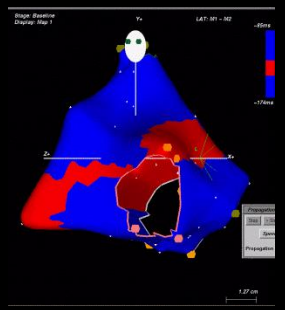
Exclusion of Fluoroscopy During Ablation Treatment of Right Accessory Pathway in Children

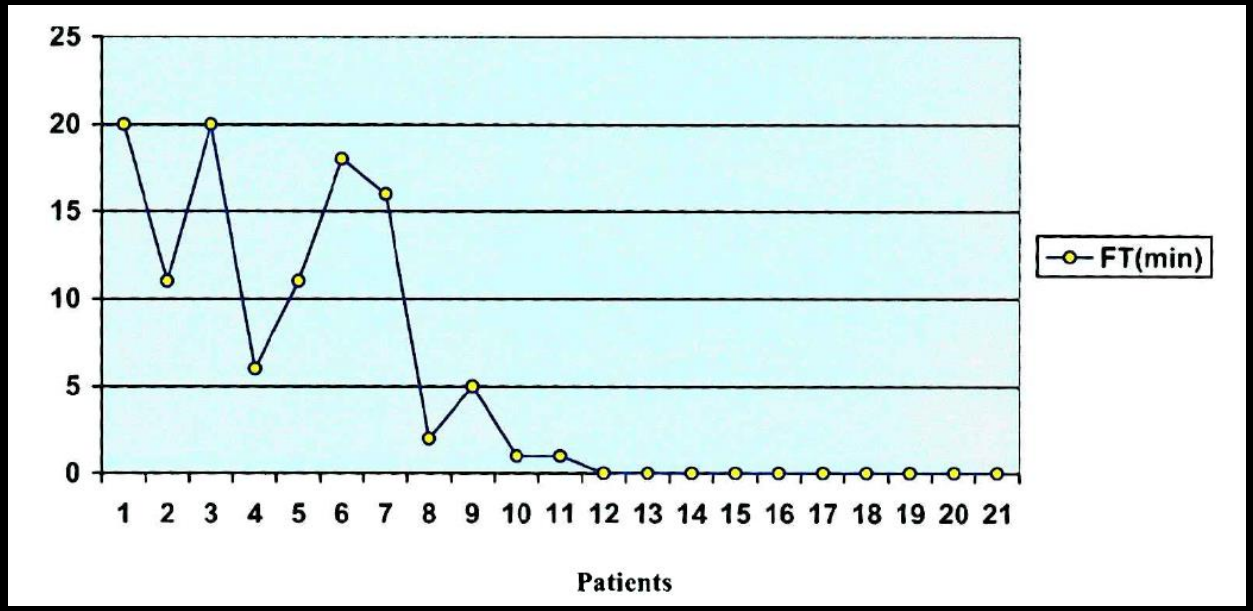
FABRIZIO DRAGO, M.D., MASSIMO STEFANO SILVETTI, M.D., ALFREDO DI PINO, M.D., GIORGIA GRUTTER, M.D., MAURIZIO BEVILACQUA, M.D., and SHOSHANA LEIBOVICH, M.D.

From the Pediatric Cardiology Department, Bambino Gesu' Hospital, Rome, Italy



21 consecutive WPW (due to a right AP) pediatric patients were submitted to radiofrequency ablation guided by CARTO system





Reduction of fluoroscopy time during the study. Considerable reduction is seen after procedure 8, with definitive elimination of fluoroscopy after procedure 13.

J Cardiovasc Electrophysiol 2002;13:778-782

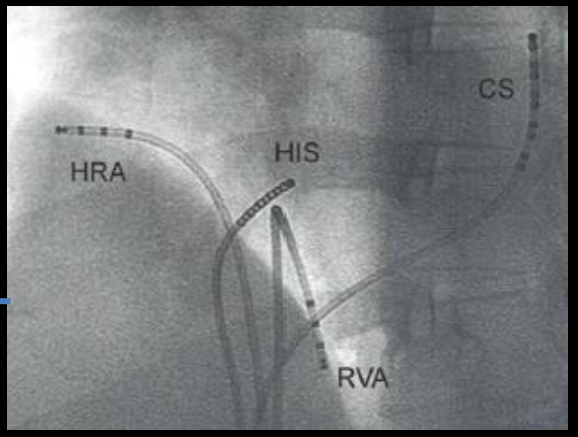
Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial

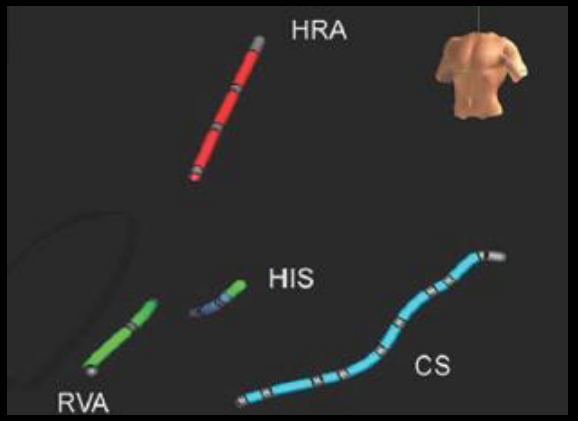
This is a randomized trial comparing Ensite NavX, Carto and conventional mapping in cases of RFCA of arrhythmias. This study showed a reductions of fluoroscopy, specially with the NavX system, that are achieved without compromising the duration, effectiveness, or safety of the procedure.

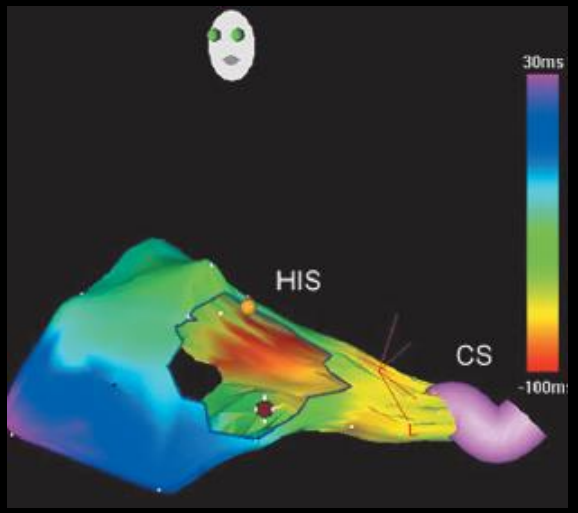
Costs increased by 50% over conventional mapping…

But cost analyses are usually invalidated by the difficulty in weighing the cost of 3D mapping system against the benefits of its use… These benefits can only be assessed meaningfully in a long-term, ''lifetime'' perspective

Earley et al. European Heart Journal 2006;27:1223-1229







Moreover in the assessing of costs we shouldn't forget these cases reported in literature of nine brain cancer in interventional cardiologists and radiologists.

Nine brain-cancer cases reported in interventionalists

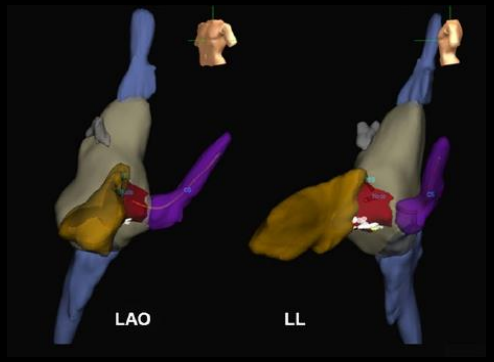
FEBRUARY 23, 2012 Reed Miller

Haifa, Israel - Researchers in Israel and France have found a few cases that suggest interventional cardiologists and radiologists may be at risk for left-side brain tumors [1].

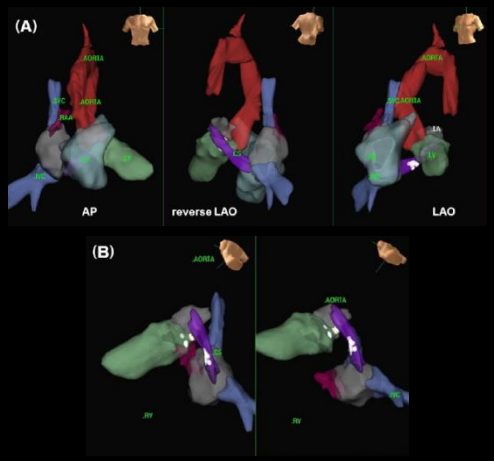
In the January 2012 issue of *Eurointervention*, **Dr Ariel Roguin** (Technion-Israel Institute of Technology, Haifa, Israel) and colleagues publish the summary of nine reports of brain tumors in people working in catheterization laboratories for 14 to 32 years, including four cases not previously reported in the literature.

The types of tumor reported include glioblastomas, meningiomas, acoustic neurinomas, and oligodendromas.

"Near-zero" fluoroscopic exposure in supraventricular arrhythmia ablation using the EnSite NavX™ mapping system: personal experience and review of the literature



EnSite NavX™ system is feasible, safe, and effective in a population of relatively young adults.



Use for both left- and right-sided ablation in a non-pediatric population

Our study demonstrates the feasibility, efficacy, and safety of using the non-fluoroscopic EnSite NavX™ mapping system as the sole or prevailing imaging modality to guide ablation of a wide range of supraventricular tachyarrhythmias in young adults……in a non-pediatric population.

Casella et al. J Interv Card Electrophysiol 2011;31:109-18.

Article in Press

Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Electroanatomic Mapping System: A Multicenter Experience

Marzia Giaccardi, MD, Attilio Del Rosso, MD, Vincenzo Guarnaccia, MD, Piercarlo Ballo, MD, Giuseppe Mascia, MD, Leandro Chiodi, MD, Andrea Colella, MD

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Publication stage: In Press Accepted Manuscript

DOI: http://dx.doi.org/10.1016/j.hrthm.2015.09.003

Abstract

Background

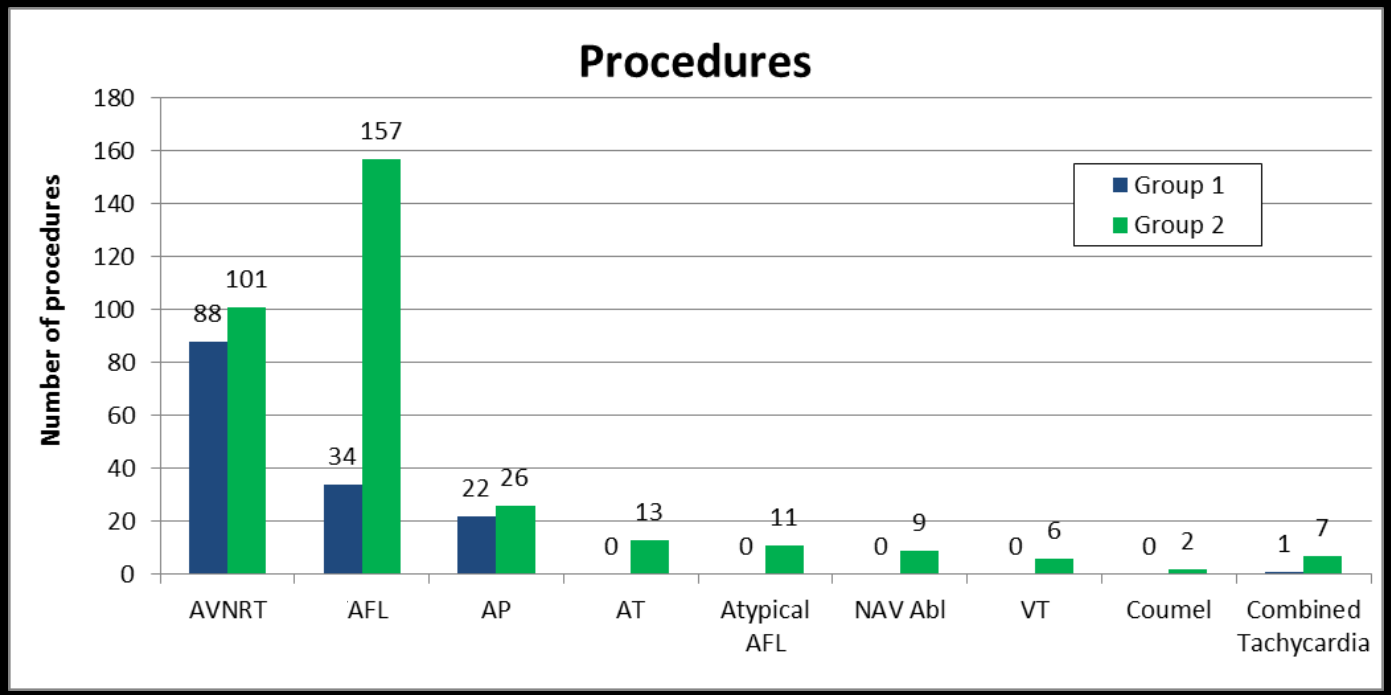
Radiation exposure related to conventional tachyarrhythmia radiofrequency catheter ablation (RFCA) carries small but not negligible stochastic and deterministic effects on health. These effects are cumulative and potentially more harmful in younger subjects. Nonfluoroscopic mapping systems may significantly reduce up to completely avoid radiological exposure.

Objective

The aim of this study was to assess the safety, feasibility and efficacy of a complete nonfluoroscopic approach for RFCA compared to ablations performed under fluoroscopic guidance.

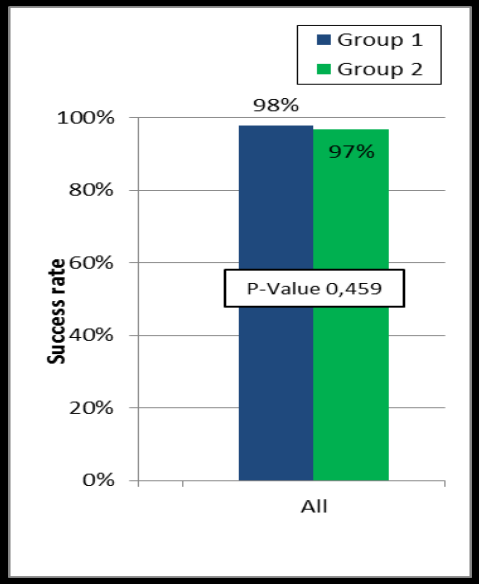
Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Mapping System: A Multicenter Experience.

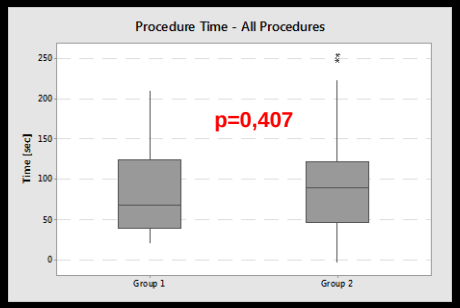
RFCA was performed in 477 consecutive patients (58 ± 20 years). The first 145 patients (group 1) were treated only with fluoroscopic guidance, the following 332 cases (group 2) were performed using Ensite Velocity system.

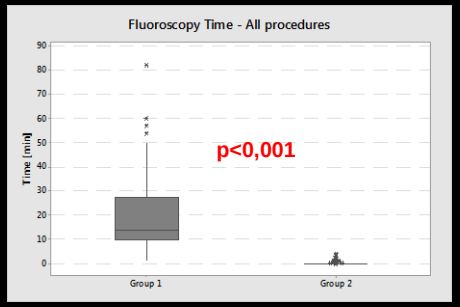


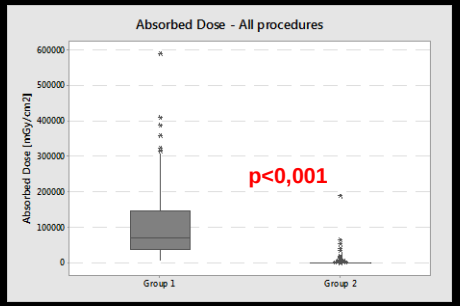
Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Mapping System: A Multicenter Experience.

The nonfluoroscopic system Ensite Velocity for catheter navigation significantly reduces or eliminates fluoroscopy exposure in RFCA. These procedures can be safely and effectively performed without radiation exposure in the majority of patients.

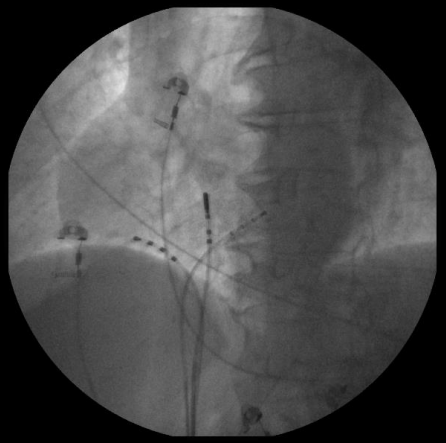








Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Mapping System: A Multicenter Experience.



Fluoroscopy was necessary in a total of 35 pts (11%) in group 2

28,6% difficult venous access
28.6% check catheter stability during RFCA
14.2 % confirm catheter location
11.4 % CS frequent dislocation
8.6% technical issues of the Ensite NavX
8.6% check guidewires

In 297 patients (89%) the RFCA was completely performed **without fluoroscopy**

Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Mapping System: A Multicenter Experience.

	n° of cases	adverse events	adverse event rate rate		
Conventional Technique	145	3	2,1%	1,062	x2
Ensite NavX	332	13	3,9%	0,303	p

5 vascular access complications (one required surgical correction for arteriovenous fistula **0.3%**)
4 atrioventricular block **(1,2%)**
all regressed spontaneously. Need for a PM **(0%)**
2 TIA **(0,6%).**
1 pulmonary microembolization **(0,3%).**
1 deep-vein thrombosis **(0,3%).**

Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Mapping System: A Multicenter Experience.

Safety Outcome	Accessory Pathways*			AVNRT			AFL		
	t	n/N	%	t	n/N	%	t	n/N	%
Mortality									
Death overall	18	7/2,267	0.3	27	2/4,748	0.0	13	4/723	0.6
Procedure related	18	2/2,267	0.1	26	0/4,296	0.0	12	0/671	0.0
Not procedure related	18	5/2,267	0.2	27	2/4,748	0.0	13	6/723	0.8
Vascular access complications									
Arteriovenous fistula	11	4/1,474	0.3	12	2/2,530	0.1	8	0/459	0.0
Hematoma	10	4/1,196	0.3	14	10/3,566	0.3	8	0/459	0.0
Pneumothorax	10	1/1,228	0.1	12	2/2,911	0.1	8	1/459	0.2
Periprocedural events									
Stroke, ischemic	12	2/1,687	0.1	16	0/1,992	0.0	12	0/673	0.0
Transient ischemic accident	13	3/1,856	0.2	16	0/1,992	0.0	12	0/673	0.0
Cardiac tamponade	13	8/1,856	0.4	17	2/2,893	0.1	12	0/673	0.0
Pulmonary embolus	13	0/1,856	0.0	19	5/3,297	0.2	12	1/673	0.1
Deep-vein thrombosis	11	0/1,443	0.0	16	2/2,648	0.1	12	0/673	0.0
Other embolism	11	1/1,443	0.1	15	1/1,747	0.1	12	0/673	0.0
Pericardial effusion	13	3/1,856	0.2	18	4/3,169	0.1	12	2/673	0.3
Atrioventricular block	15	16/2,044	0.8	25	78/4,661	1.7	12	3/673	0.4
CHF exacerbation	13	0/1,856	0.0	16	1/1,992	0.1	16	0/926	0.0
Need for a pacemaker	9	3/1,095	0.3	24	34/4,625	0.7	11	1/550	0.2
Total no. of patients with even	11	39/1,417	2.8	12	61/2,013	3.0	8	2/409	0.5

Spector et al. Am J Cardiol, 2009

Follow-up 132 pts 0 RX

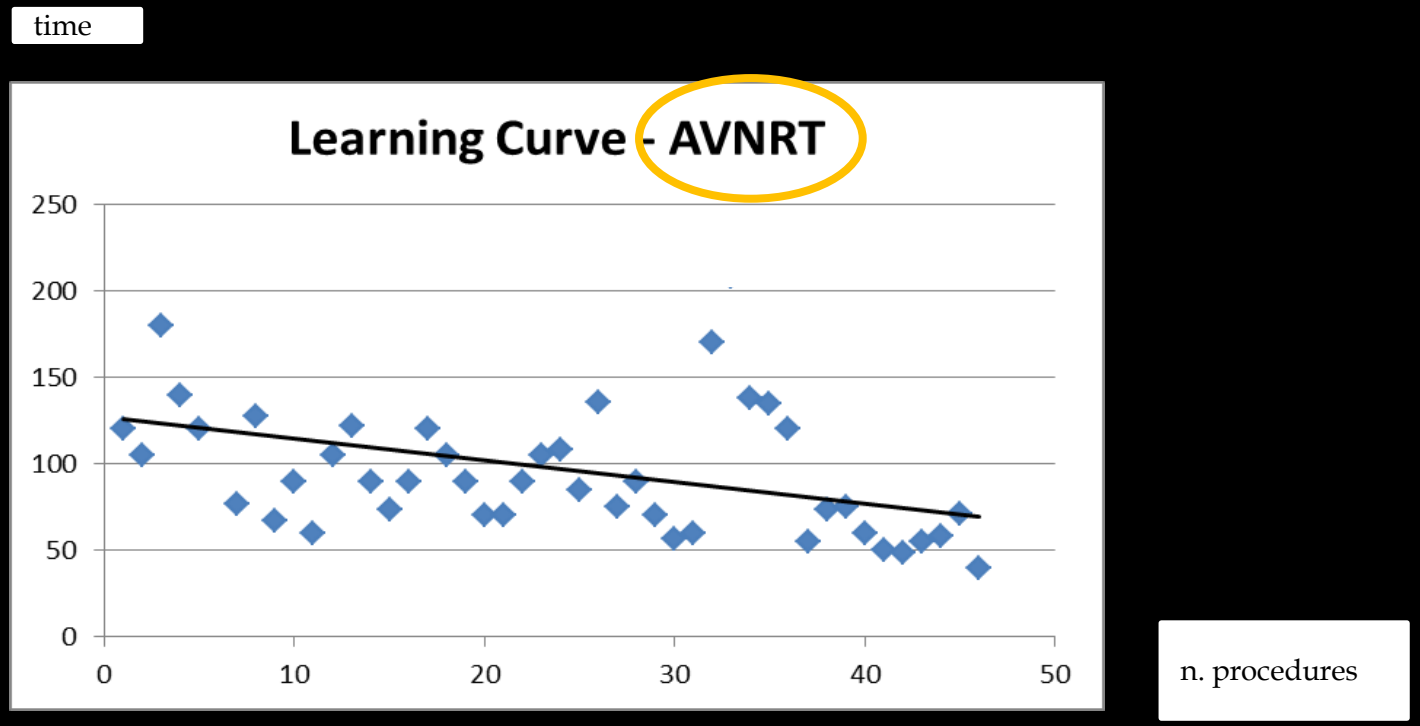
RELAPSES

15/132 (11,36%)
Single procedure success total 89%
Multiple procedure success total 97.73 %

Meta-Analysis of Ablation of Atrial Flutter and Supraventricular Tachycardia	Accessory Pathways*	AVNRT	AFL
	M-A % (95% CI)	M-A % (95% CI)	M-A % (95% CI)
Single-procedure success total	90.91 (87.71–94.11)†	94.33 (91.24–97.41)†	91.66 (88.40–94.93)†
Multiple-procedure success total	93.32 (89.41–97.22)†	95.97 (93.40–98.53)†	97.04 (94.72–99.36)†
Postablation arrhythmia	7.16 (4.68–9.64)†	4.91 (2.92–6.91)†	13.20 (7.54–18.86)†
Repeat ablation procedure	8.04 (4.70–11.37)†	5.57 (3.56–7.58)†	7.97 (4.53–11.42)†

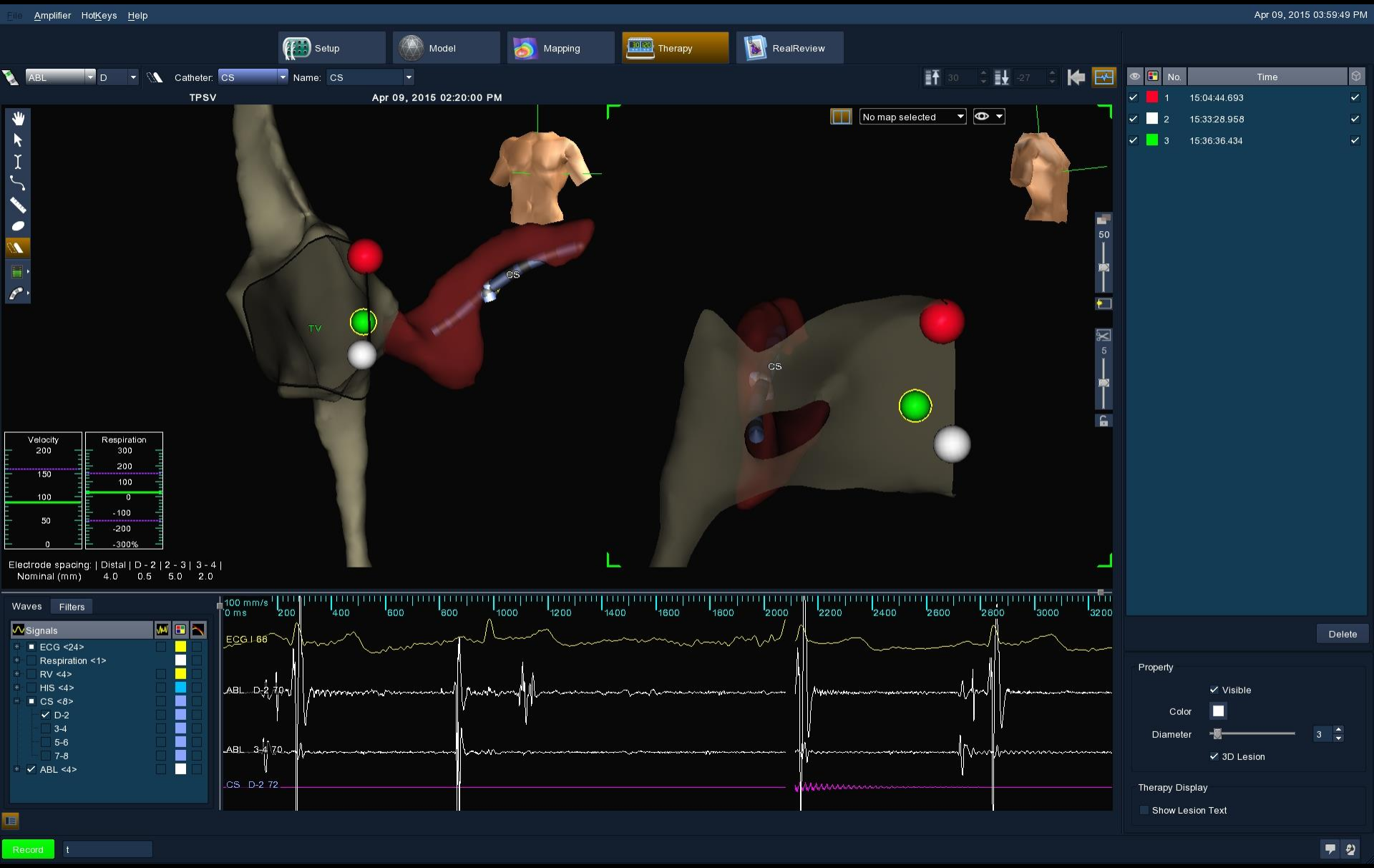
Spector et al. Am J Cardiol, 2009

Near Zero X-Ray in Arrhythmias Ablation Using a Three-Dimensional Mapping System: A Multicenter Experience.

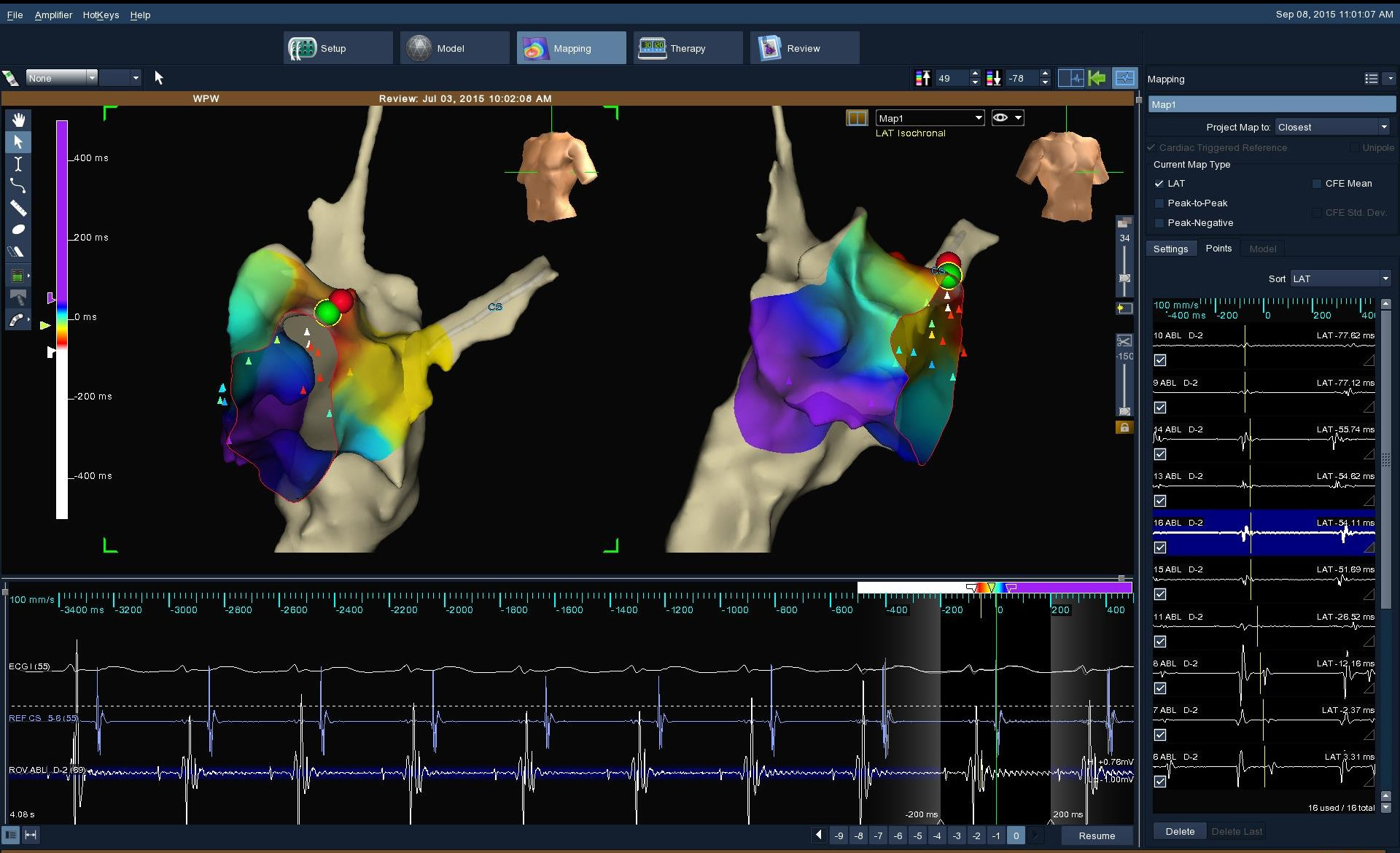


Procedure time shortens as a function of experience. After an adequate learning curve, the procedure can be performed in a very acceptable amount of time

S.M. 14 anni AVNRT



M.C. 17 anni WPW parahisiano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Sep 08, 2015 11:01:07 AM
Setup
Model
Mapping
Therapy
Review
None
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-78
WPW
Review: Jul 03, 2015 10:02:08 AM
Map1
LAT Isochronal
400 ms
200 ms
0 ms
-200 ms
-400 ms
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Mapping
Map1
Project Map to: Closest
Cardiac Triggered Reference
Unipole
Current Map Type
LAT
CFE Mean
Peak-to-Peak
Peak-Negative
CFE Std. Dev.
Settings
Points
Model
Sort LAT
100 mm/s
-400 ms -200 0 200 400
10 ABL D-2 LAT -77.62 ms
9 ABL D-2 LAT -77.12 ms
14 ABL D-2 LAT -55.74 ms
13 ABL D-2 LAT -54.62 ms
16 ABL D-2 LAT -54.11 ms
15 ABL D-2 LAT -51.69 ms
11 ABL D-2 LAT -26.52 ms
8 ABL D-2 LAT -12.16 ms
7 ABL D-2 LAT -2.37 ms
6 ABL D-2 LAT 3.31 ms
16 used / 16 total
Delete
Delete Last
100 mm/s
-3400 ms -3200 -3000 -2800 -2600 -2400 -2200 -2000 -1800 -1600 -1400 -1200 -1000 -800 -600 -400 -200 0 200 400
ECG I (55)
REF CS 5-6 (55)
ROV ABL D-2 (69)
+0.76mV
-1.00mV
4.08 s
-200 ms
200 ms
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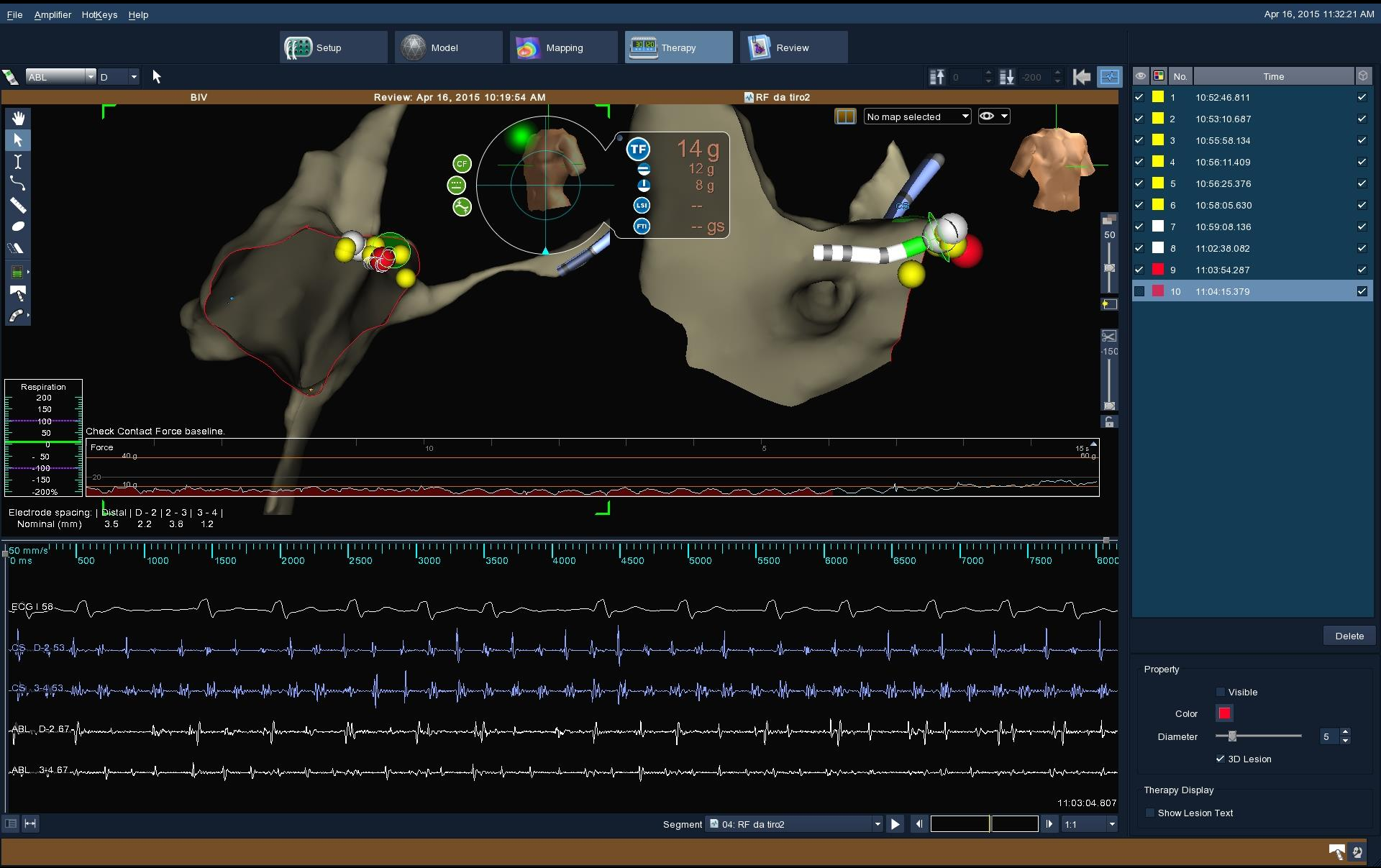
Resume
Review: Heart Rate 146 bpm, Cycle Length 409 ms, LAT -54.11 ms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Apr 16, 2015 11:32:21 AM
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Mapping
Therapy
Review
ABL
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Review: Apr 16, 2015 10:19:54 AM
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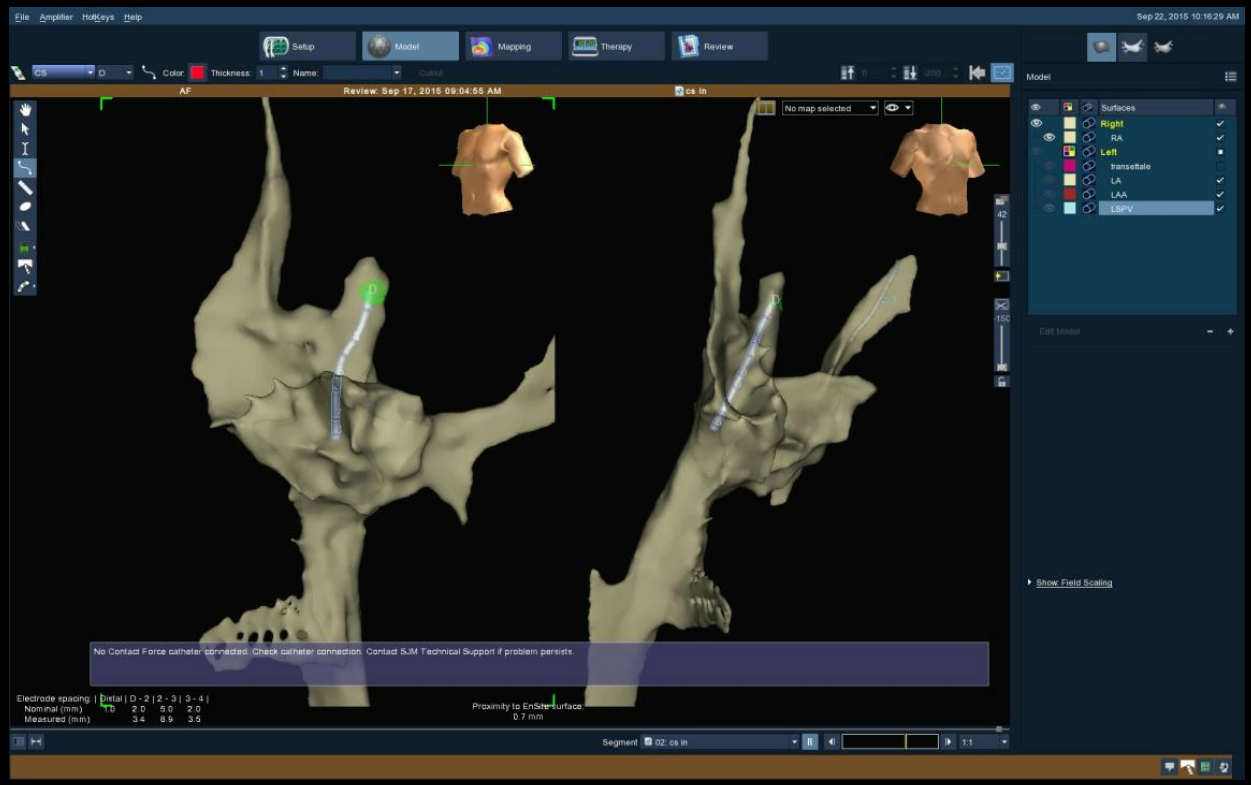
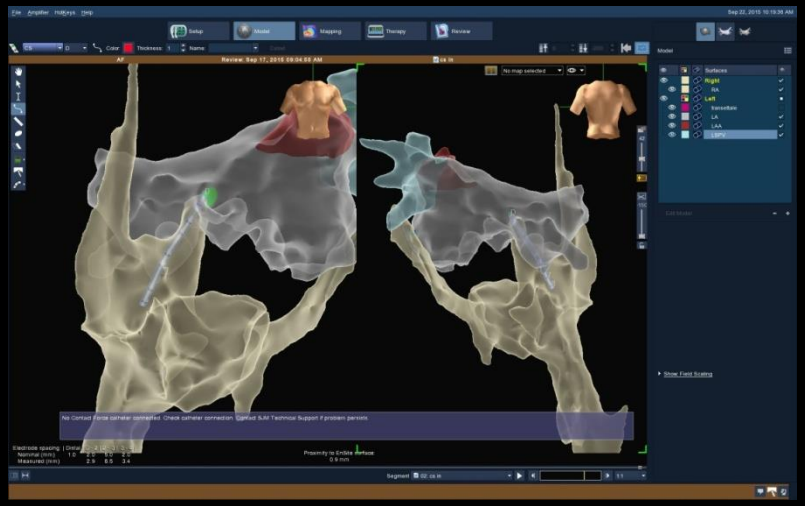
2 10:53:10.687
3 10:55:58.134
4 10:56:11.409
5 10:56:25.376
6 10:58:05.630
7 10:59:08.136
8 11:02:38.082
9 11:03:54.287
10 11:04:15.379
Delete
Property
Visible
Color
Diameter
5
3D Lesion
Therapy Display
Show Lesion Text
Respiration
Check Contact Force baseline.
Force
Electrode spacing: | Distal | D - 2 | 2 - 3 | 3 - 4 |
Nominal (mm) 3.5 2.2 3.8 1.2
50 mm/s
0 ms
ECG I 58
CS D-2 53
CS 3-4 53
ABL D-2 67
ABL 3-4 67
11:03:04.807
Segment
04: RF da tiro2
1:1


File Amplifier HotKeys Help
Apr 16, 2015 11:29:17 AM
Setup
Model
Mapping
Therapy
Review
ABL
D
BIV
Review: Apr 16, 2015 10:19:54 AM
RF da tiro2
No map selected
TF
20 g
17 g
10 g
LSI
FTI
29 gs
CF
CS
No.
Time
1 10:52:46.811
2 10:53:10.687
3 10:55:58.134
4 10:56:11.409
5 10:56:25.376
6 10:58:05.630
7 10:59:08.136
8 11:02:38.082
9 11:03:54.287
10 11:04:15.379
Delete
Property
Visible
Color
Diameter
5
3D Lesion
Therapy Display
Show Lesion Text
Respiration
Check Contact Force baseline.
Force
Electrode spacing: | Distal | D - 2 | 2 - 3 | 3 - 4 |
Nominal (mm) 3.5 2.2 3.8 1.2
50 mm/s
0 ms
ECG I
CS D-2
CS 3-4
ABL D-2
ABL 3-4
11:03:52.948
Segment
04: RF da tiro2
1:1


File Amplifier HotKeys Help
Sep 22, 2015 10:16:29 AM
Setup
Model
Mapping
Therapy
Review
AF
Review: Sep 17, 2015 09:04:55 AM
cs in
No map selected
Model
Surfaces
Right
RA
Left
transeptale
LA
LAA
LSPV
Show Field Scaling
No Contact Force catheter connected. Check catheter connection. Contact SJM Technical Support if problem persists.
Electrode spacing: | Distal | D - 2 | 2 - 3 | 3 - 4 |
Nominal (mm) 1.0 2.0 5.0 2.0
Measured (mm) 3.4 8.9 3.5
Proximity to EnSite surface
0.7 mm
Segment 02: cs in


Im: 19/2013
Se: 3
2015091701
F
2015091720150917
MainSeries:None:None:RUN3(1-2013)
WL: 128 WW: 256 [D]
17/09/2015 08:49:48



CASE REPORT

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'Zero' fluoroscopic exposure for ventricular tachycardia ablation in a patient with situs viscerum inversus totalis

Marzia Giaccardi[1]*, Leandro Chiodi[1], Attilio Del Rosso[2], and Andrea Colella[3]

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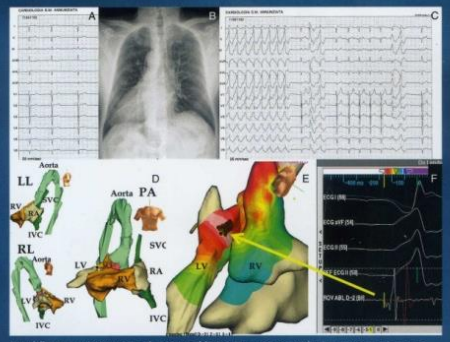

'Zero' fluoroscopic exposure during VT ablation in a patient with situs viscerum inversus totalis. See figure legend on page 449.

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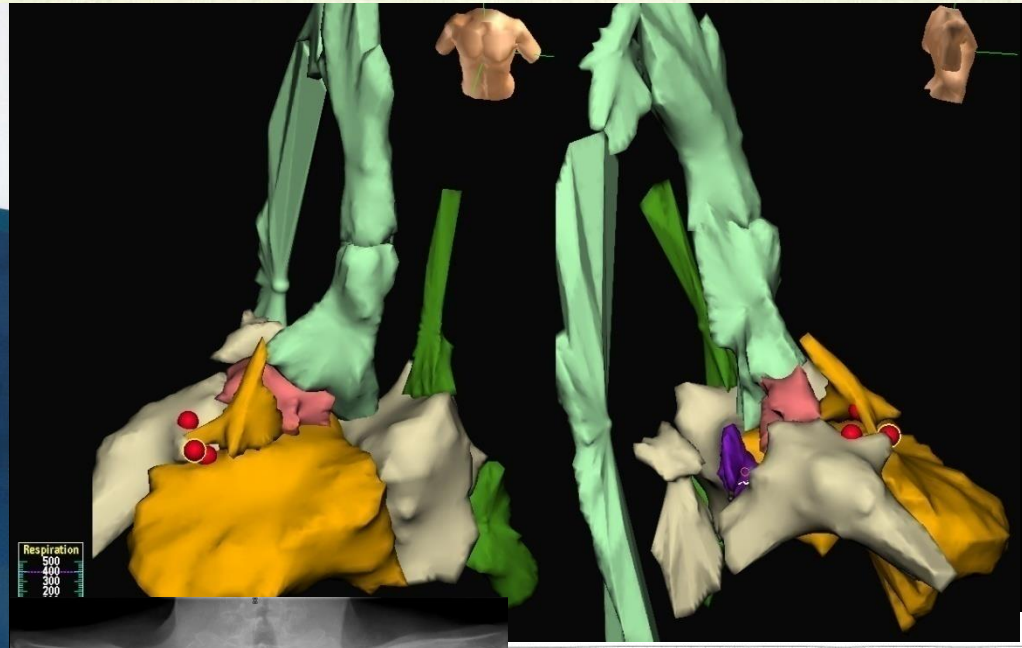
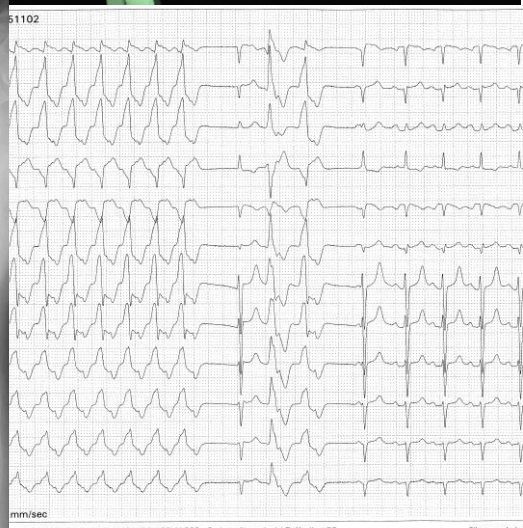
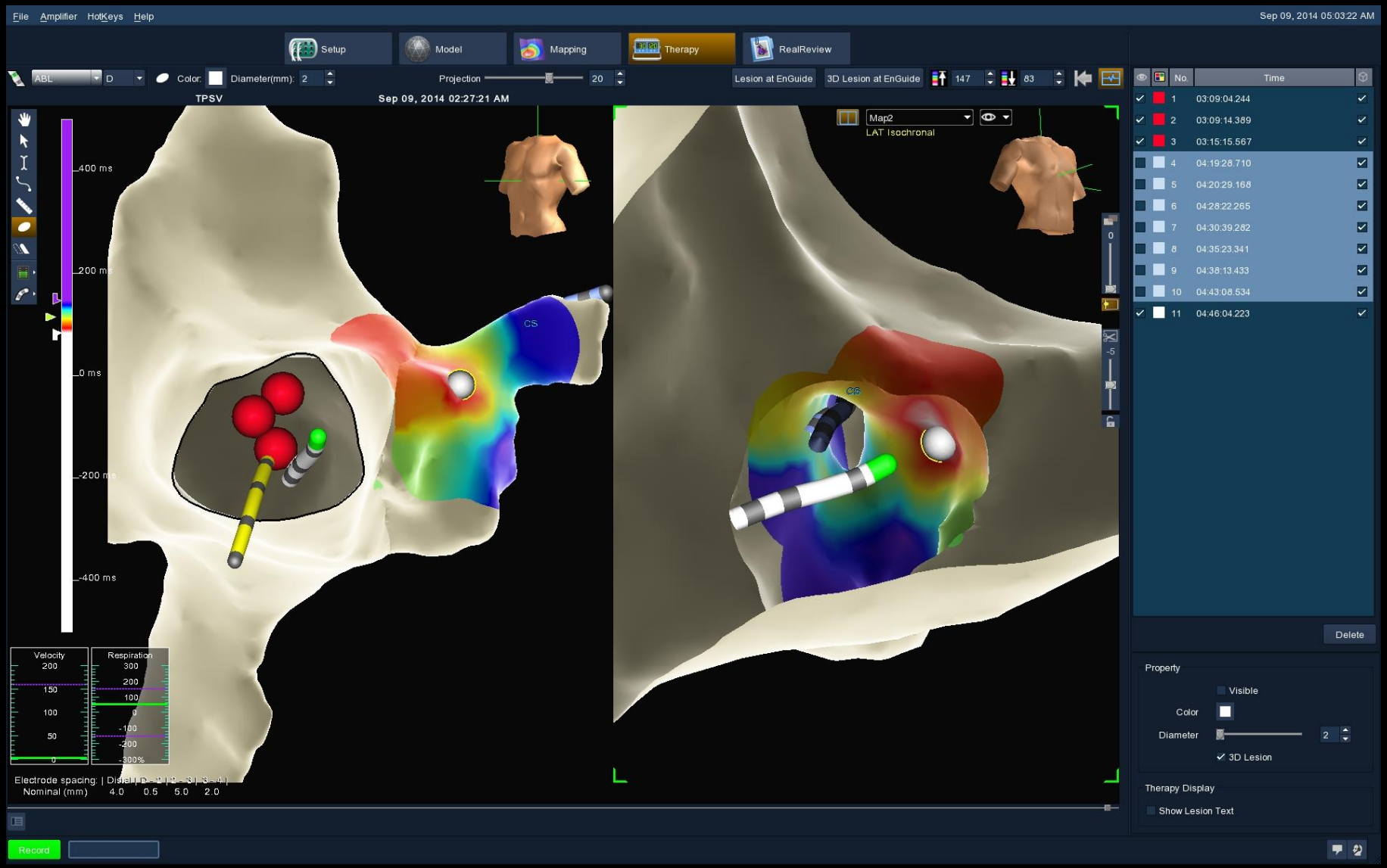


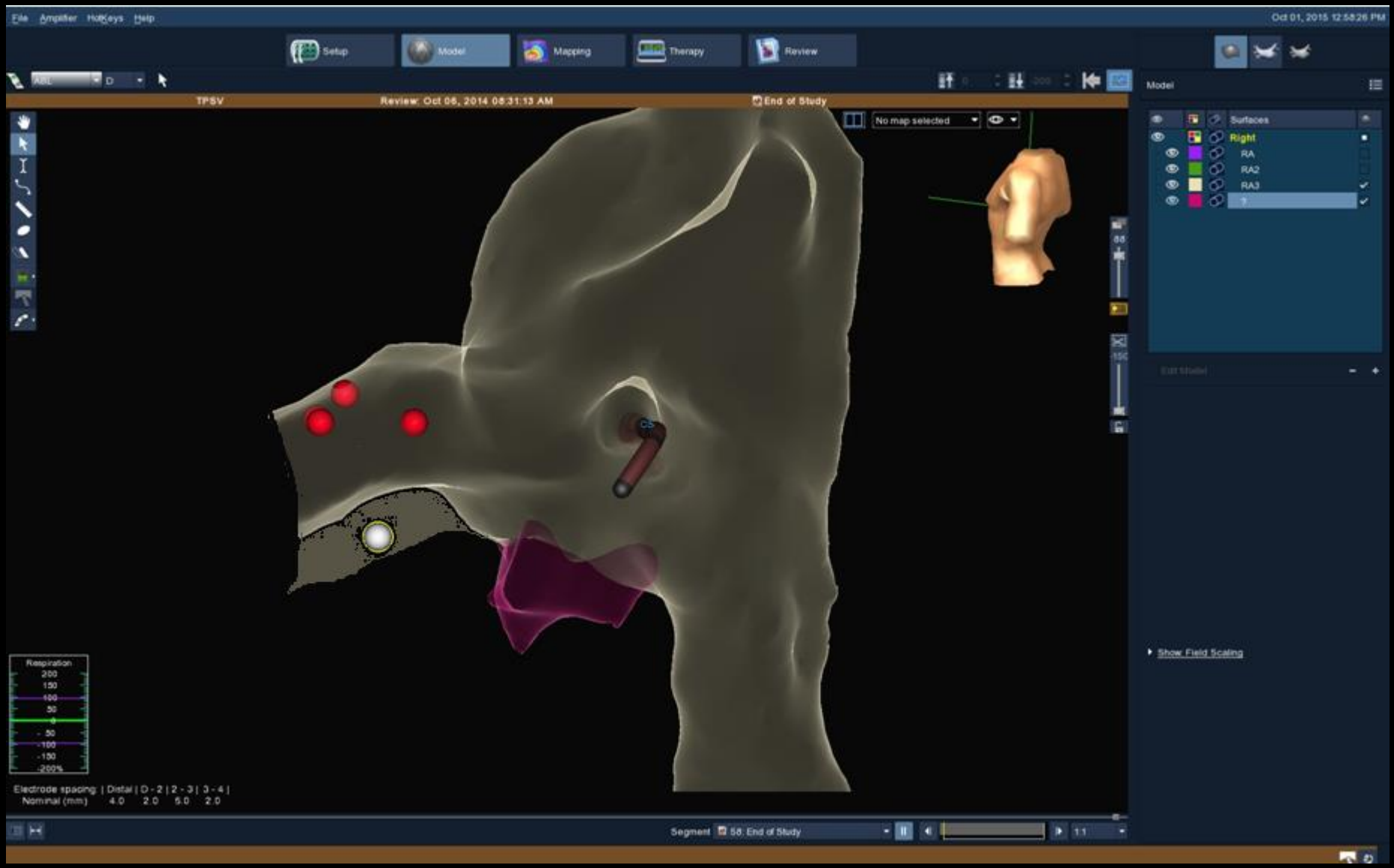


“Congenital diverticulum of the right atrium and concealed WPW”
ZERO RX approach – anatomical mapping

“Congenital diverticulum of the right atrium and concealed WPW”
ZERO RX approach – ablation



“Congenital diverticulum of the right atrium and AVNRT”
ZERO RX approach – ablation



EDITORIAL

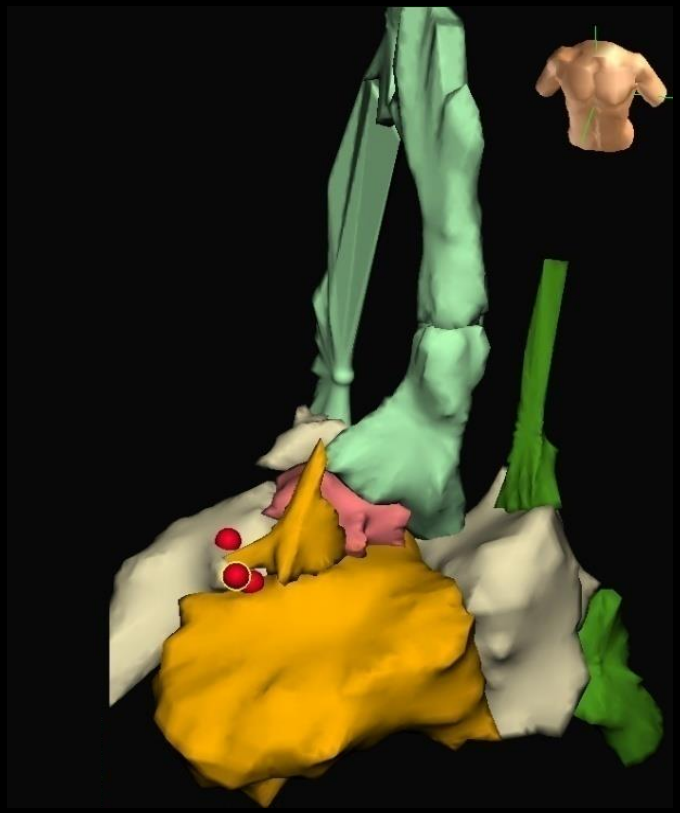
The Risk of Ionizing Radiation in Electrophysiology Studies and Ablations

DOUGLAS MAH, M.D. and JOHN K. TRIEDMAN, M.D.

From the Department of Cardiology, Children's Hospital Boston; and the Department of Pediatrics Harvard Medical School

Although fluoroscopy-free procedures cannot yet be routinely performed by most practitioners, **the hope of it one day becoming the standard of care** brings with it the promise of decreased occupational health risks, chromosomal abnormalities, and malignancy.

PACE 2010;34:261-263



Wisdom is a point of view on things

The real voyage of discovery consists not in seeking new landscapes, but in having new eyes.

Marcel Proust