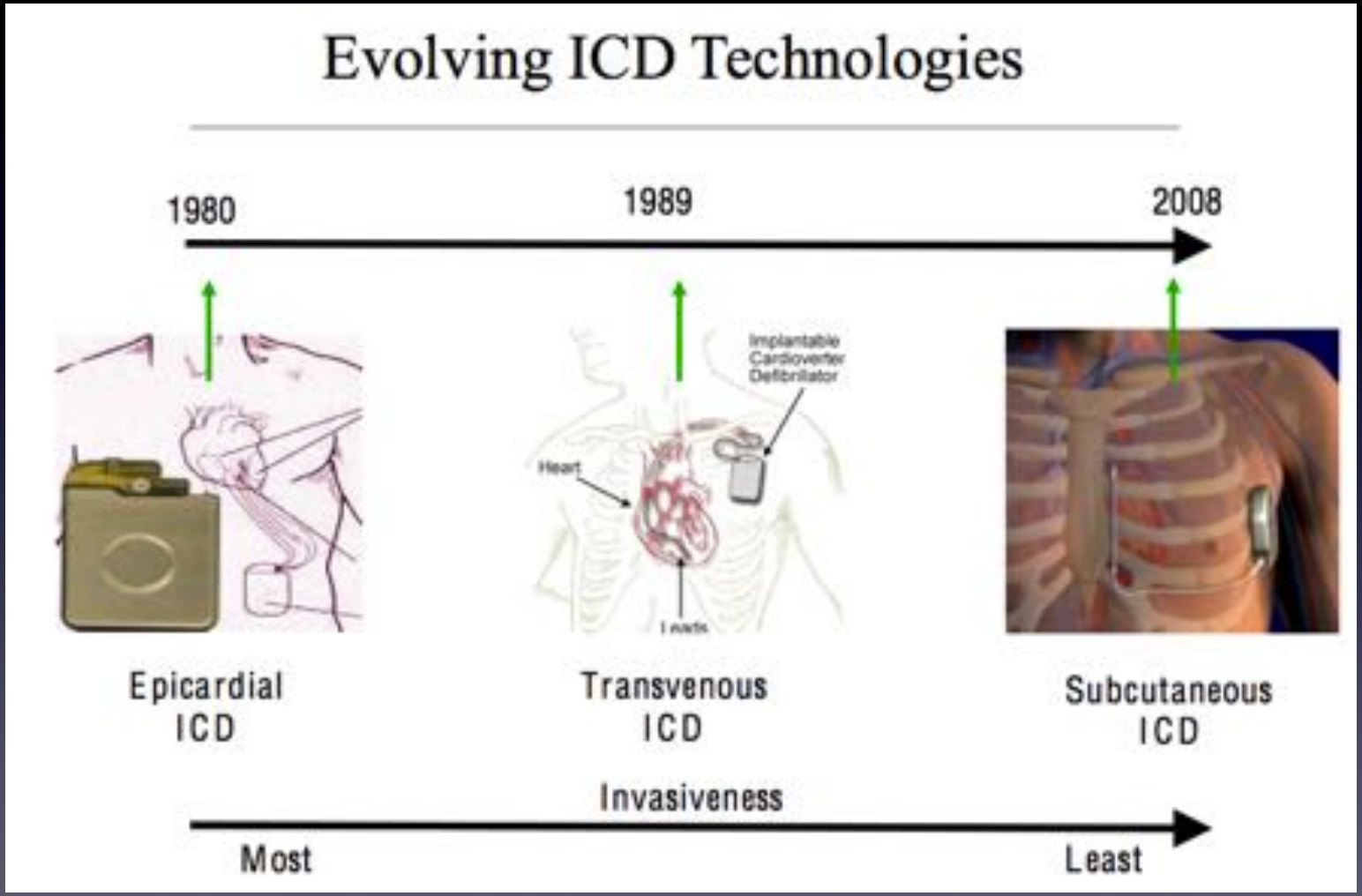
Long term follow up of the Two Incision Technique for implantation of the Subcutaneous implantable cardioverter defibrillator (S-ICD)

Reinoud Knops, MD, Academic Medical Center, Amsterdam

Venice Arrhythmias, Saturday October 17th, 2015

The subcutaneous ICD



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CLINICAL RESEARCH

The learning curve associated with the introduction of the subcutaneous implantable defibrillator

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[1]Academic Medical Center, Amsterdam, The Netherlands; [2]Russells Hall Hospital, Dudley, UK; [3]Erasmus Medical Center, Rotterdam, The Netherlands; [4]St. Antonius Ziekenhuis, Nieuwegein, The Netherlands; [5]Ohio State University, Columbus, OH, USA; [6]Na Homolce Hospital, Prague, Czech Republic; [7]Medisch Spectrum Twente, Enschede, The Netherlands; [8]The Heart Hospital, University College London, London, UK; [9]Emory University, Atlanta, GA, USA; [10]Auckland City Hospital, Auckland, New Zealand; [11]Boston Scientific, Minneapolis, MN, USA; [12]Papworth Hospital NHS Foundation Trust, Cambridge, UK; and [13]University of Chicago, Chicago, IL, USA

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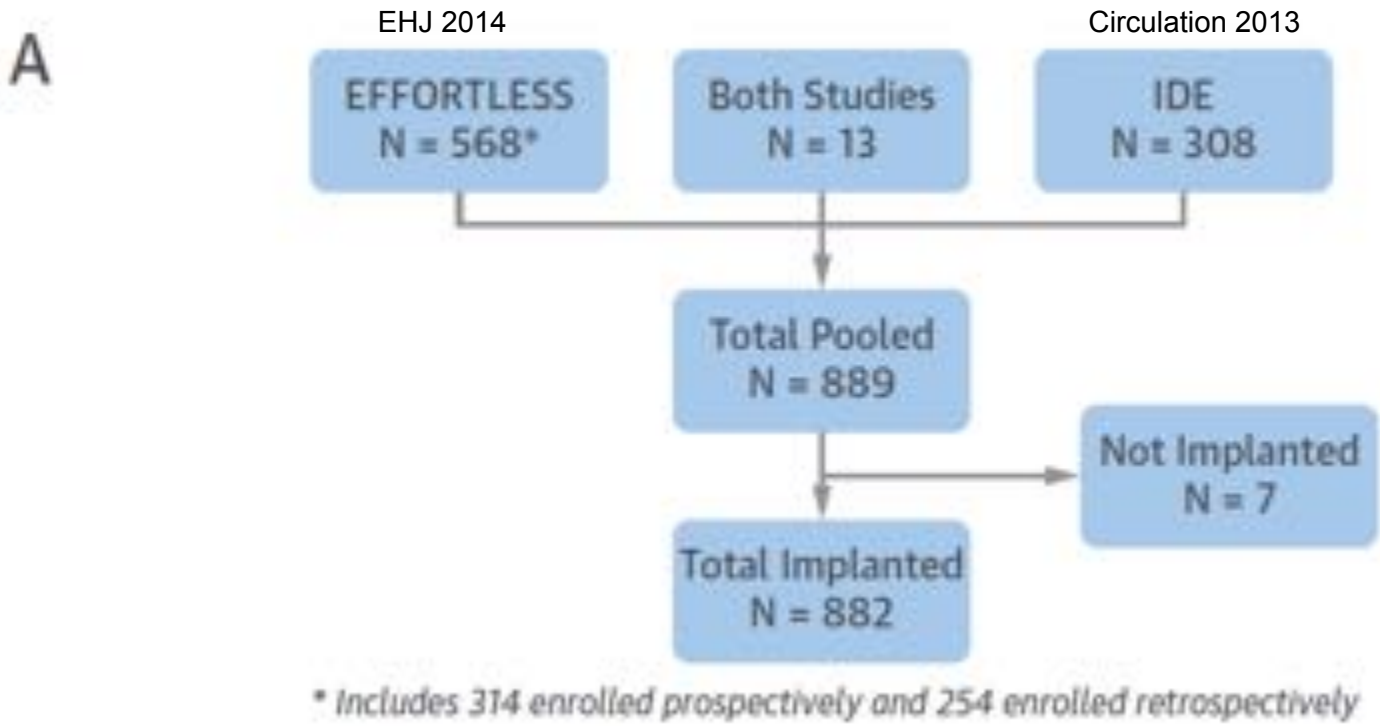
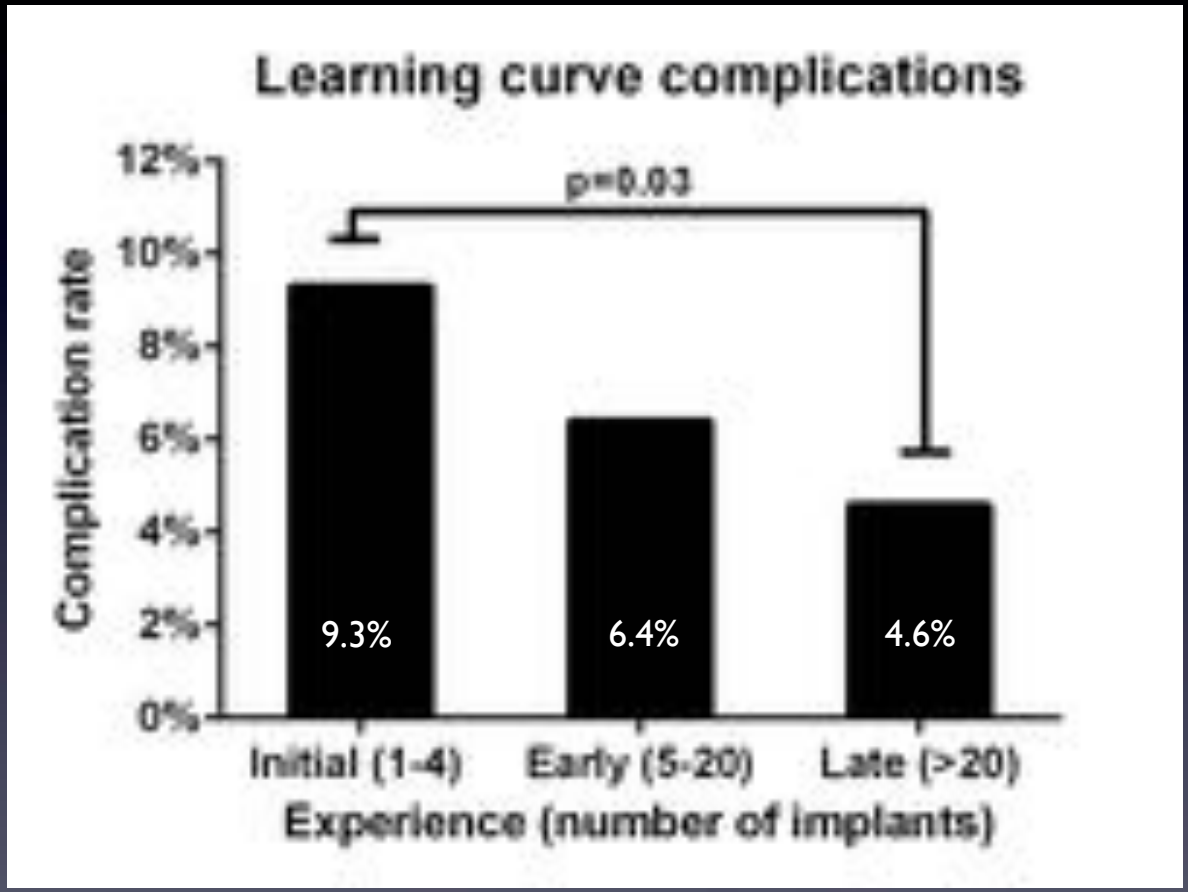
FIGURE 1 Pooled Data Population



(A) A flowchart depicts the pooled cohort of study patients broken down by each contributing study. The designation **Both Studies** represents patients enrolled into both EFFORTLESS and the IDE studies. Patients **Not Implanted** underwent an implant procedure but due to high defibrillation thresholds did not leave the hospital with the S-ICD. **(B)** The

Effect of learning on complications at 6 months:
(in 882 patients, Effortless/IDE)



Infection/erosion:	2.9%
Suboptimal position:	2.0%
Erosion/hematoma: 1.3%	

Procedure time:

75 → 65 minutes

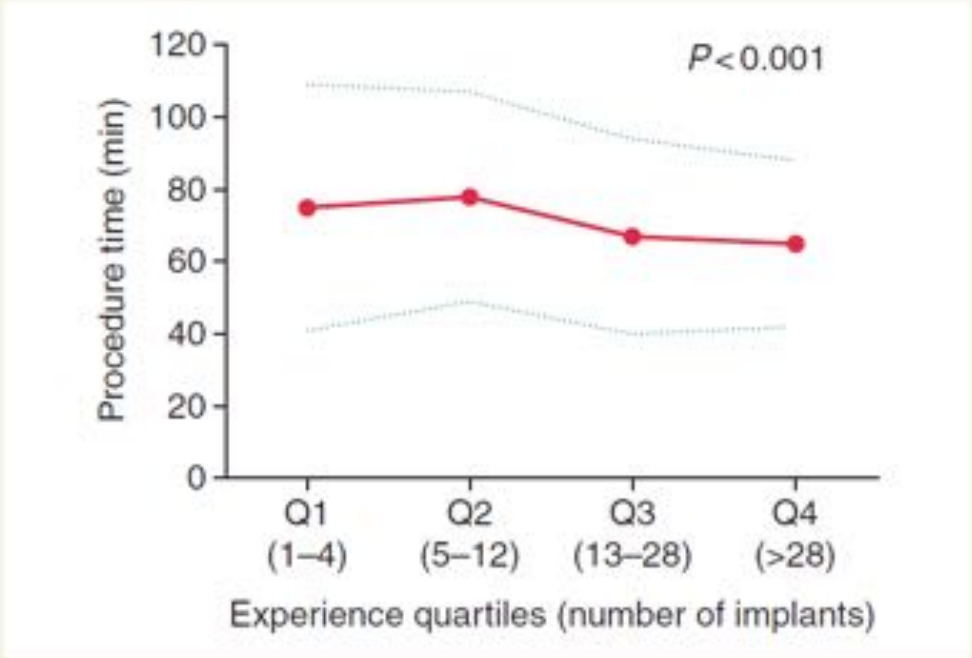
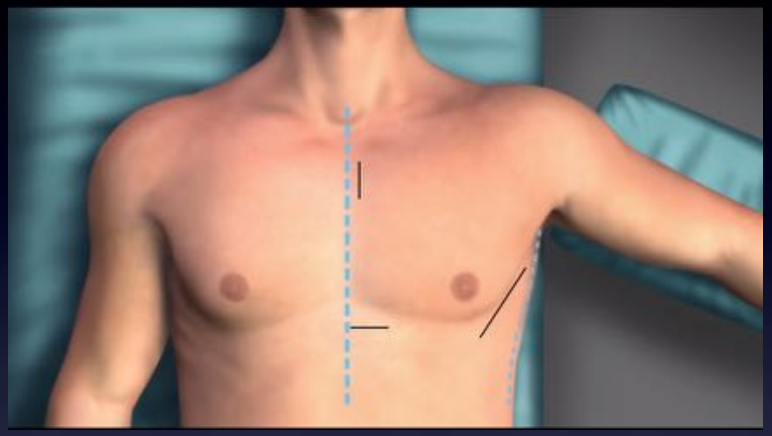
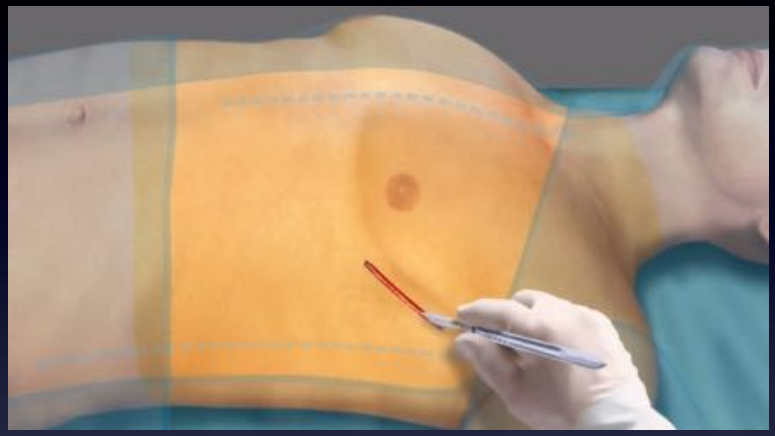
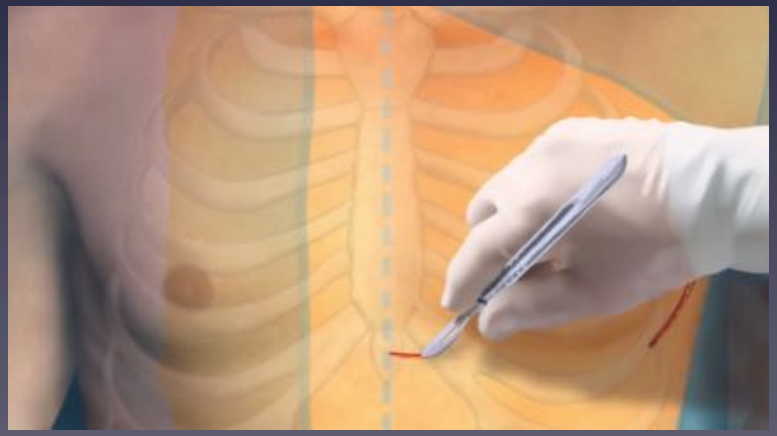


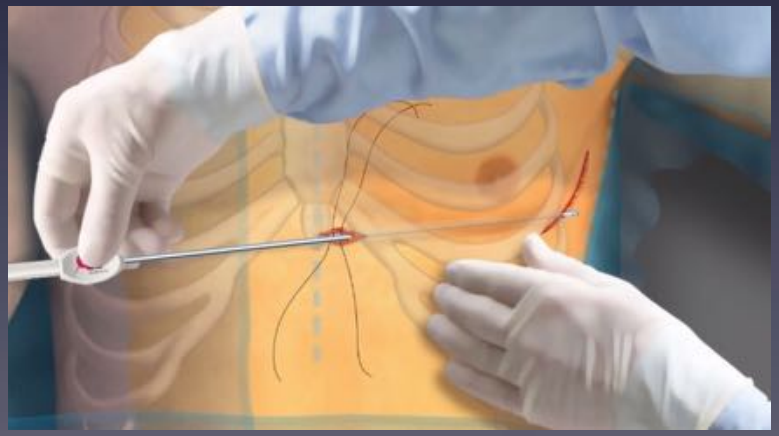
Figure 2 Skin-to-skin procedure time by experience quartiles. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28). Solid line is mean, and dashed lines are ±1 SD. *P* value is trend test.

S-ICD Implant procedure

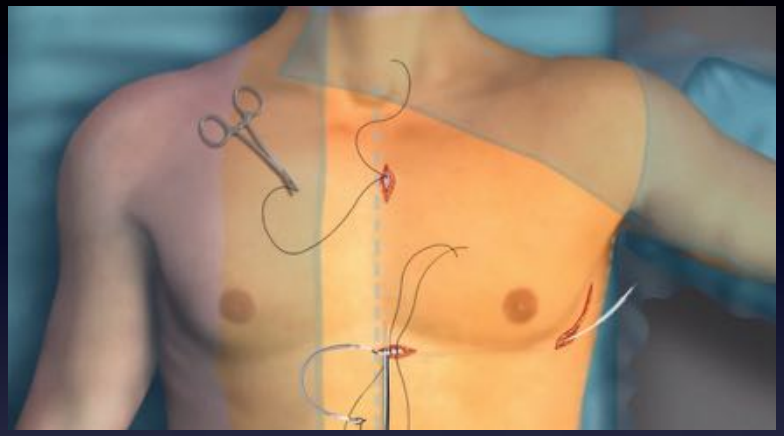


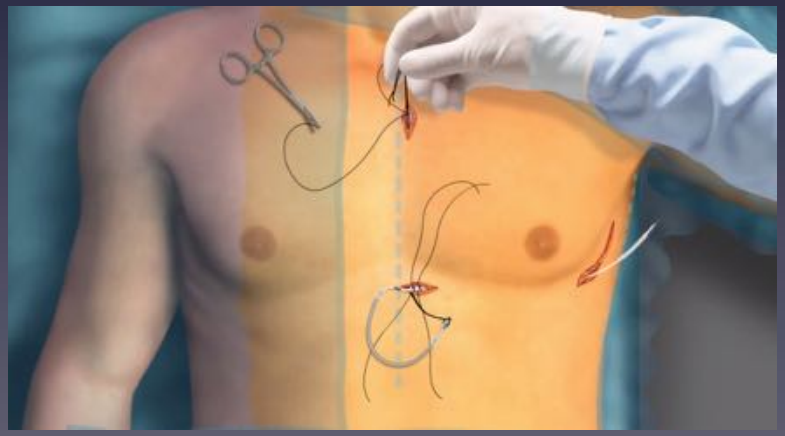






S-ICD Implant procedure

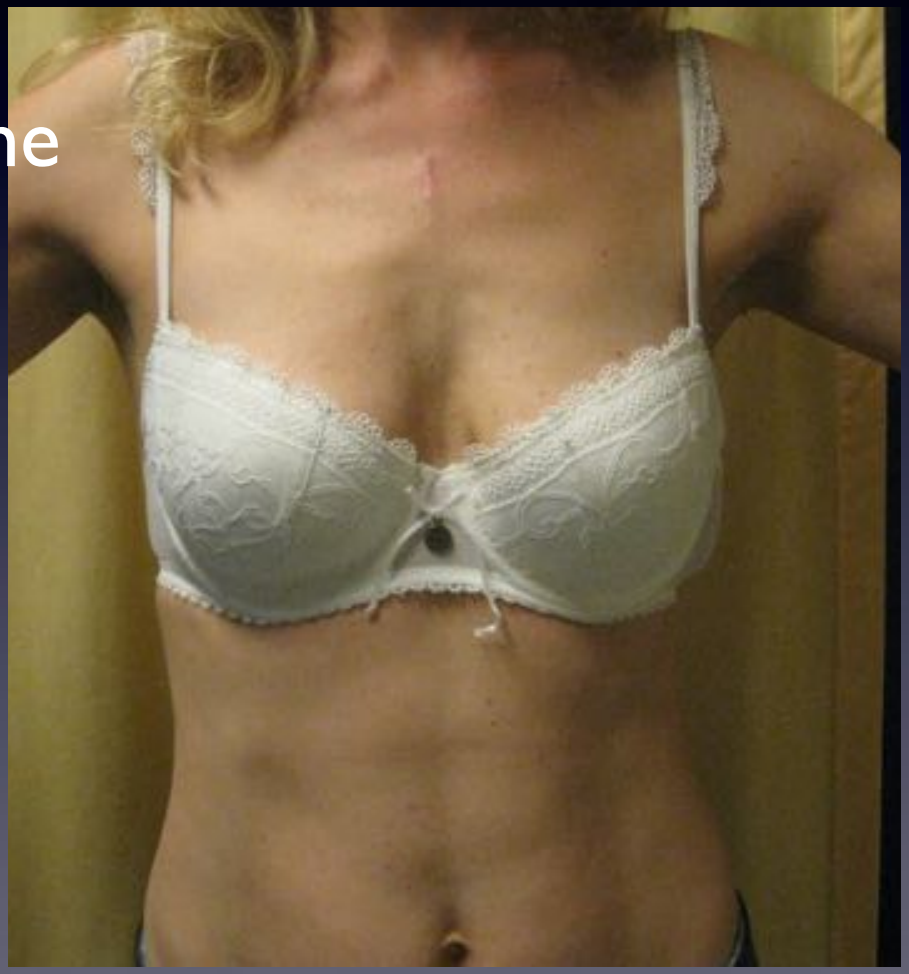




Different implant technique:

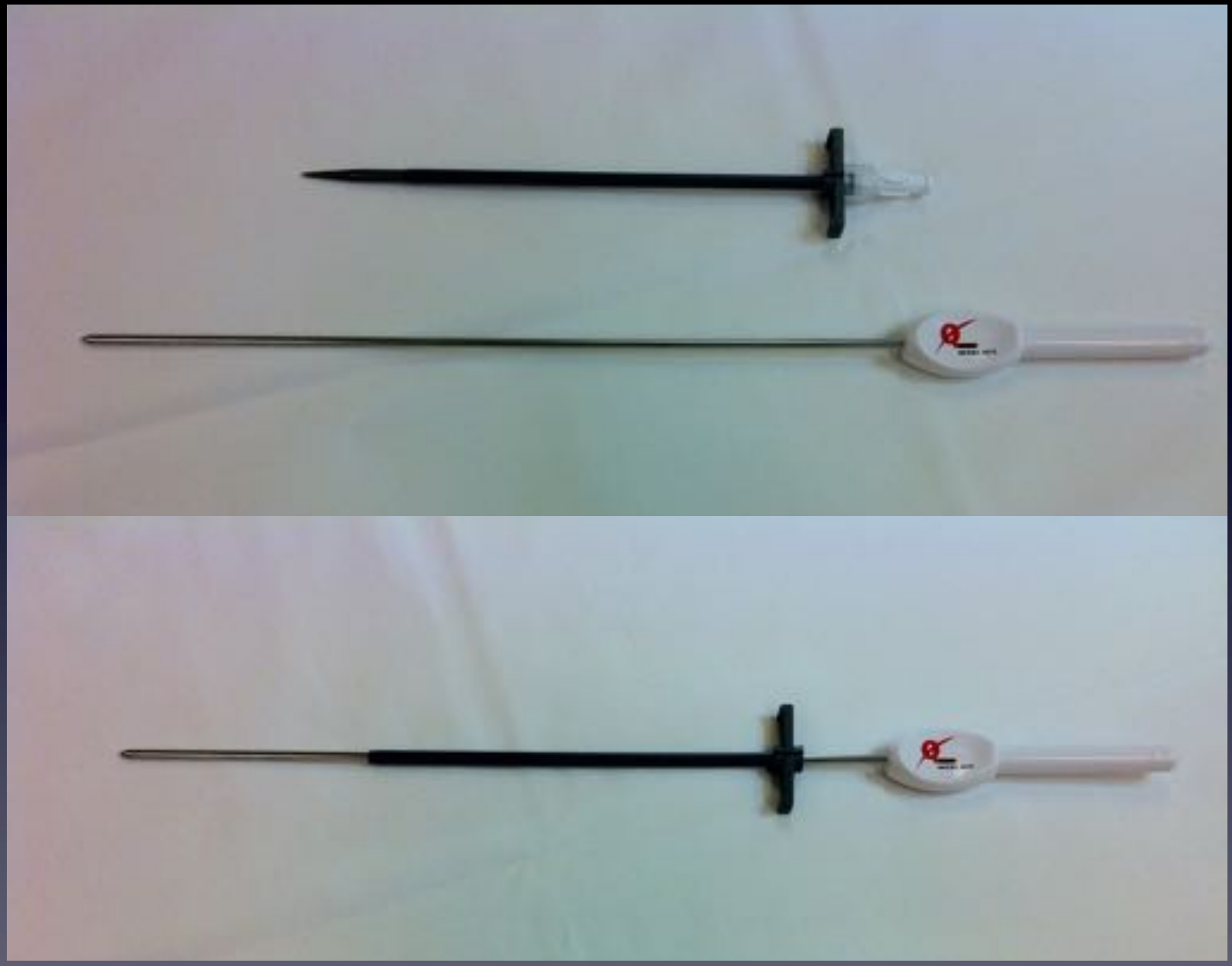
Rationale:

1. Reduce procedure time
2. Reduce incisions
3. Reduce infections
4. Improve cosmetics

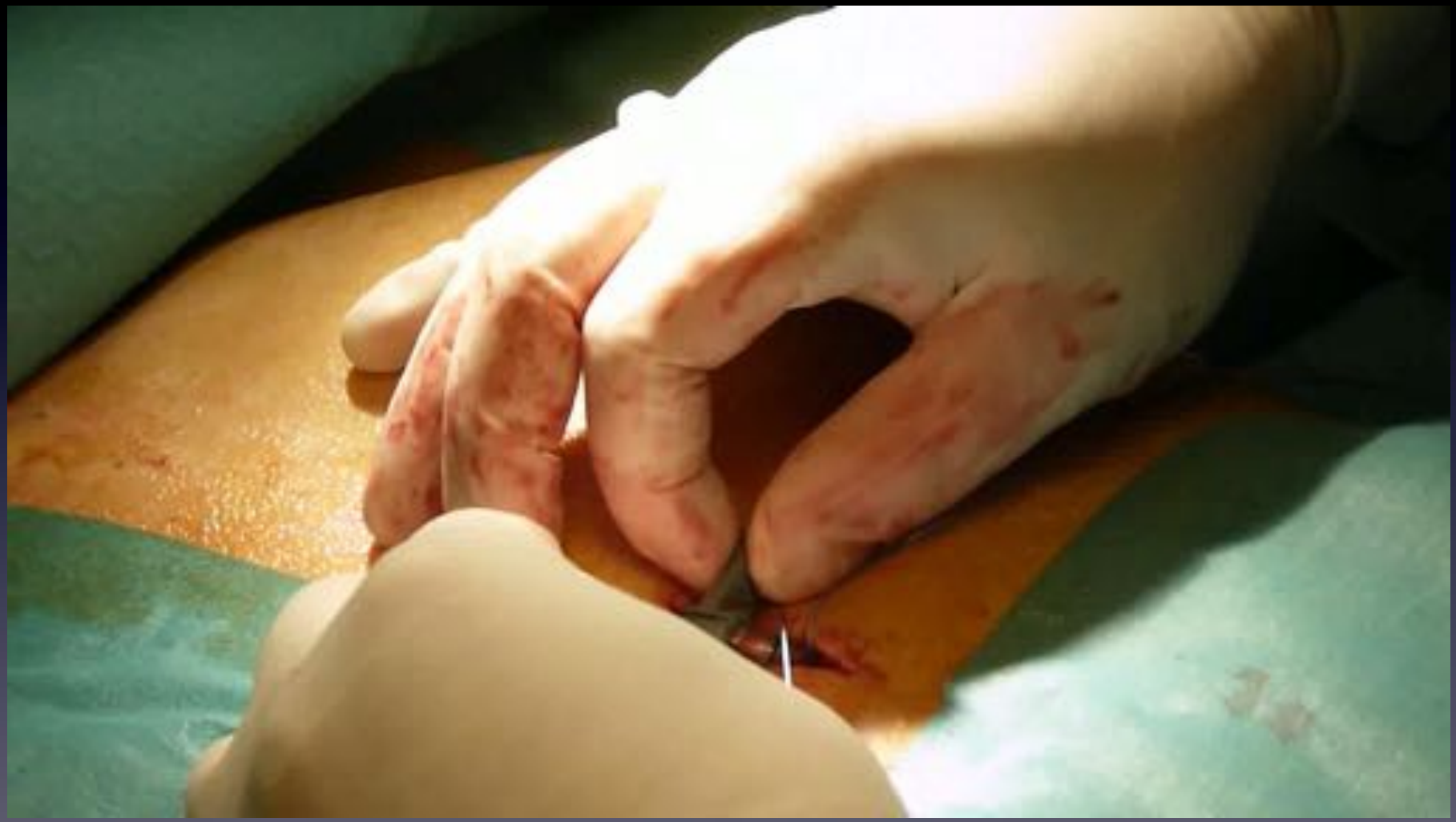


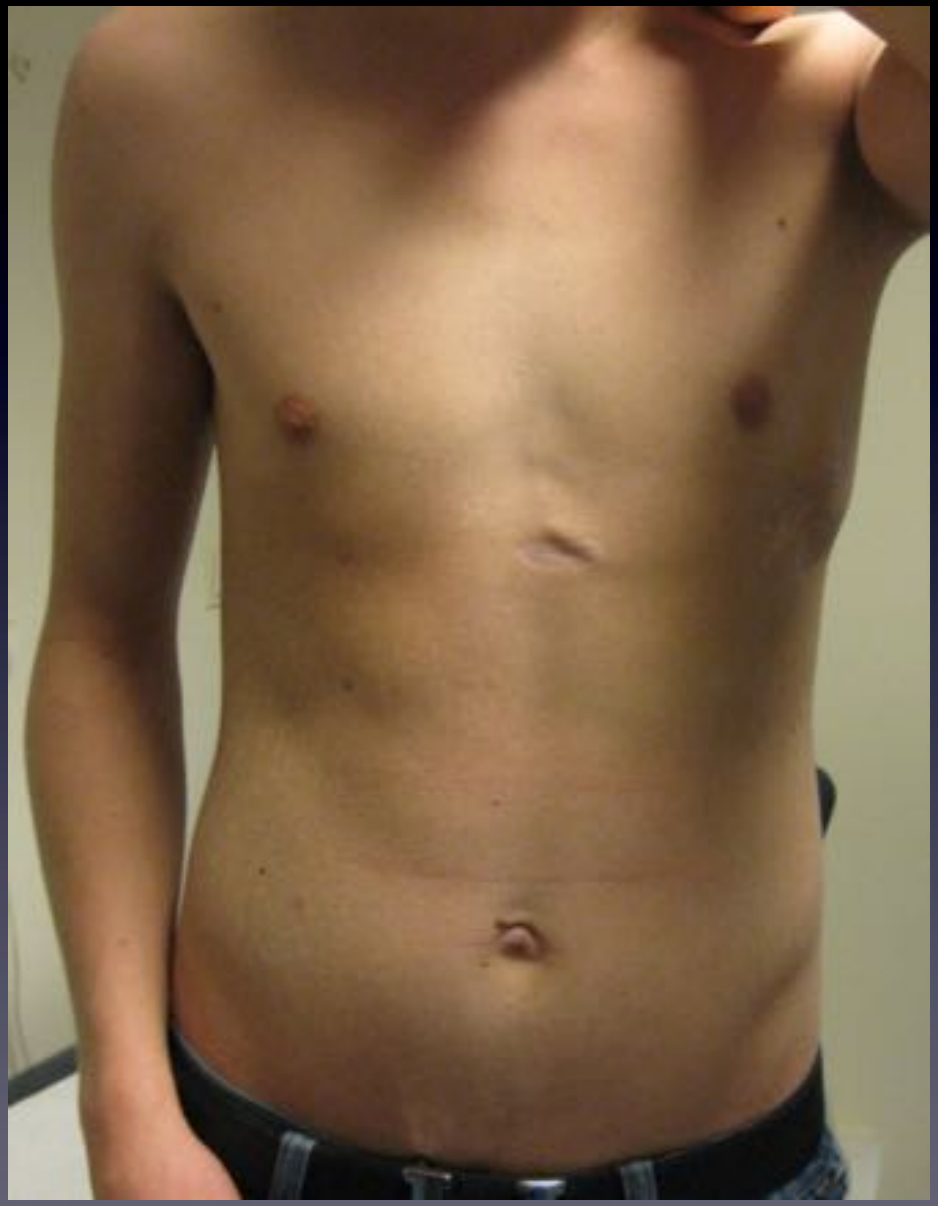
Alternative implant technique

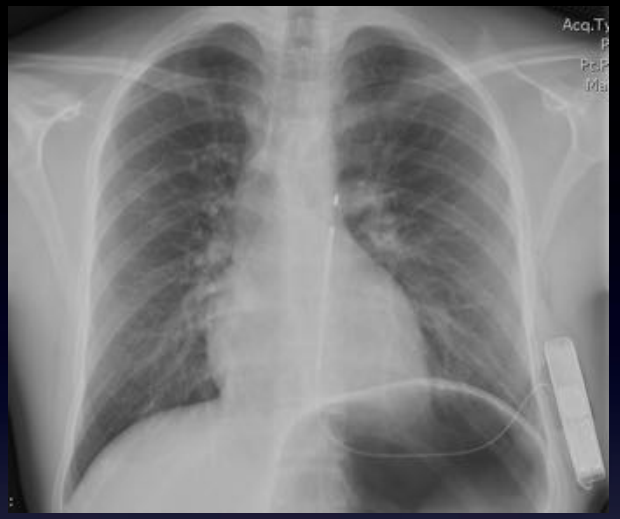
"The two incision technique"

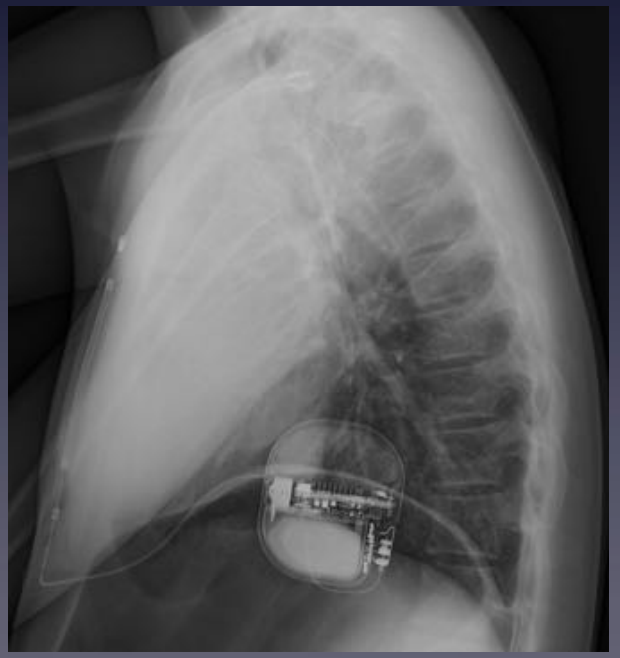


11 French!!









Publication Heart Rhythm 2013
First 39 patients with 1 y FU
No dislocations
No infections

HANDS ON

Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator

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From the Department of Cardiology, Academic Medical Center, Amsterdam, The Netherlands.

BACKGROUND Three incisions in the chest are necessary for implantation of the entirely subcutaneous implantable cardioverter-defibrillator (S-ICD). The superior parasternal incision is a possible risk for infection and a potential source of discomfort. A less invasive alternative technique of implanting the S-ICD electrode—the two-incision technique—avoids the superior parasternal incision.

OBJECTIVE The purpose of this prospective cohort study was to evaluate the safety and efficacy of the two-incision technique for implantation of the S-ICD.

METHODS Consecutive patients who received an S-ICD between October 2010 and December 2011 were implanted using the two-incision technique, which positions the parasternal part of the S-ICD electrode using a standard 11Fr peel-away sheath. All patients were routinely evaluated for at least 1 year for complications and device interrogation at the outpatient clinic.

RESULTS Thirty-nine patients (46% male, mean age 44 ± 15 years) were implanted with a S-ICD using the two-incision technique. During mean follow-up of 18 months (range 14–27 months) no dislocations were observed, and there was no need for repositioning of either the ICD or the electrode. No serious infections occurred during follow-up except for 2 superficial wound infections of the pocket incision site. Device function was normal in all patients, and no inappropriate sensing occurred related to the implantation technique.

CONCLUSION The two-incision technique is a safe and efficacious alternative for S-ICD implantations and may help to reduce complications. The two-incision technique offers physicians a less invasive and simplified implantation procedure of the S-ICD.

KEYWORDS Implantable cardioverter-defibrillator; Implantation technique; Subcutaneous implantable cardioverter-defibrillator

ABBREVIATIONS **DFT** = defibrillation threshold; **EIT** = electrode insertion tool; **ICD** = implantable cardioverter-defibrillator; **S-ICD** = subcutaneous implantable cardioverter-defibrillator; **VF** = ventricular fibrillation

(Heart Rhythm 2013;10:1240–1243)

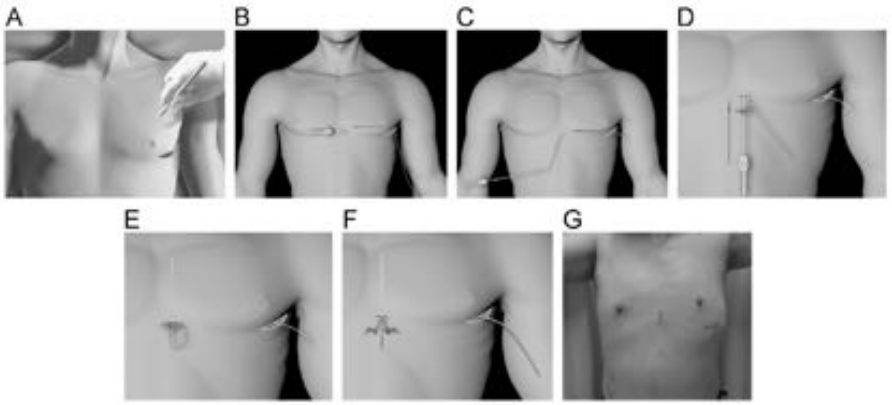


Figure 1 **A:** Creating the device pocket. **B:** Connecting distal end of electrode to the electrode insertion tool (EIT). **C:** Pulling the lead to the inferior parasternal incision. **D:** Tunneling the EIT and peel-away sheath to the superior parasternal position without making a parasternal incision. **E:** After the EIT is removed, the electrode is inserted in the sheath. **F:** Peeling away the sheath, leaving the electrode in the desired subcutaneous position. **G:** Final result after 2 weeks of follow-up.

Follow up Two Incision Technique (TIT) in Amsterdam:

Feb 2009 – Aug 2015

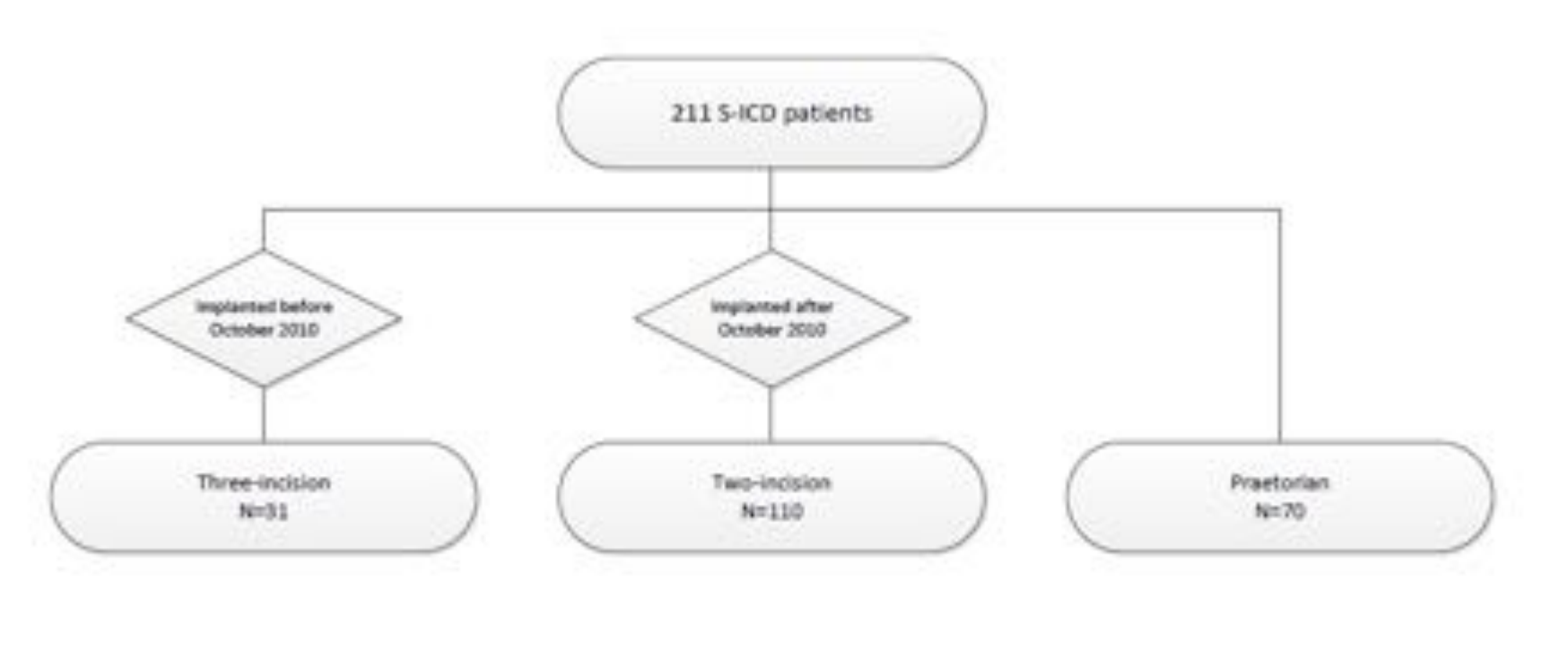


Table 1: Baseline characteristics

	Three-incision (N=31)	Two-incision (N=110)	P-value
Age (mean ± SD)	39±17	40±16	0.63
Female (%)	12 (39)	48 (44)	0.68
BMI (median, IQR)	23 (20, 25)	25 (22, 29)	0.06
LVEF (median, IQR)	52 (41, 57)	50 (30, 57)	0.45
QRS duration (ms)	100 (89, 111)	96 (90, 108)	0.38
Previous transvenous implant (%)	2 (6)	17 (15%)	0.24
Diabetes Mellitus (%)	1 (3)	6 (5)	1.00
Hypertension (%)	7 (22)	15 (14)	0.26
Atrial fibrillation (%)	2 (6)	10 (9)	1.00
eGRF <60ml (%) (N=106)	0 (0)	9 (11)	0.20
Dyslipidemia (%)	1 (3)	11 (10)	0.46
Primary prevention (%)	21 (68)	72 (65)	1.00
Diagnosis			0.74
iCMP (%)	5 (16)	19 (17)	
Non-iCMP (%)	7 (23)	22 (20)	
Genetic (%)	19 (61)	59 (54)	
Congenital (%)	0 (0)	5 (5)	
Other (%)	0 (0)	5 (5)	
Therapy zones programming			
- **Lower rate conditional zone**	190 (190, 200)	190 (180, 200)	.22
- **Upper rate conditional zone**	230 (220, 230)	250 (250, 250)	<0.01
Sensing vector post-implant			.59
- **Primary (%)**	12 (39)	54 (49)	
- **Secondary (%)**	14 (45)	42 (38)	
- **Alternate (%)**	5 (16)	14 (13)	
Follow-up months (median, IQR)	61 (58, 66)	20 (7, 38)	<0.01

Values are given as n (%), mean SD, or median (interquartile range [IQR]).
BMI – body mass index, LVEF – left ventricular ejection fraction, eGRF – estimated glomerular filtration rate, iCMP – ischemic cardiomyopathy.

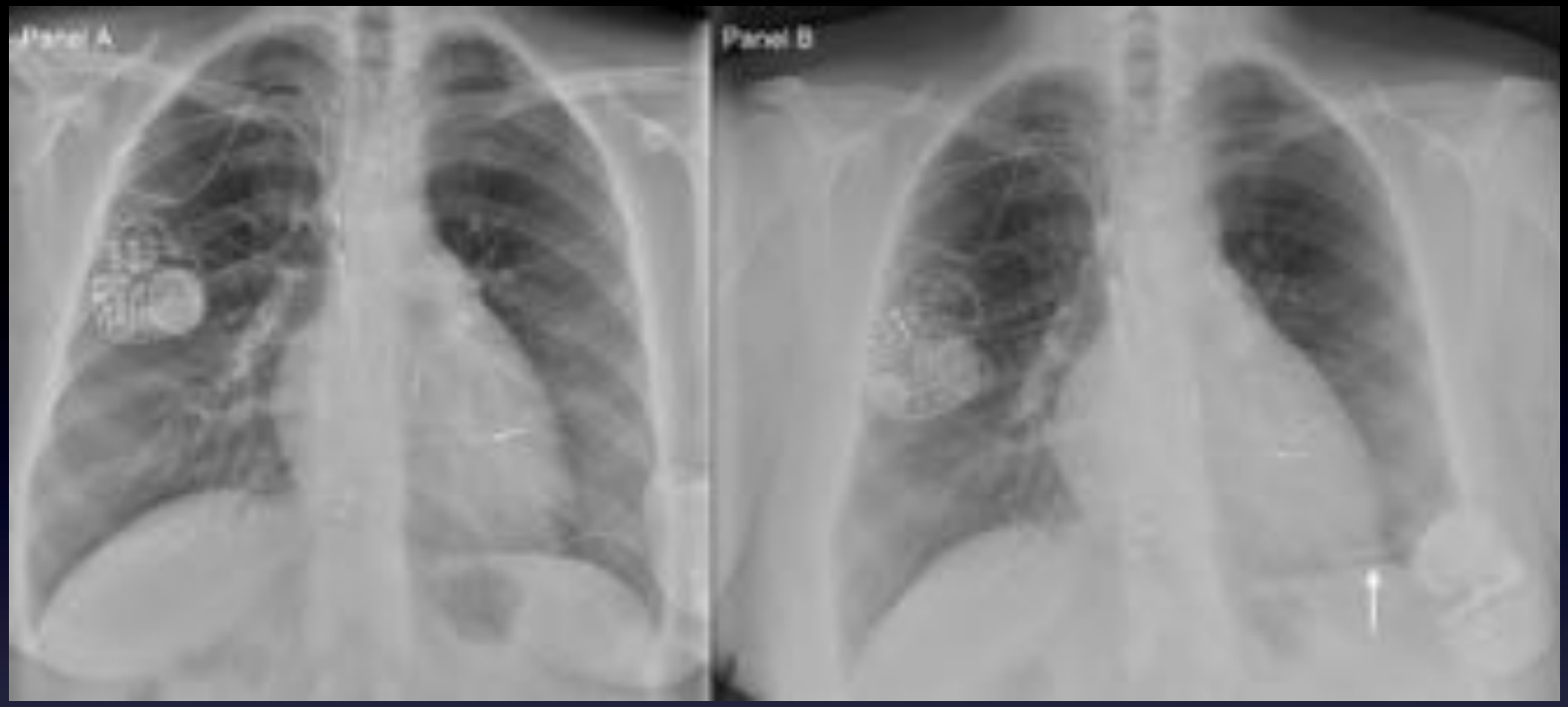
Table 2:
Procedural outcomes during S-ICD implantation.

Procedural outcomes	Three-incision N=31	Two-incision N=110	P-value
DF-test performed	31	100	0.12
First shock success DF-test	100%	96%	0.57
Shock impedance (median, IQR)	88 (72-100)	65 (57-79)	<0.001

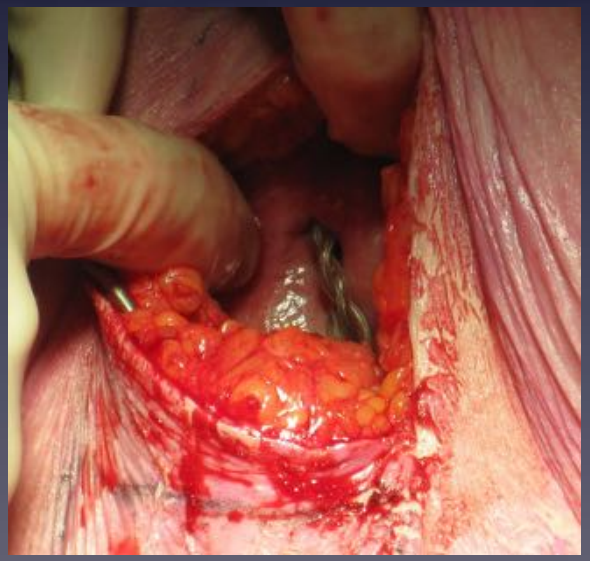
DF-test : Defibrillation test

Table 3:
Clinical outcomes of S-ICD therapy.

Clinical outcomes	Three-incision N=31	Two-incision N=110	P-value
First shock efficacy spontaneous episodes (%)	80%	75%	1.00
Conversion spontaneous episodes (N, %)	5/5 (100%)	8/8 (100%)	1.00
Infection (N,%)	3 (9.7%)	2 (1.8%)	0.07
Erosion (N,%)	0	3 (2.7%)	1.00
Lead Dislocations (N)	1	0	0.22



S-ICD Twiddler !
No dislocation !!



Pacing Clin Electrophysiol. 2015 Aug 26. **Subcutaneous Implantable Cardioverter Defibrillator Lead Failure due to Twiddler Syndrome.**
Kooiman KM[1], Brouwer TF[1], Halm VP[1], Knops RE[1].

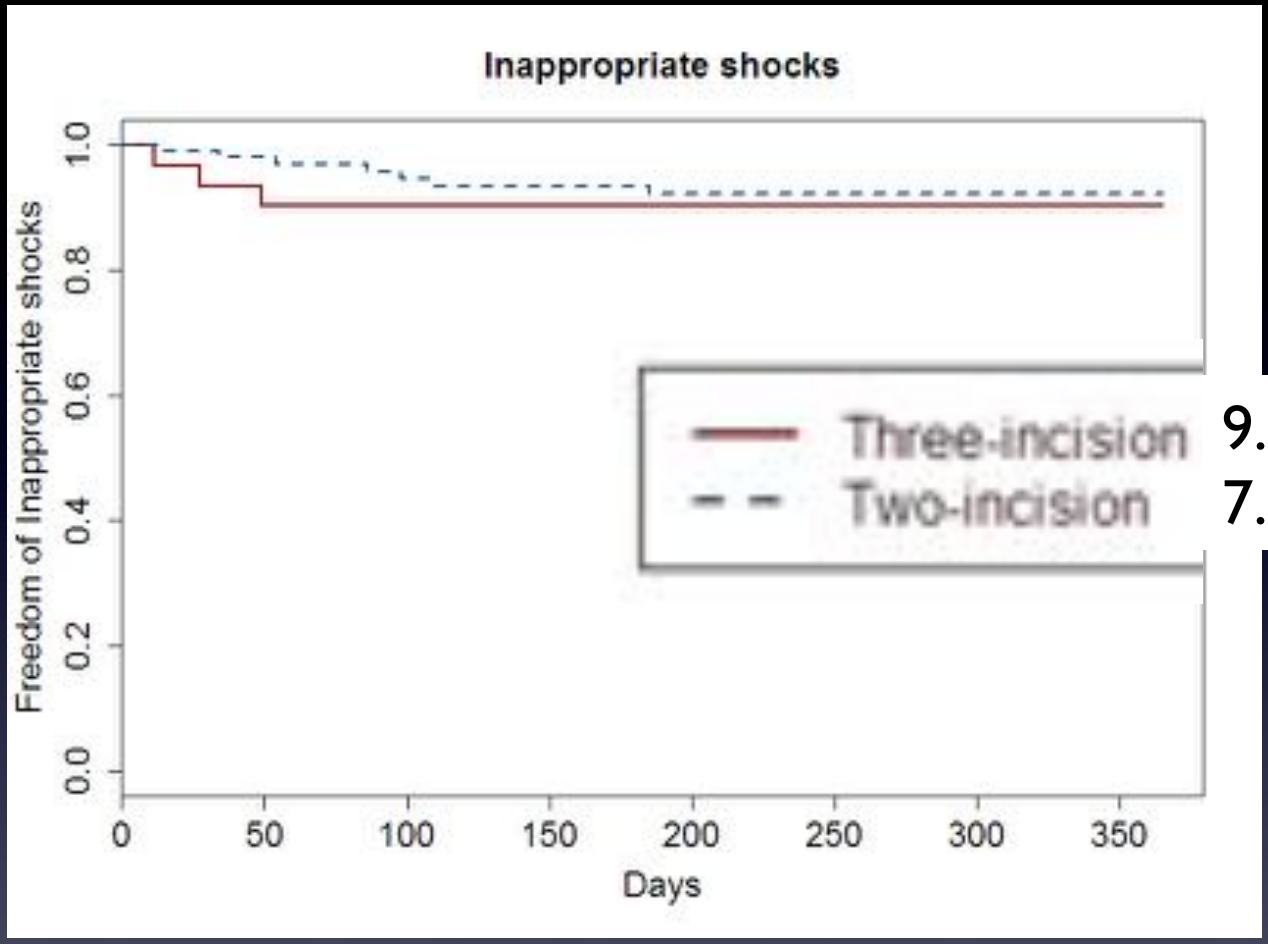
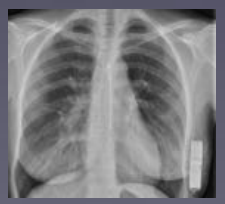
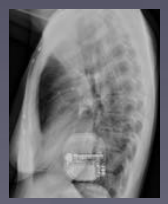
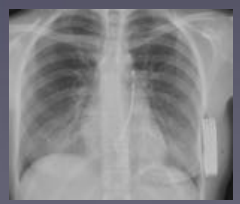


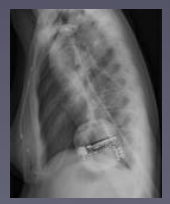
Figure 2: Kaplan-Meier of inappropriate shock free survival for the three-incision group and two-incision group, Log-rank test P=0.65.

Cosmetic outcome:
3 vs 2 incision technique:

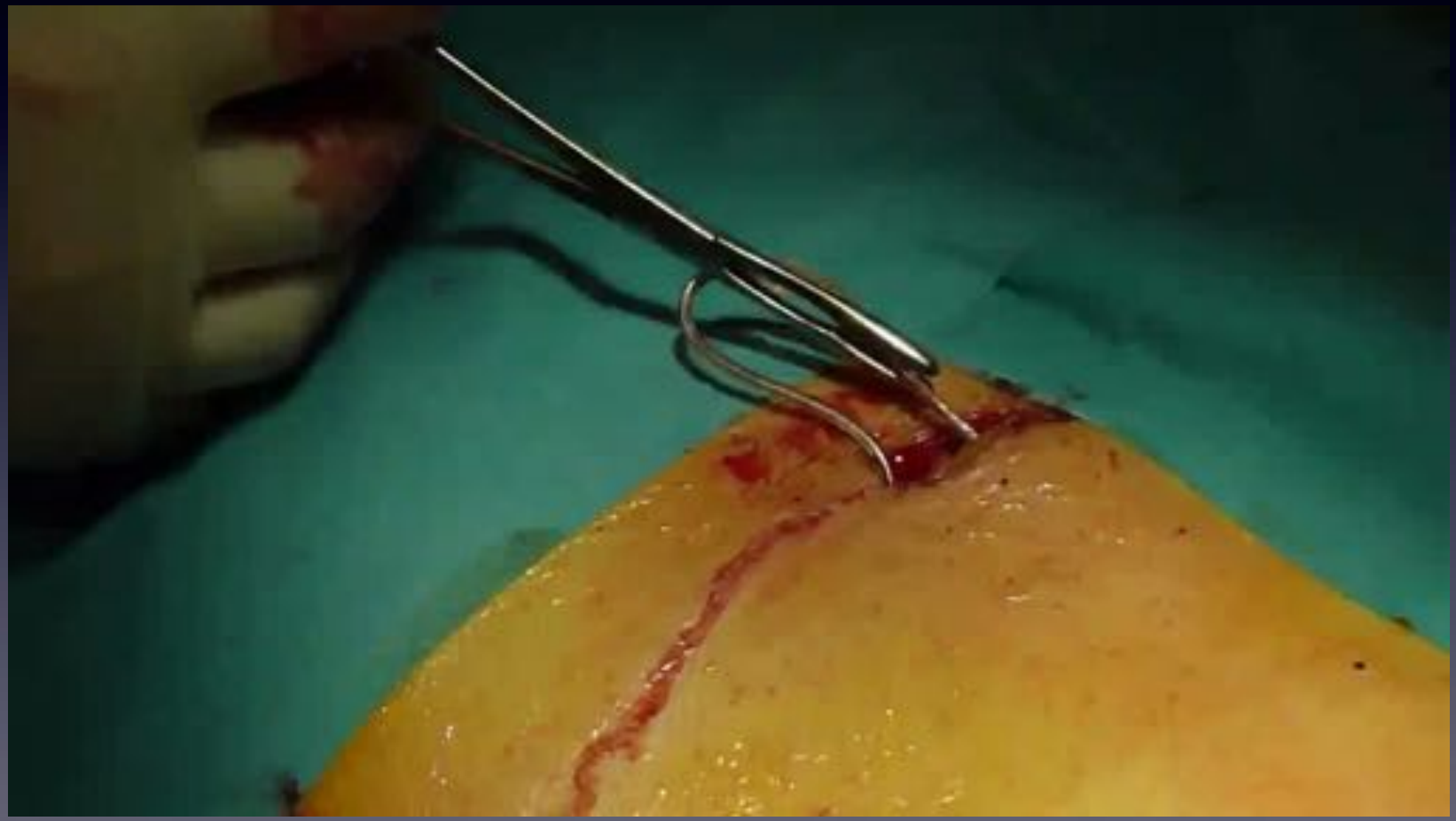








Lead extraction after two incision technique:



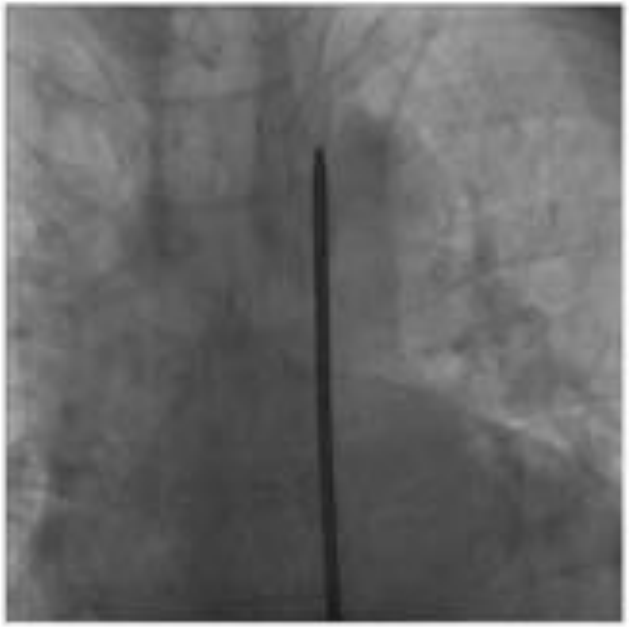
Conclusions
Two Incision Technique (TIT):

- Cuts procedure time by at least 5-10 minutes
- Better cosmetic results
- Trend towards less infections
- No influence on device function (DFT/sensing)
- No dislocations
- Extractions: also only two incisions
- First get experienced with the 3 incision technique!!!!

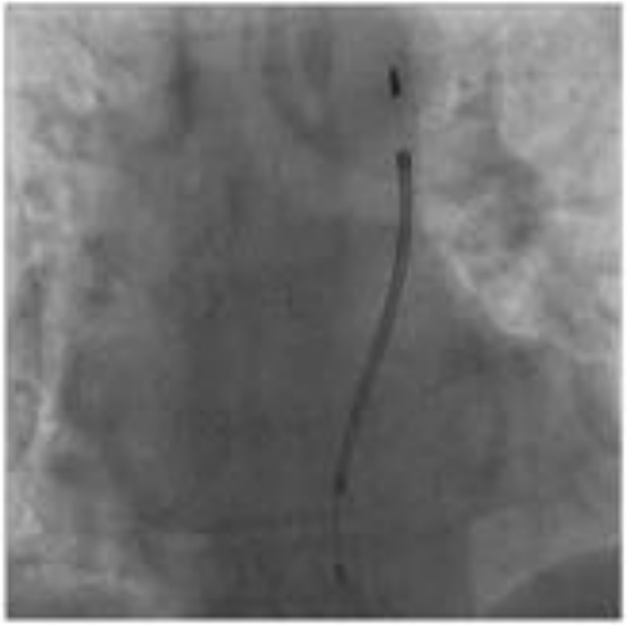

Thank you
Amsterdam

TIT gone bad

Initial implantation 5/1/15



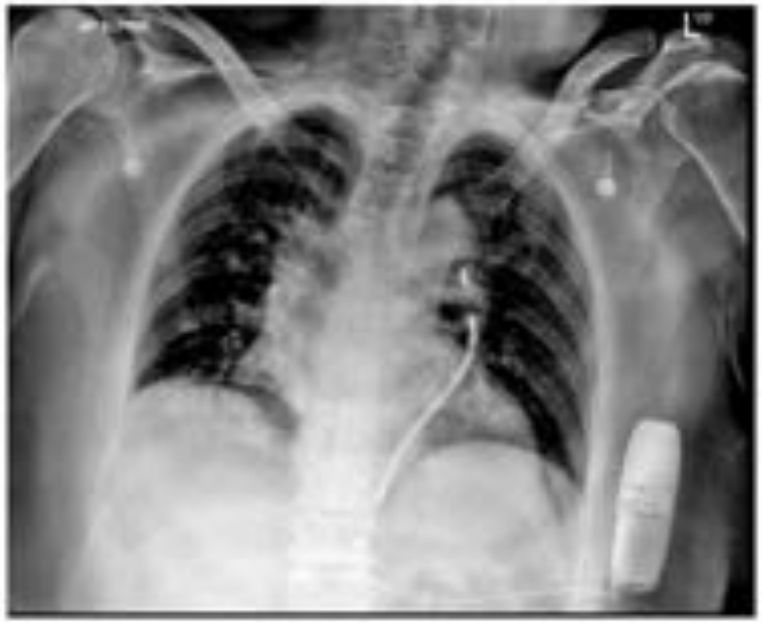
Tunnelling tool in place

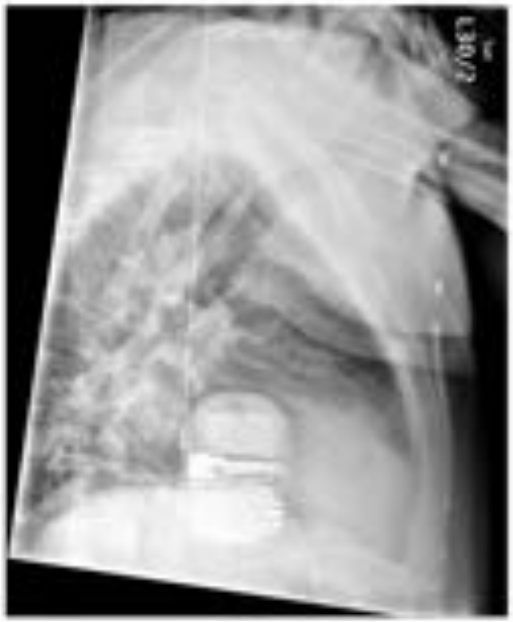


Lead in place

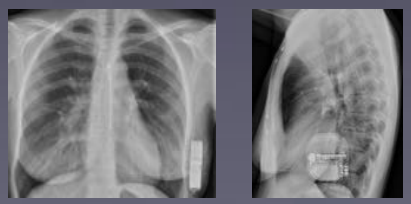
TIT gone bad

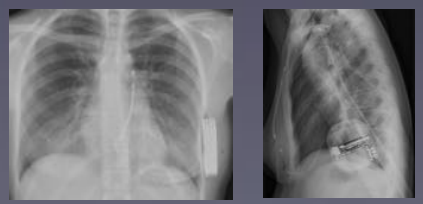
5/1/15





Follow up 3 vs 2 incision technique:

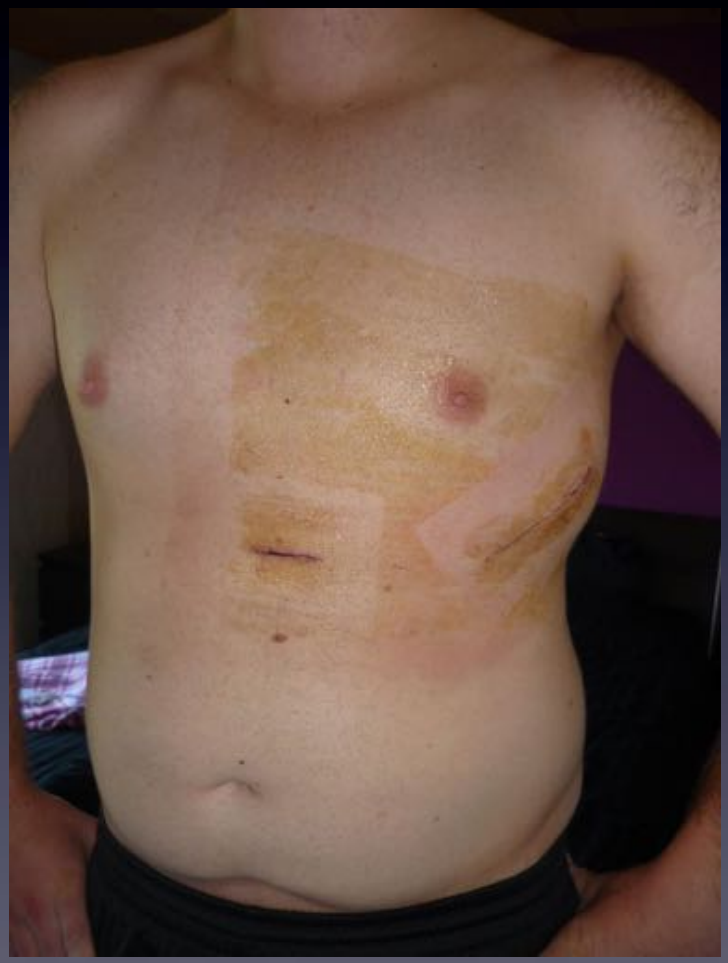




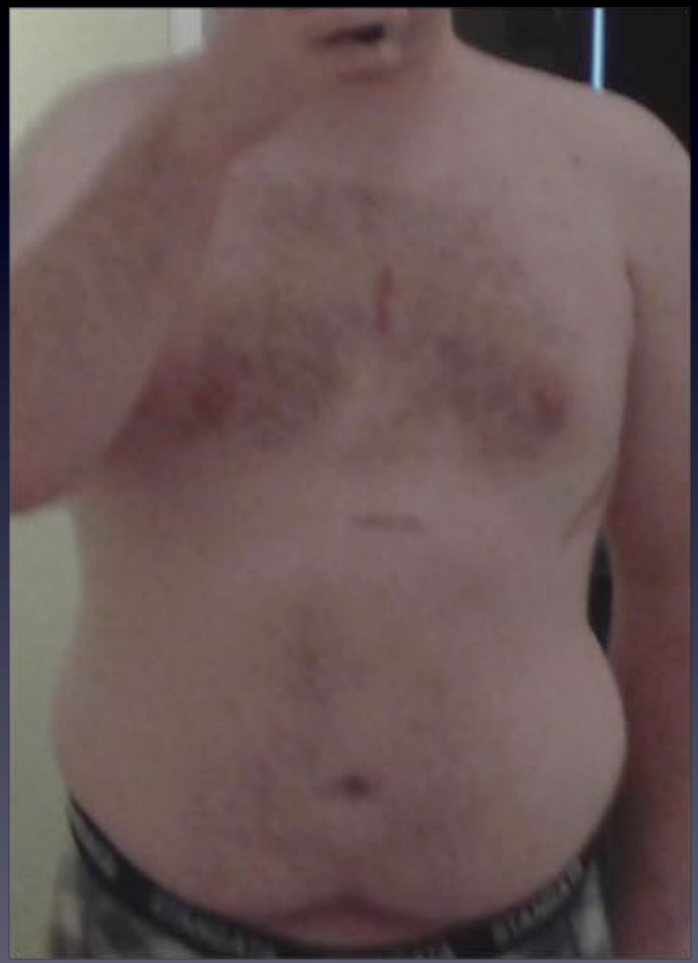
Case of suboptimal device position:

Obesity and DFT

Identical twins: ICD for idiopathic VF



86 kg = 190 lb



118 kg = 260 lb

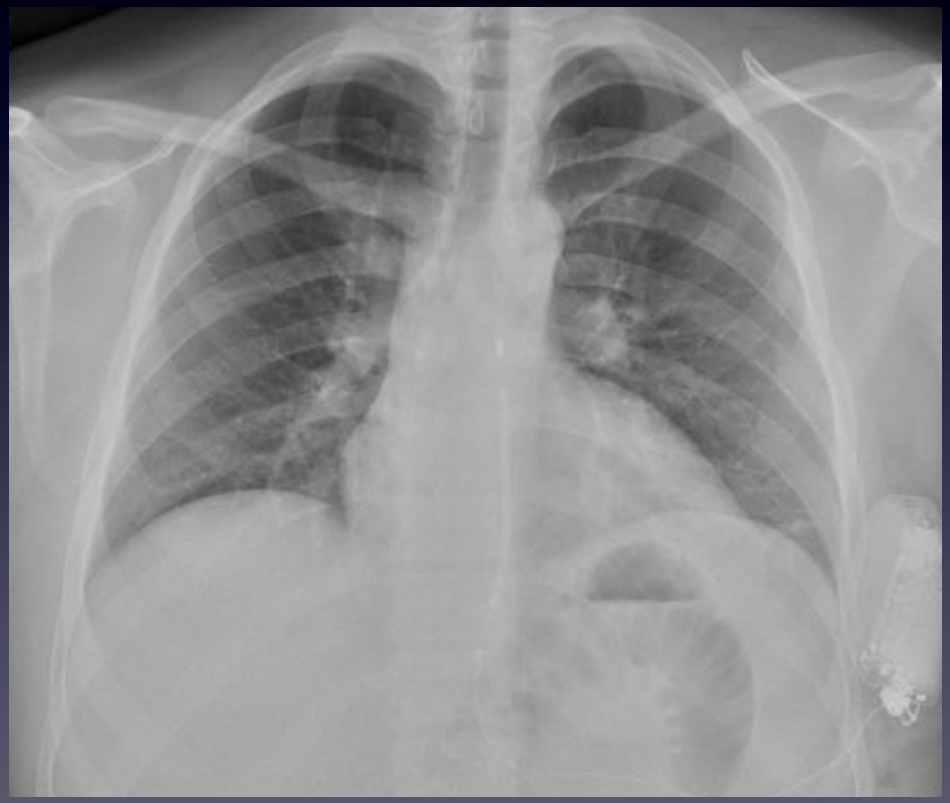
DFT +

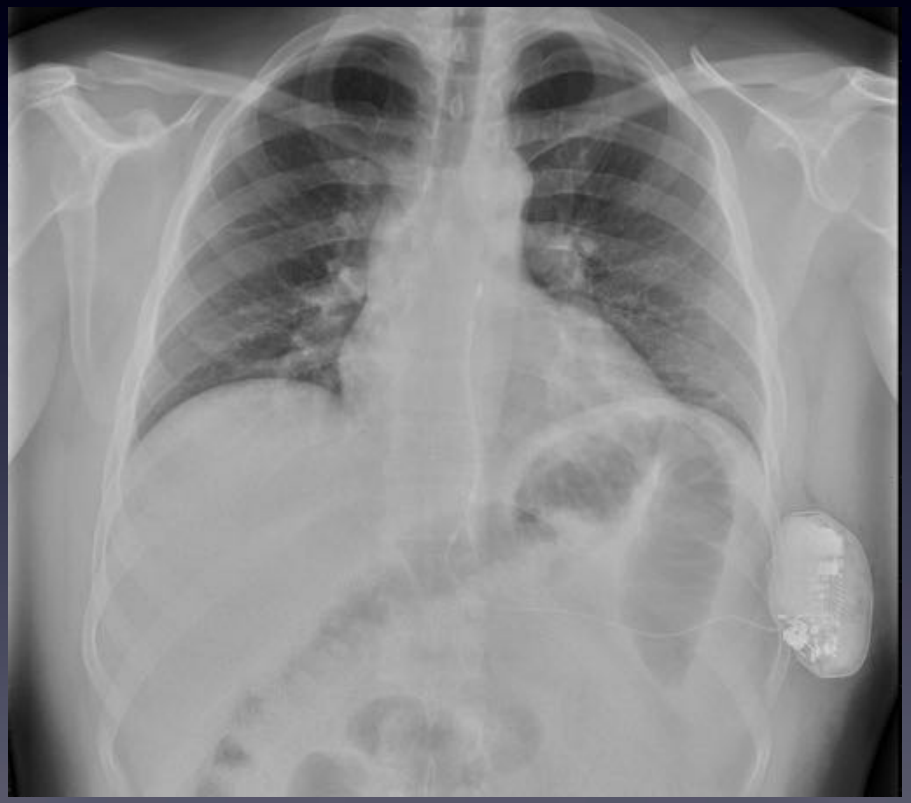
DFT

–

Successful at 65J

Failed at 65J





86 kg = 190 lb

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DFT +

DFT

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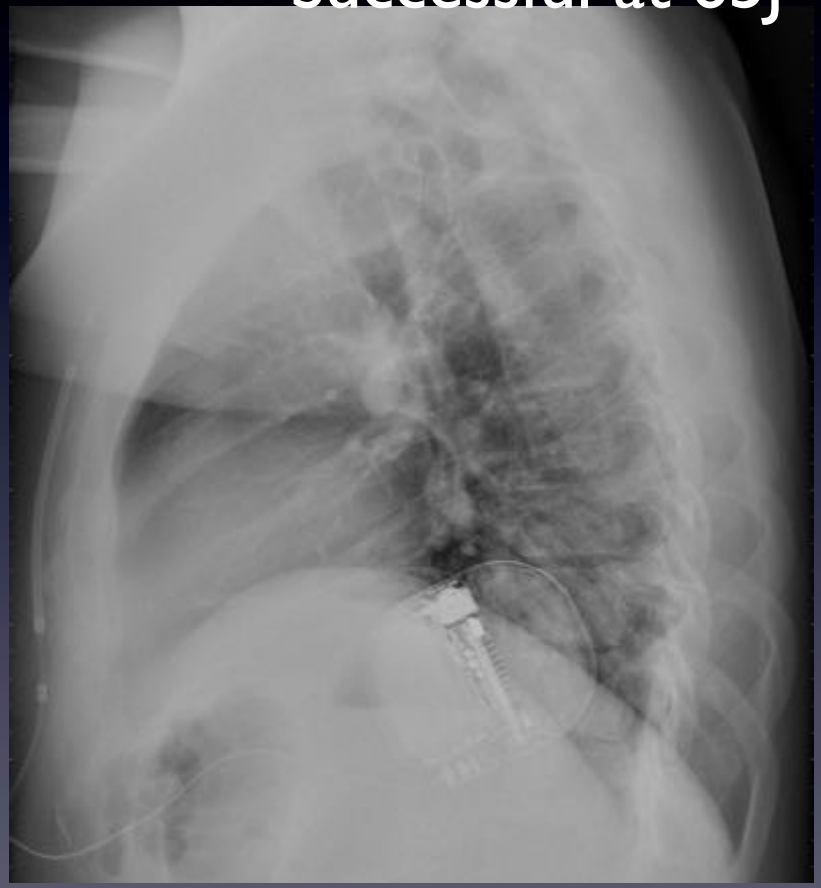
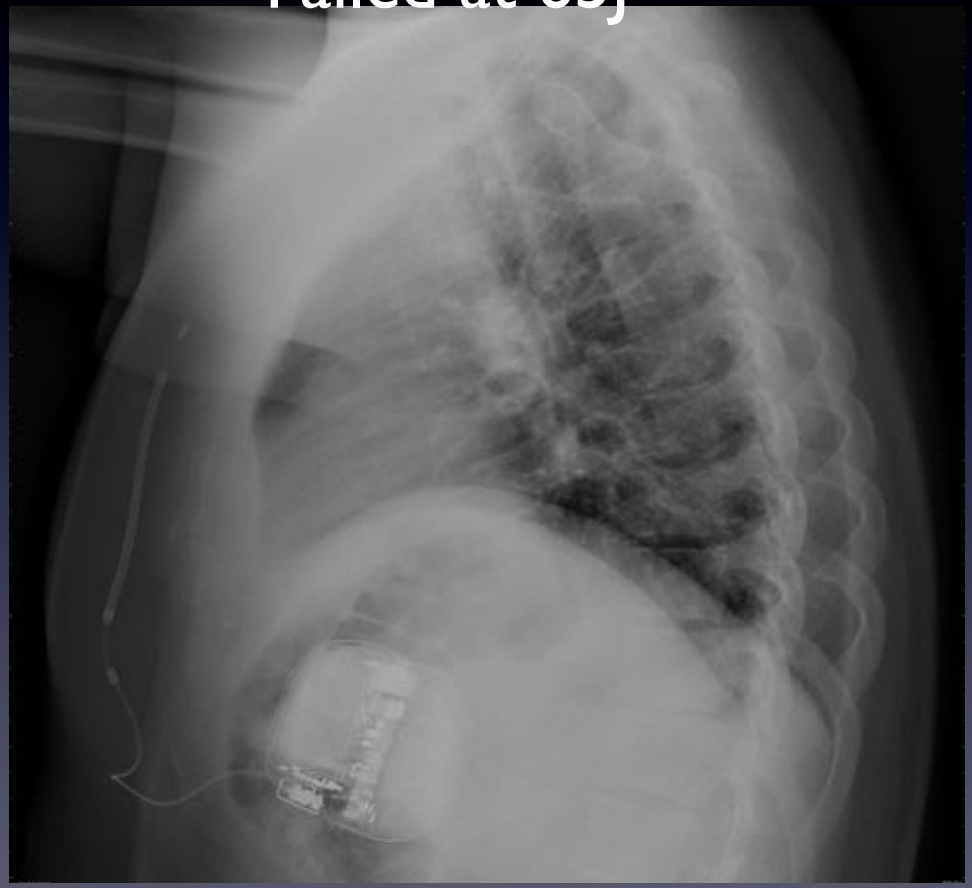
Successful at 65J



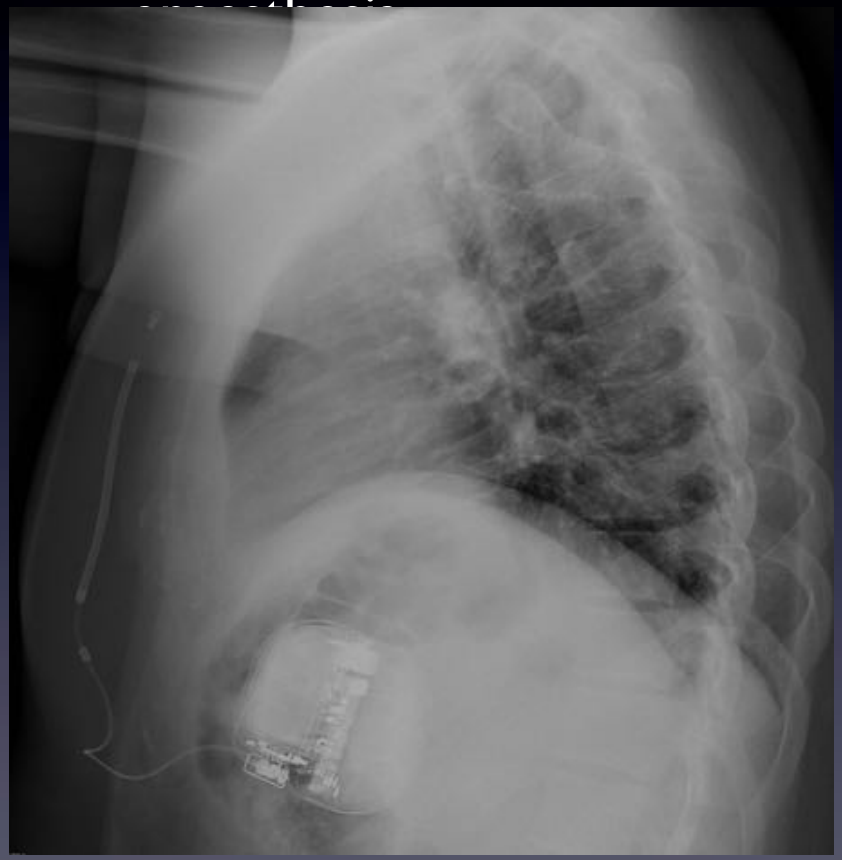
Failed at 65J

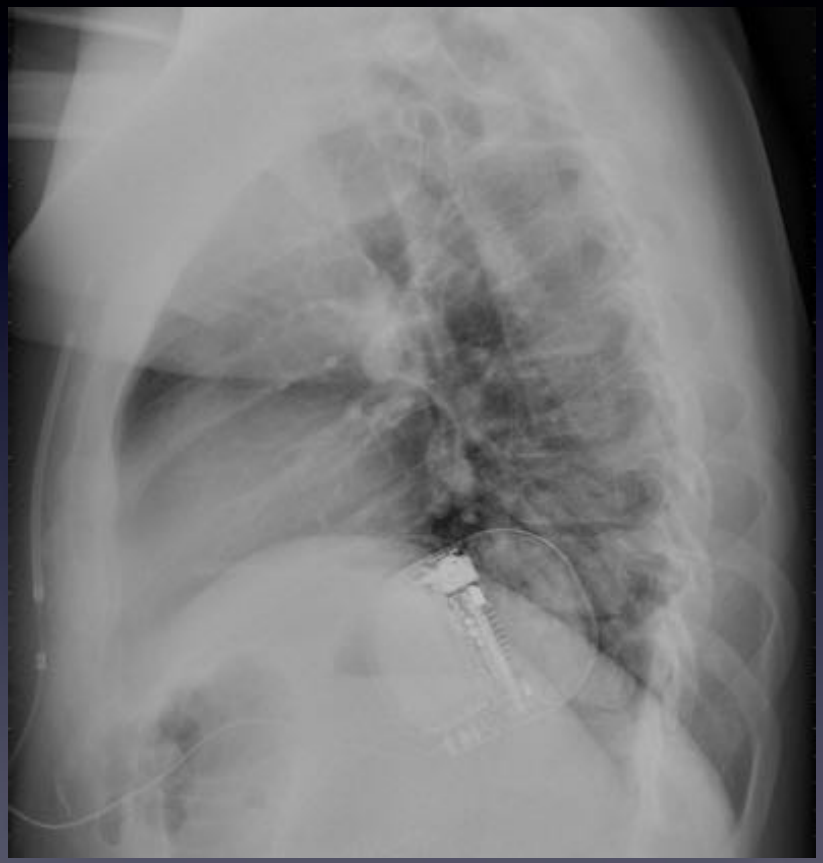


86 kg = 190 lb

118 kg = 260 lb

In case of failed DFT:
Don't take the device out!
Check x-ray and reposition





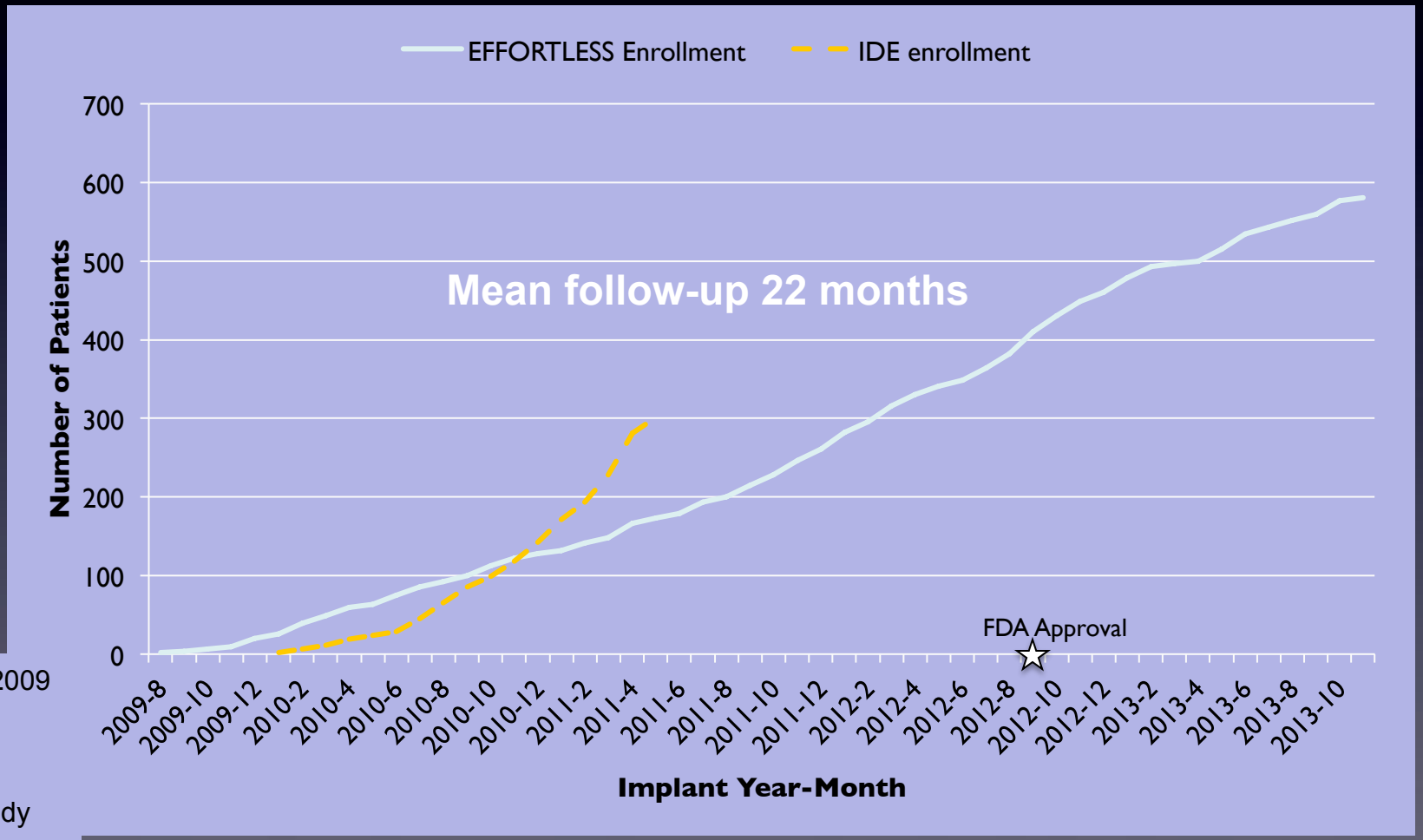
118 kg = 260 lb

AMC (Amsterdam) experience with the S-ICD

- 2009: First In Man (FIM) Trial (NEJM 2010)
- 2009 → Participated in Effortless registry (EHJ 2014)
  2nd largest contributor (n=95)
- 2011: Initiated first RCT with S-ICD
  (PRAETORIAN, EU + US, n=461, goal: 850)
- To date: > 200 implants
  (largest single centre experience)

Combining these two studies provides a unique opportunity to evaluate safety and efficacy over a longer follow-up period and larger group of patients

Enrollment Timeline



2008-2009

↓

FIM-Study
NEJM
N=55

Clinical Science:

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator

2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry

Martin C. Burke, DO,* Michael R. Gold, MD, PhD,† Bradley P. Knight, MD,‡ Craig S. Barr, MD,§ Dominic A.M.J. Theuns, PhD,|| Lucas V.A. Boersma, MD, PhD,¶ Reinoud E. Knops, MD,# Raul Weiss, MD,** Angel R. Leon, MD,†† John M. Herre, MD,‡‡ Michael Husby, MS, MPH,§§ Kenneth M. Stein, MD,§§ Pier D. Lambiase, PhD|||

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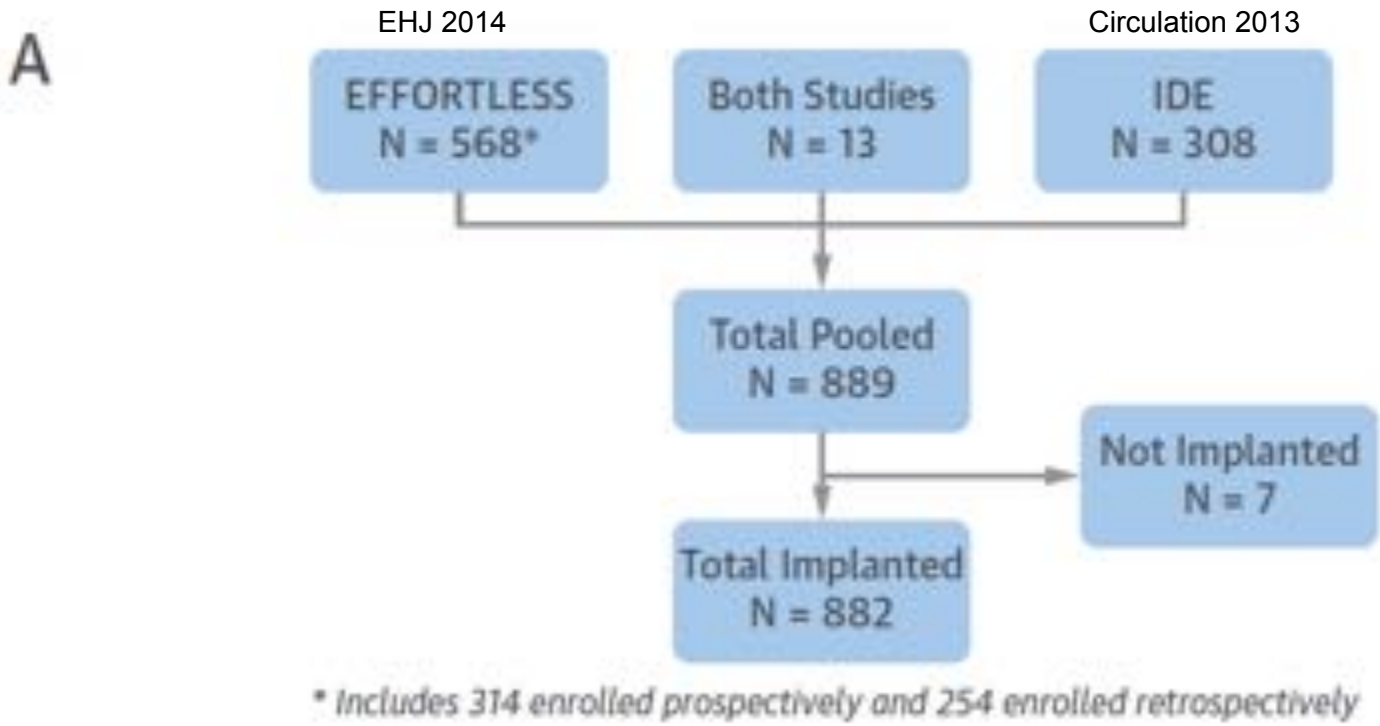
(J Am Coll Cardiol 2015;65:1605–15)

FIGURE 1 Pooled Data Population

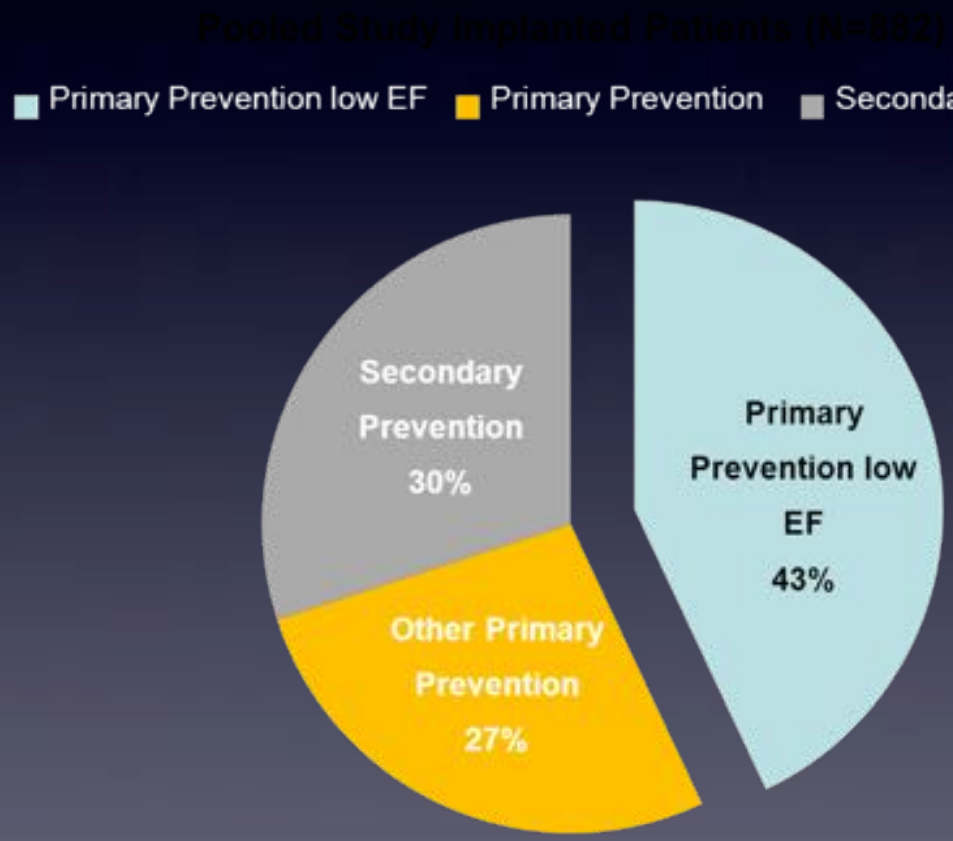


(A) A flowchart depicts the pooled cohort of study patients broken down by each contributing study. The designation **Both Studies** represents patients enrolled into both EFFORTLESS and the IDE studies. Patients **Not Implanted** underwent an implant procedure but due to high defibrillation thresholds did not leave the hospital with the S-ICD. **(B)** The

S-ICD Pooled Results

Demographics

43% of implanted patients primary prevention with EF ≤35



Demographic	N (%)
Age (years)	50.3 ± 16.9
Male (n, %)	636 (72.5)
Ischemic	330 (37.8%)
Genetic	58 (6.7%)
Idiopathic VF	40 (4.6%)
Channelopathies	90 (10.3%)
NYHA Classification II-IV	327 (37.5%)
Atrial Fibrillation	143 (16.4%)
Previous Defibrillator	120 (13.7%)

Efficacy!

S-ICD and TV-ICD Spontaneous Conversion Efficacy

	Spontaneous Shock Efficacy	
	First Shock	Final Shock in episode
S-ICD Pooled Data*	90.1%	98.2%
ALTITUDE First Shock Study[1]	90.3%	99.8%
SCD-HeFT[2]	83%	
PainFree Rx II[2]	87%	
MADIT-CRT[3]	89.8%	
LESS Study[4]		97.3%

* S-ICD Pooled Data excluded VT/VT Storm events

S-ICD Pooled Data
100% Clinical conversion to normal sinus rhythm

Of two "unconverted" episodes
- **One spontaneously terminated after the 5th shock**
- **In the other episode, the device prematurely declared the episode ended. A new episode was immediately reinitiated and the VF was successfully terminated with one shock**

1. Cha YM et al. *Heart Rhythm* 2013;10:702–708.
2. Swerdlow CD et al. *PACE* 2007; 30:675–700
3. Kutyifa V, et al. *J Cardiovasc Electrophysiol* 2013;24:1246-52
4. Gold MR et al. *Circulation* 2002;105:2043-2048.

1. Tips and Tricks for S-ICD implantation

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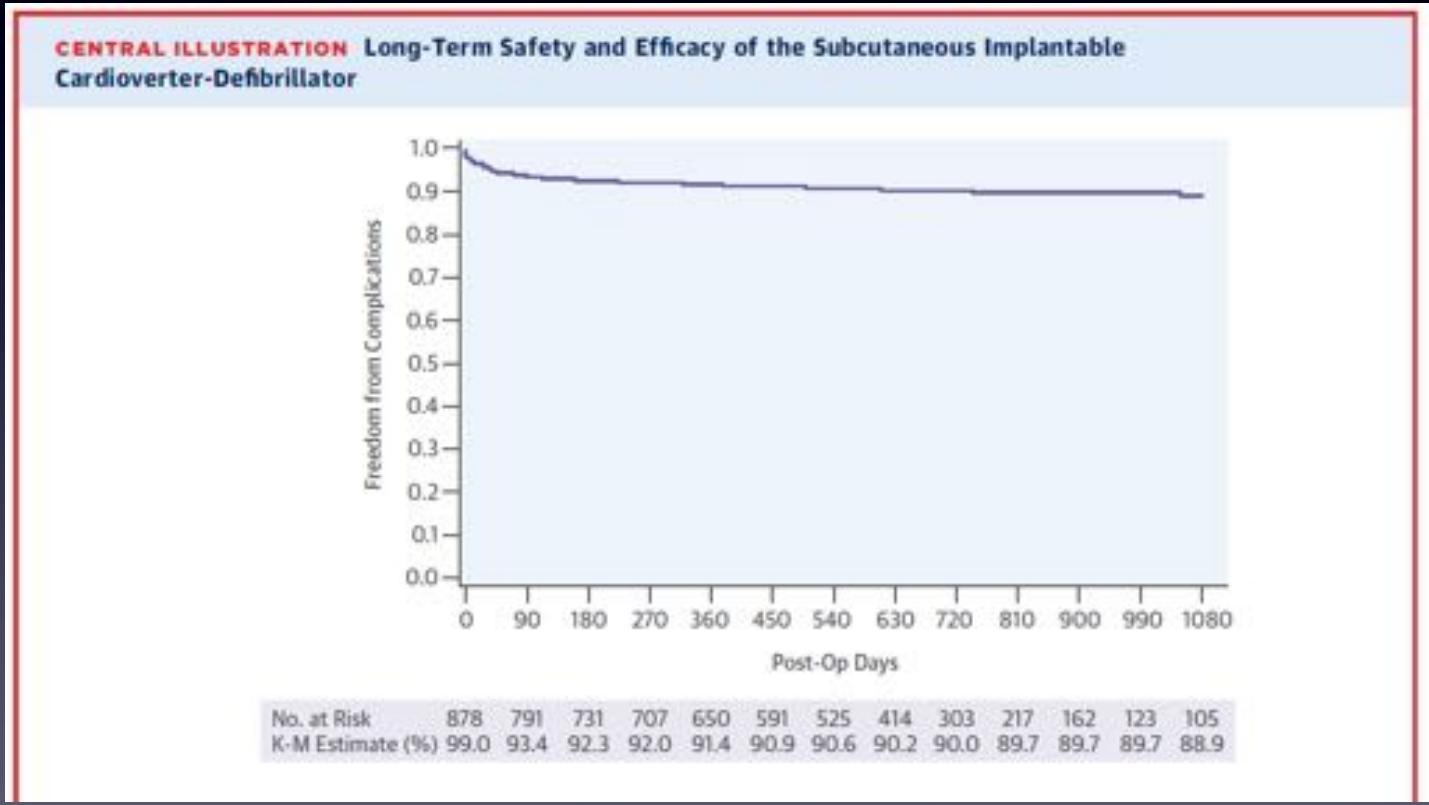
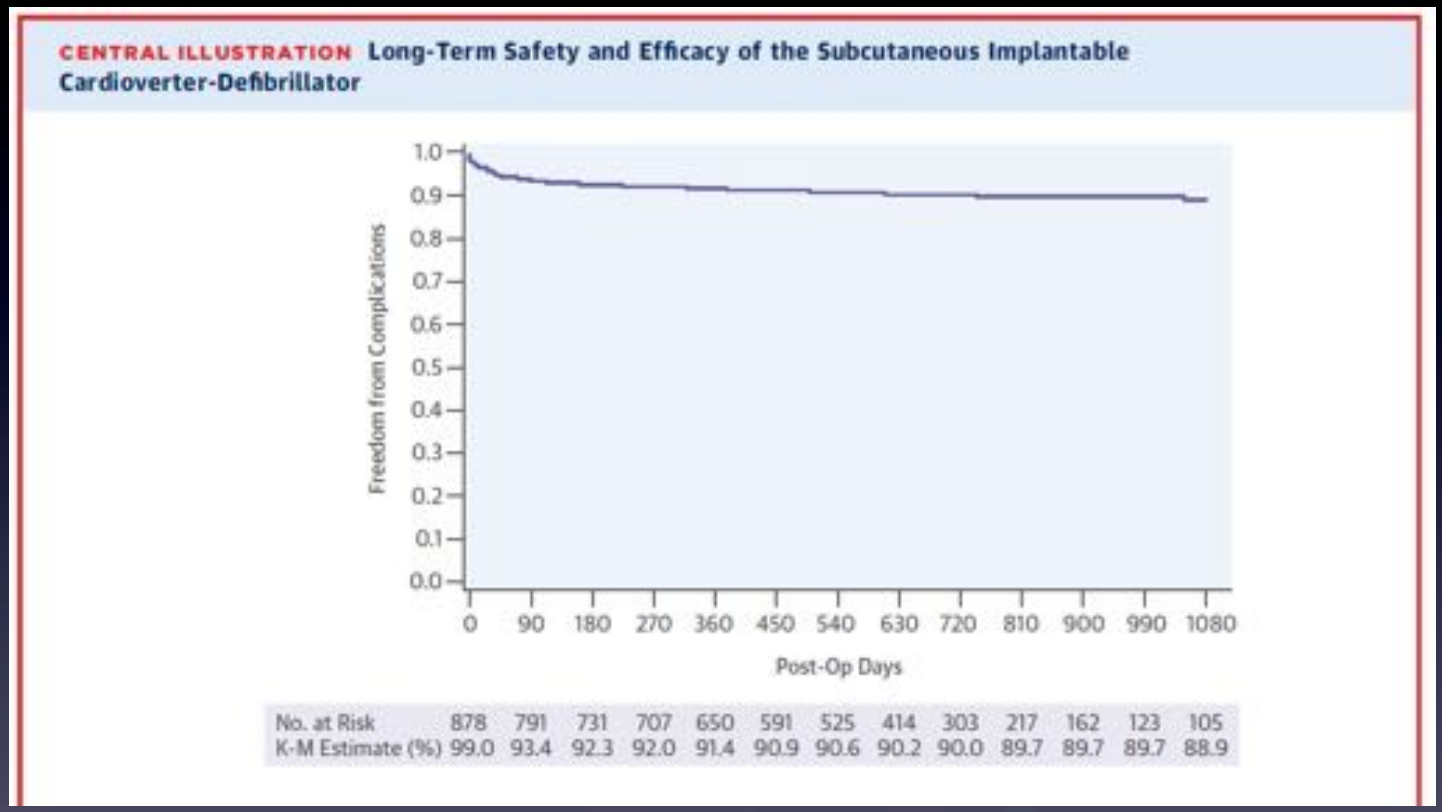
SICD and complications



(Top) This survival curve represents the 3-year complication-free rate for type I to III complications that require invasive action to correct. The majority of complications occurred in the first 30 days from implantation. **(Bottom)** This survival curve represents a comparison of the

S-ICD 3 yrs complication-free rate



(Top) This survival curve represents the 3-year complication-free rate for type I to III complications that require invasive action to correct. The majority of complications occurred in the first 30 days from implantation. **(Bottom)** This survival curve represents a comparison of the

11.3% at 3 yrs: haematoma, ICD repositioning, infection

No systemic infections !

Complications related to implant technique:

TABLE 3 All Type I to III Complications

Description	Complications	
	Events	Patients
Infection requiring device removal/revision	17	14 (1.7)
Erosion	12	11 (1.2)
Discomfort	8	8 (0.9)
Inappropriate shock: oversensing	8	8 (0.9)
Suboptimal electrode position	7	7 (0.8)
Electrode movement	7	5 (0.6)
Inappropriate shock: SVA above discrimination zone (normal device function)	6	6 (0.7)
Premature battery depletion	5	5 (0.6)
Hematoma	4	4 (0.4)
Suboptimal PG and electrode position	4	4 (0.4)
Adverse reaction to medication	3	3 (0.3)
Inability to communicate with the device	3	3 (0.3)
Inadequate/prolonged healing of incision site	3	3 (0.3)
Incision/superficial infection	3	3 (0.3)
Suboptimal PG position	2	2 (0.2)
Other procedural complications	11	8 (0.9)
Other technical complications	5	5 (0.6)
Total	108	85 (9.6)

Values are n (%).

PG = pulse generator; SVA = supraventricular arrhythmia.

1.7+1.2+0.9 = 3.8%

0.8

0.6

0.4

0.2

---- +

2.0%

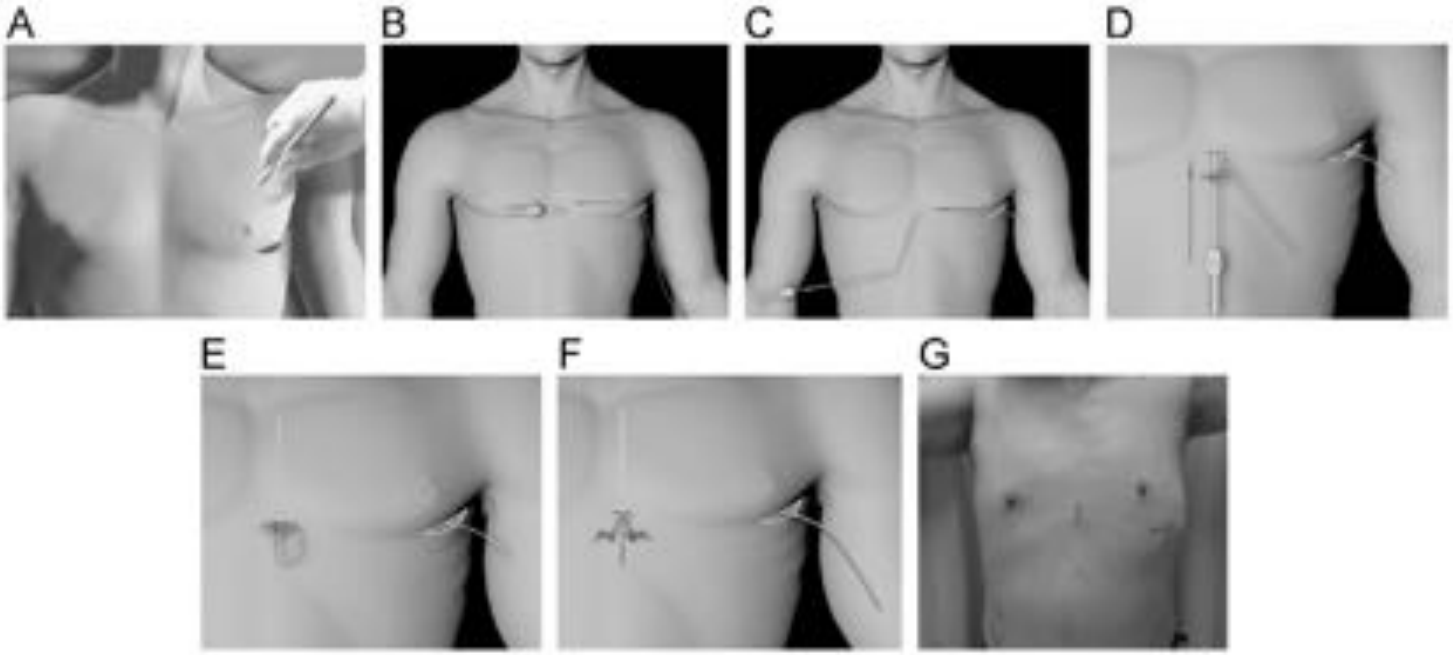


Figure 1 **A:** Creating the device pocket. **B:** Connecting distal end of electrode to the electrode insertion tool (EIT). **C:** Pulling the lead to the inferior parasternal incision. **D:** Tunneling the EIT and peel-away sheath to the superior parasternal position without making a parasternal incision. **E:** After the EIT is removed, the electrode is inserted in the sheath. **F:** Peeling away the sheath, leaving the electrode in the desired subcutaneous position. **G:** Final result after 2 weeks of follow-up.

Follow up Two Incision Technique: (TIT)

- > 150 patients
- All with > 2 months chest x-ray
- All leads successfully implanted
- No dislocations!
- First get experienced with the 3 incision technique!!!!

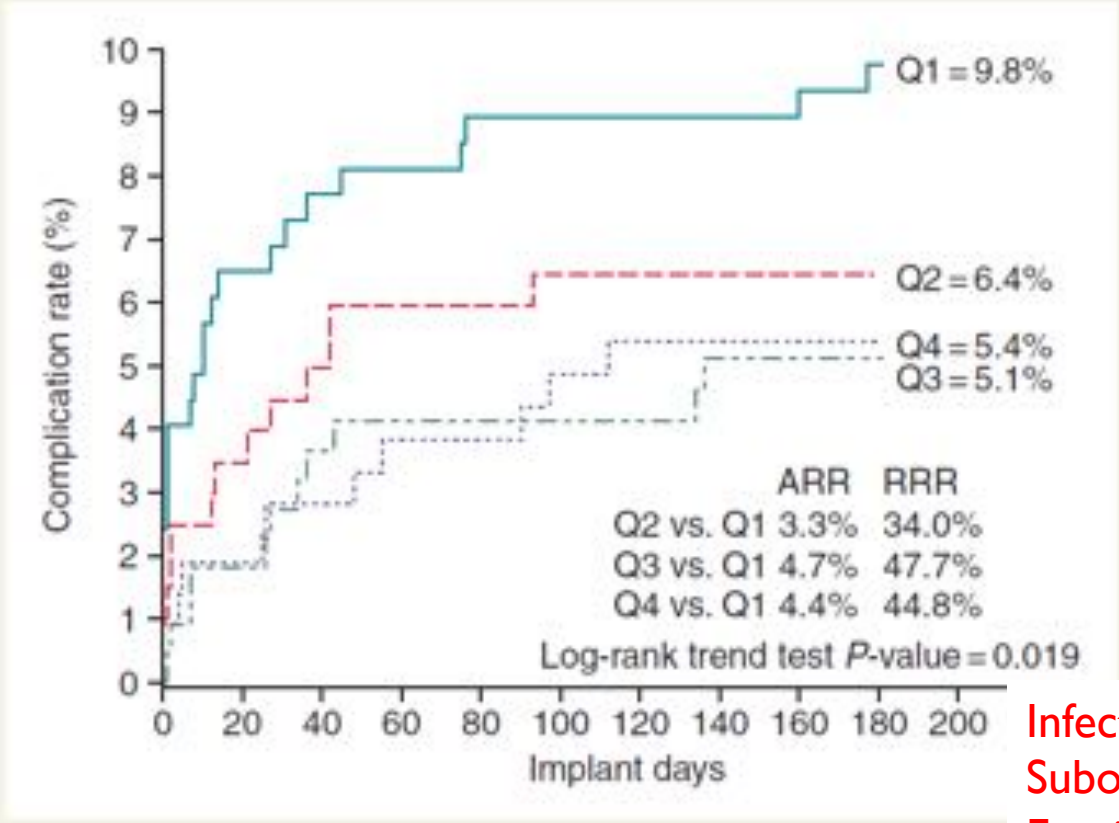


Figure 1 Kaplan–Meier analysis of experience quartiles and complications at 180 days. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28); ARR, absolute risk reduction; RRR, relative risk reduction. *P* value is Kaplan–Meier trend test.

Q1: 1-4 implants

Q2: 5-12 implants

Q3: >13 implants

Q3: 13-28 implants
Q4: >28 implants

Infection/erosion: 2.9%
Suboptimal position: 2.0%
Erosion/hematoma: 1.3%

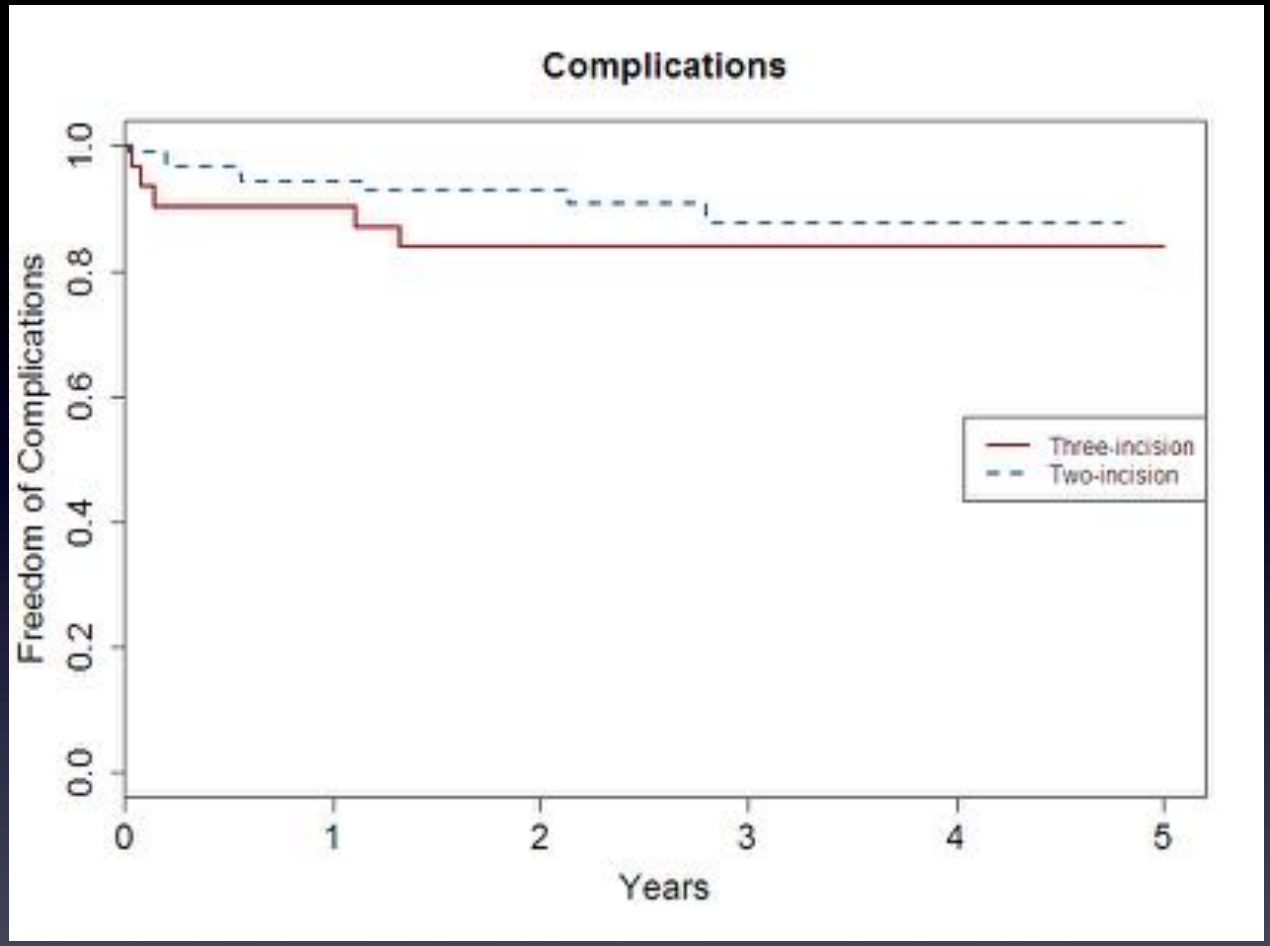


Figure 1: Kaplan-Meier of complication free survival for the three-incision group and two-incision group, Log-rank test P=0.40.