# Actualización de los Dispositivos de Oclusión de la Orejuela

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# Fibrilación Auricular y Embolia Cerebral

- En FA no valvular >90% de las embolias provienen de la orejuela

*Table 1. Review of Published Reports Detailing the Frequency and Site of Thrombus Location in Patients With Nonrheumatic Atrial Fibrillation*

| Setting | No. of Patients | Thrombus Location: LA Appendage | Thrombus Location: LA Cavity | Reference No. |
|---|---|---|---|---|
| TEE[a] | 317 | 66 | 1 | 40 |
| TEE | 233 | 34 | 1 | 25 |
| Autopsy | 506 | 35 | 12 | 39 |
| TEE | 52 | 2 | 2 | 28 |
| TEE | 48 | 12 | 1 | 41 |
| TEE and Operation | 171 | 8 | 3 | 24 |
| SPAF III TEE Study | 359 | 19 | 1 | 42 |
| TEE | 272 | 19 | 0 | 26 |
| TEE | 60 | 6 | 0 | 43 |
| Total | 1,288 | 201 | 21 | |

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Blackshear *Ann Thorac Surg* 61 (1996), pp. 755–759.

# Oclusion Percutánea de la Orejuela

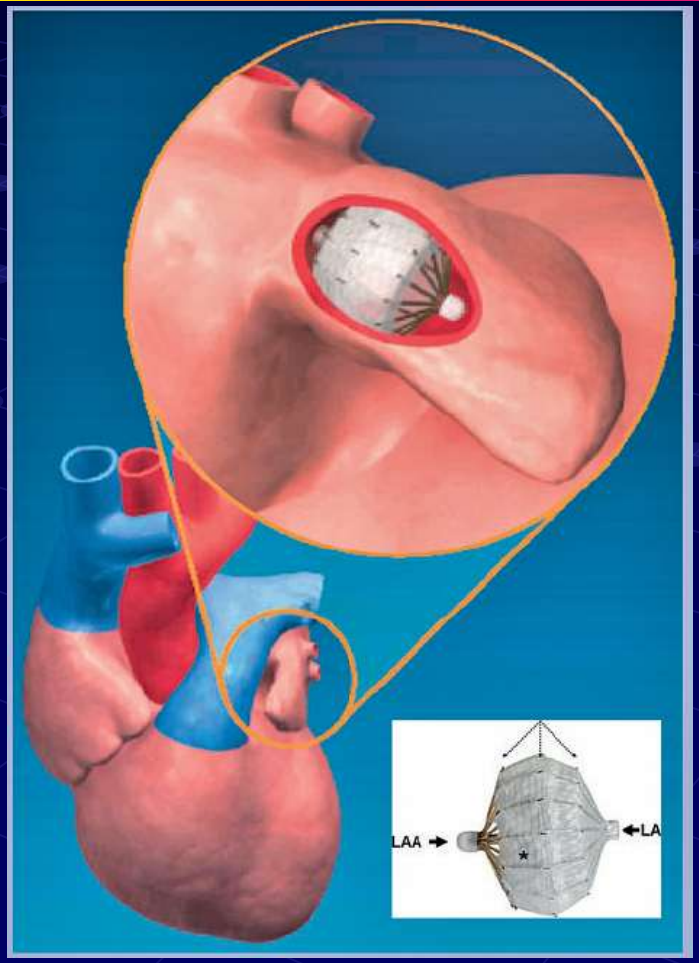
- Abordaje trans-septal
  - PLAATO
  - Watchman (Boston Scientific)
  - Cardiac Plug (AGA, St Jude Medical)
  - Transcatheter patch (Custom Medical Devices)
- Abordaje epicárdico
- Abordaje híbrido



Friedman PA and Holmes DR *J Cardiovasc Electrophysiol* In press

# PLAATO

- Implantado on éxito en 108/111
- Mortalidad 1/108
- Tamponamiento en 3
- 2 embolias cerebrales

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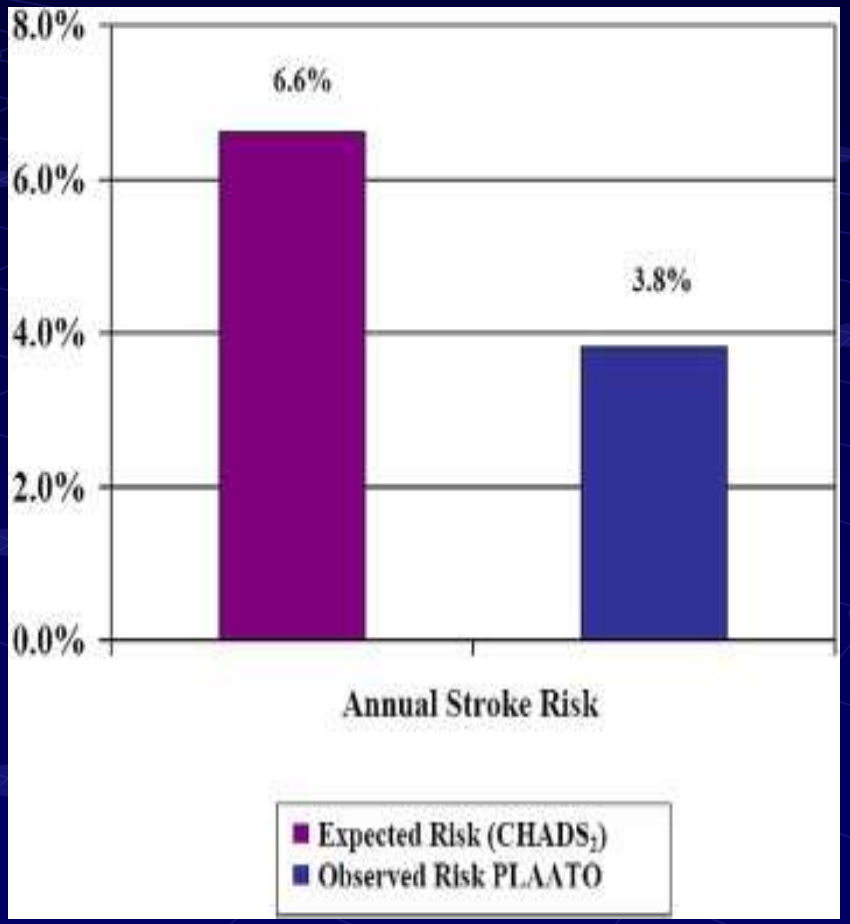
Ostermayer *J Am Card Coll Cardiol* 46 (2005), pp. 9–14

# PLAATO seguimiento a 5 años

- 64 pacientes
- 100% éxito de implante
- 1 tamponamiento
- Diseño abandonado

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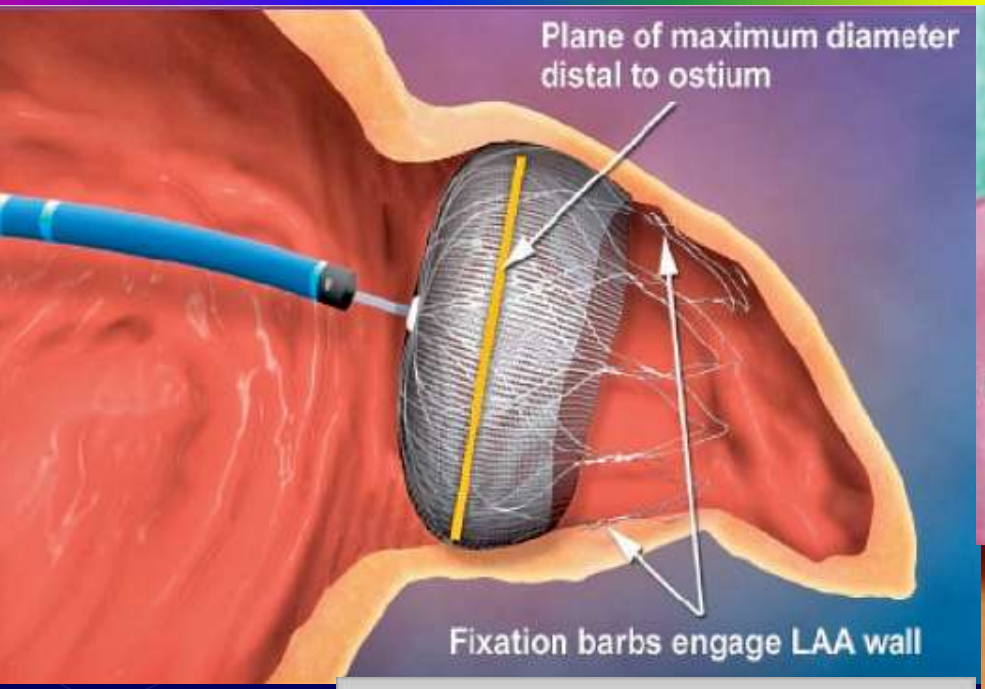
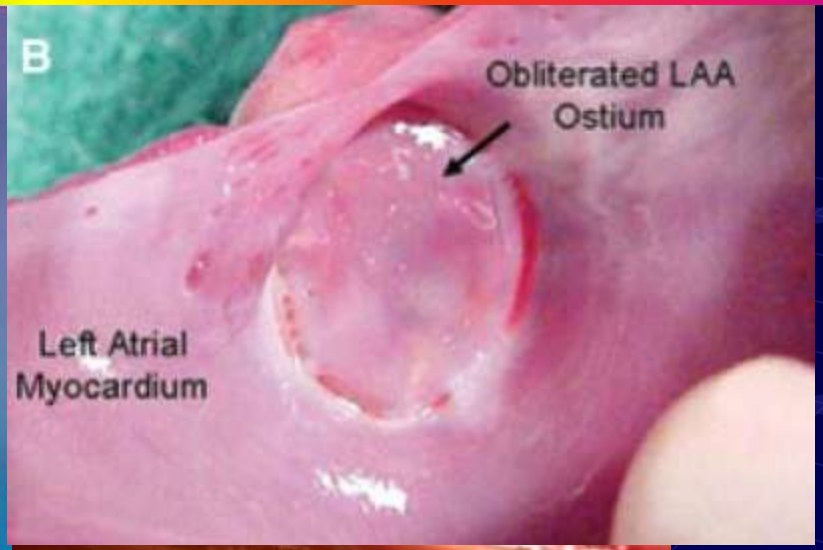
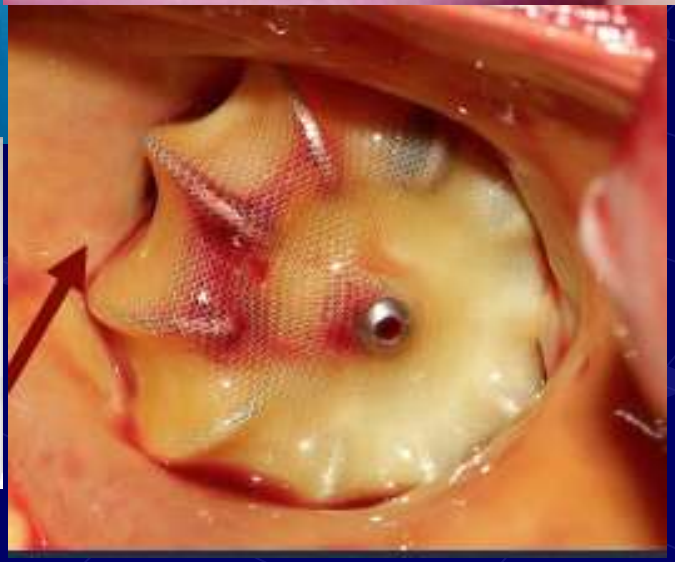
Block P et a; *JACC* Interventions 2 (2009), pp. 594-600

# Dispositivo Watchman



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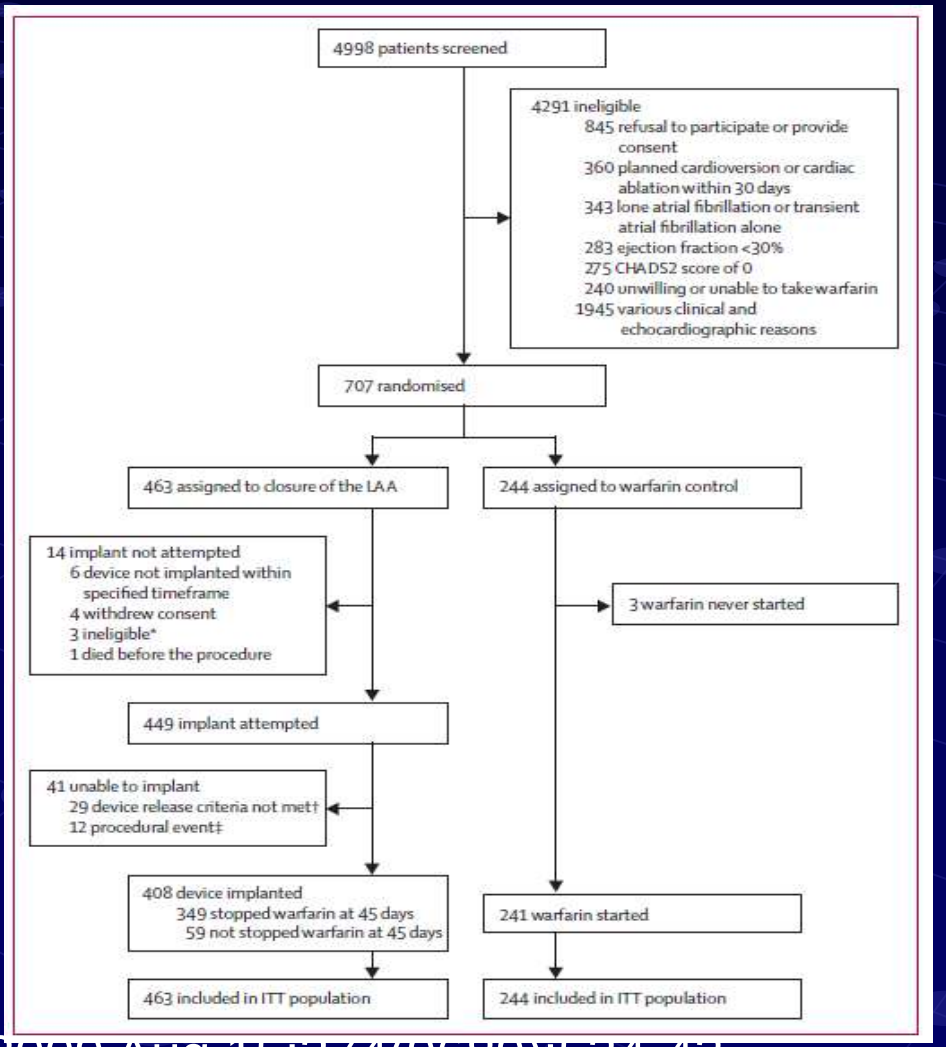
# Dispositivo Watchman: **Protect AF**

- Diseño de no-inferioridad
- FA No-valvular
- CHADS2 de 1 or más
- Efficacy endpoints
  - Ischemic stroke
  - CV/unexplained death
  - Embolism
- Safety endpoint
  - Bleeding
  - Procedure complications

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Holmes et al *Lancet*. 2009 Aug 15;374(9689):534-42

# Protect AF

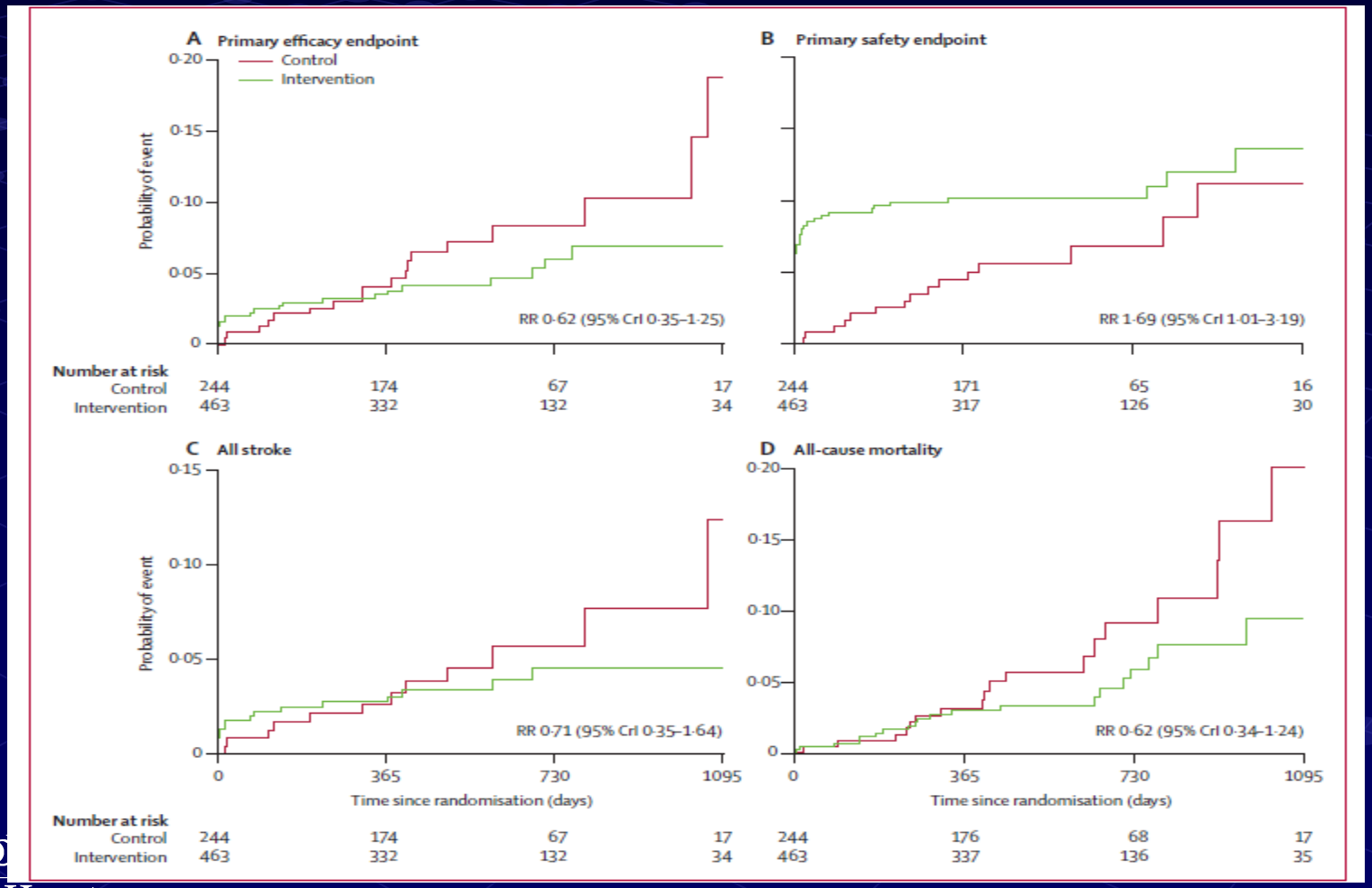
| | Intervention group | | Control group | | Rate ratio (intervention/control [95% CrI]) | Posterior probabilities | |
|---|---|---|---|---|---|---|---|
| | Events/patient-years | Observed rate (events per 100 patient-years [95% CrI]) | Events/patient-years | Observed rate (events per 100 patient-years [95% CrI]) | | Non-inferiority | Superiority |
| **ITT population*** | | | | | | | |
| Primary efficacy† | 21/694·1 | 3·0 (1·9–4·5) | 18/370·8 | 4·9 (2·8–7·1) | 0·62 (0·35–1·25) | >99·9% | 90·0% |
| Ischaemic stroke | 15/694·6 | 2·2 (1·2–3·5) | 6/372·3 | 1·6 (0·6–3·0) | 1·34 (0·60–4·29) | 71·8% | 20·1% |
| Cardiovascular/unexplained death | 5/708·4 | 0·7 (0·2–1·5) | 10/374·9 | 2·7 (1·2–4·4) | 0·26 (0·08–0·77) | >99·9% | 99·3% |
| Haemorrhagic stroke | 1/708·4 | 0·1 (0·0–0·5) | 6/373·4 | 1·6 (0·6–3·1) | 0·09 (0·00–0·45) | >99·9% | 99·8% |
| Systemic embolism | 2/707·8 | 0·3 (0·0–0·8) | 0/374·9 | 0 | .. | .. | .. |
| All stroke | 16/694·6 | 2·3 (1·3–3·6) | 12/370·8 | 3·2 (1·6–5·2) | 0·71 (0·35–1·64) | 99·3% | 76·9% |
| All-cause mortality | 21/708·4 | 3·0 (1·9–4·5) | 18/374·9 | 4·8 (2·8–7·1) | 0·62 (0·34–1·24) | >99·9% | 90·7% |
| Primary safety‡ | 49/658·8 | 7·4 (5·5–9·7) | 16/364·2 | 4·4 (2·5–6·7) | 1·69 (1·01–3·19) | .. | .. |
| **Successfully treated population§** | | | | | | | |
| Primary efficacy | 11/593·6 | 1·9 (1·0–3·2) | 17/370·2 | 4·6 (2·6–6·8) | 0·40 (0·19–0·91) | >99·9% | 98·6% |
| Primary safety | 9/592·1 | 1·5 (0·7–2·8) | 16/363·6 | 4·4 (2·5–6·7) | 0·35 (0·15–0·80) | .. | .. |

CrI=credible interval. ITT=intention-to-treat. ..=not applicable. Different events have different numbers of patient-years because patients without an event or lost to follow-up were censored at the time of the last known event status. Posterior probabilities of non-inferiority are based on a two-fold non-inferiority margin. Posterior probabilities and CrIs are based on a Bayesian model stratified by CHADS2 score. *The ITT population consists of all randomised patients (intervention, n=463; control=244). †The primary composite endpoint for efficacy was the occurrence of stroke (including ischaemic or haemorrhagic stroke), cardiovascular or unexplained death, or systemic embolism. ‡The primary composite endpoint for safety consisted of events related to excessive bleeding (eg, intracranial or gastrointestinal bleeding) or procedure-related complications (eg, serious pericardial effusion, device embolisation, procedure-related stroke). §Successful treatment was defined in the intervention group as device implantation followed by discontinuation of warfarin and in the control group as the start of warfarin treatment (intervention, n=389; control=241).



Holmes et al *Lancet.* 2009 Aug 15;374(9689):534-42

# Protect AF

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Holmes et al *Lancet.* 2009 Aug 15;374(9689):534-42

# Protect AF Complicaciones

- Embolias cerebrales: 6 (de 15 totales)
  - 1 antes del procedimiento
  - 5 por embolismo aéreo durante el procedimiento
- Embolias Post-procedimiento:
  - 1.3 per 100 pt-years vs 1.6 in warfarin
- Derrame pericárdico:
  - 4.8%
- Embolización del dispositivo en 3 pacientes

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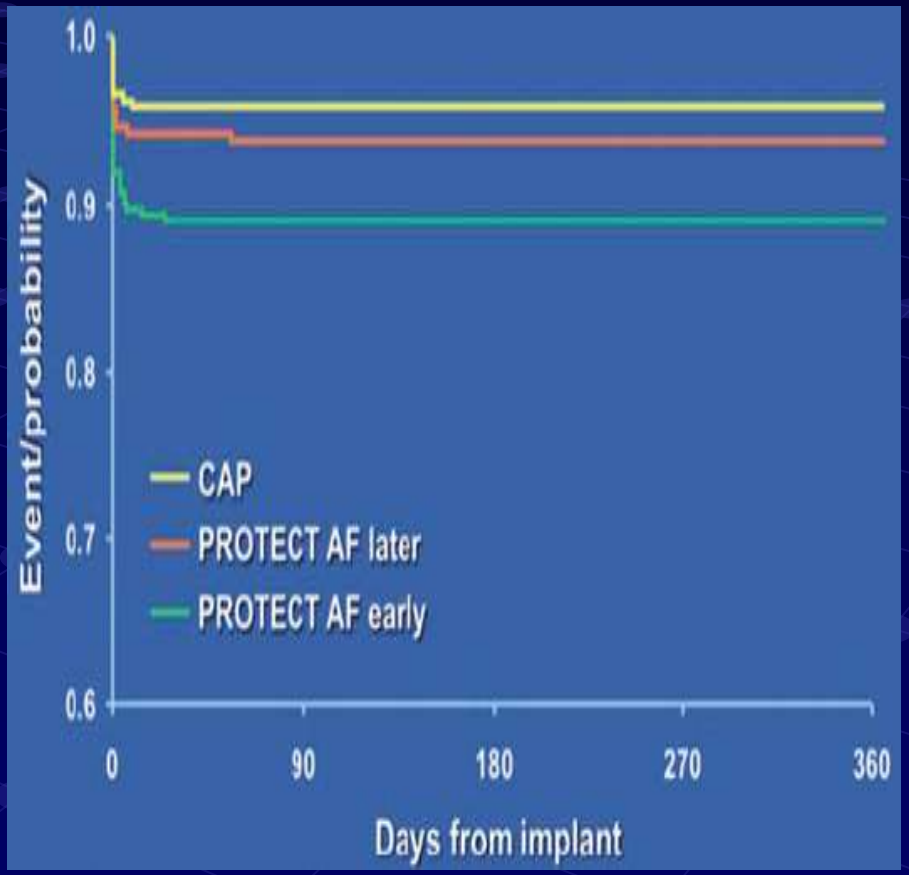
Holmes et al *Lancet.* 2009 Aug 15;374(9689):534-42

# CAP Registry

- 460 pacientes (542 en Protect AF)
- Embolias cerebrales: 0
- Derrame pericárdico: 2.2%, tratado sin cirugía (vs 5%)

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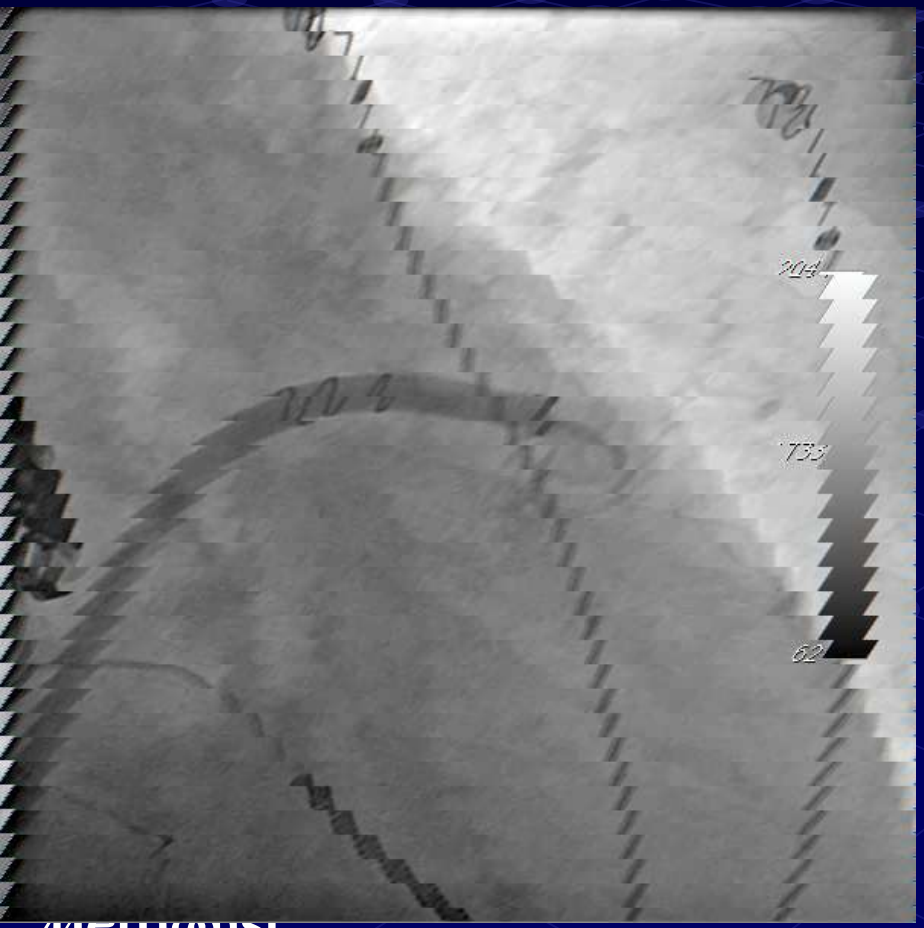
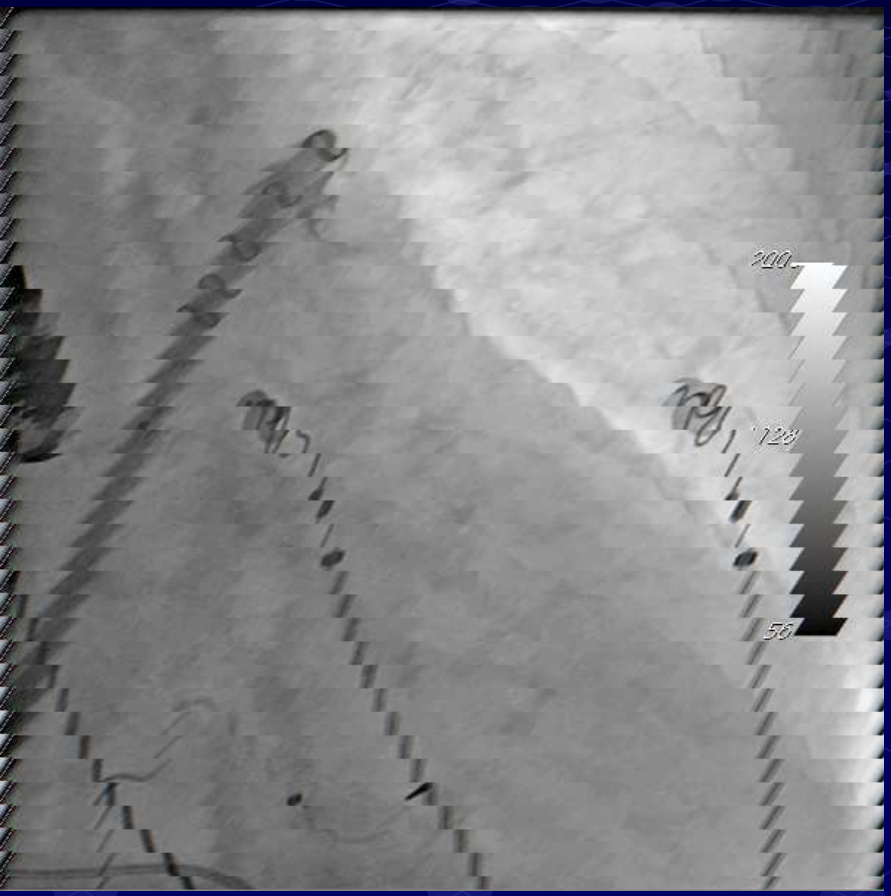
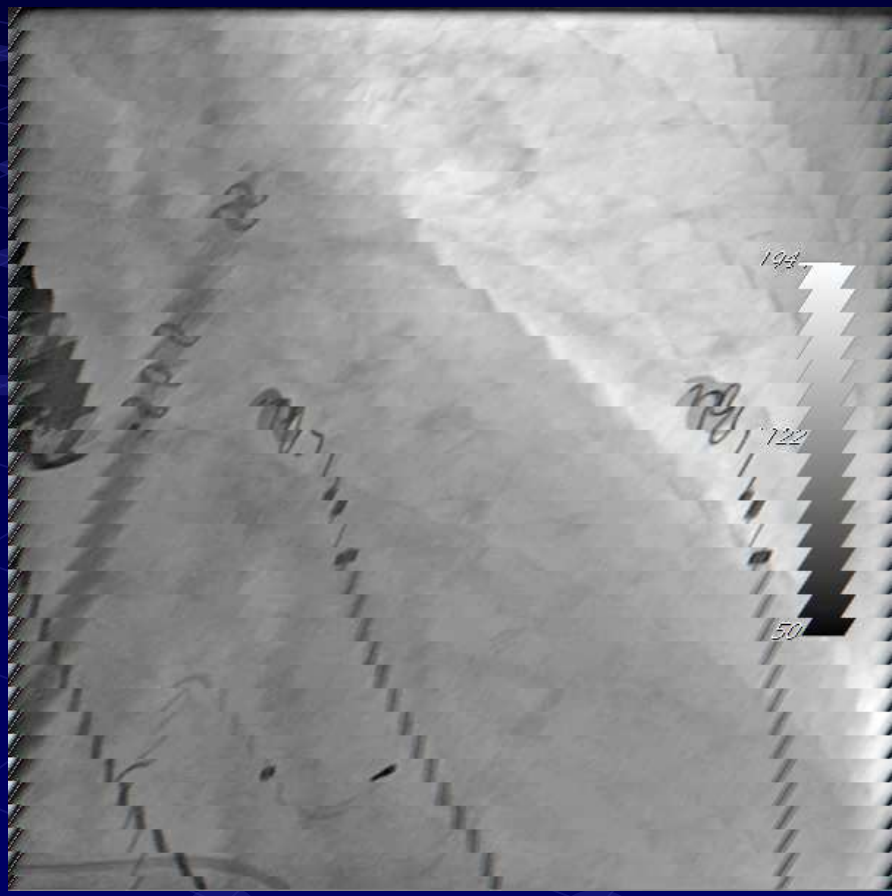
Reddy et al *Circulation.* 2011;123:417-424

# Orejuela Multilobular




# Orejuela Multilobular

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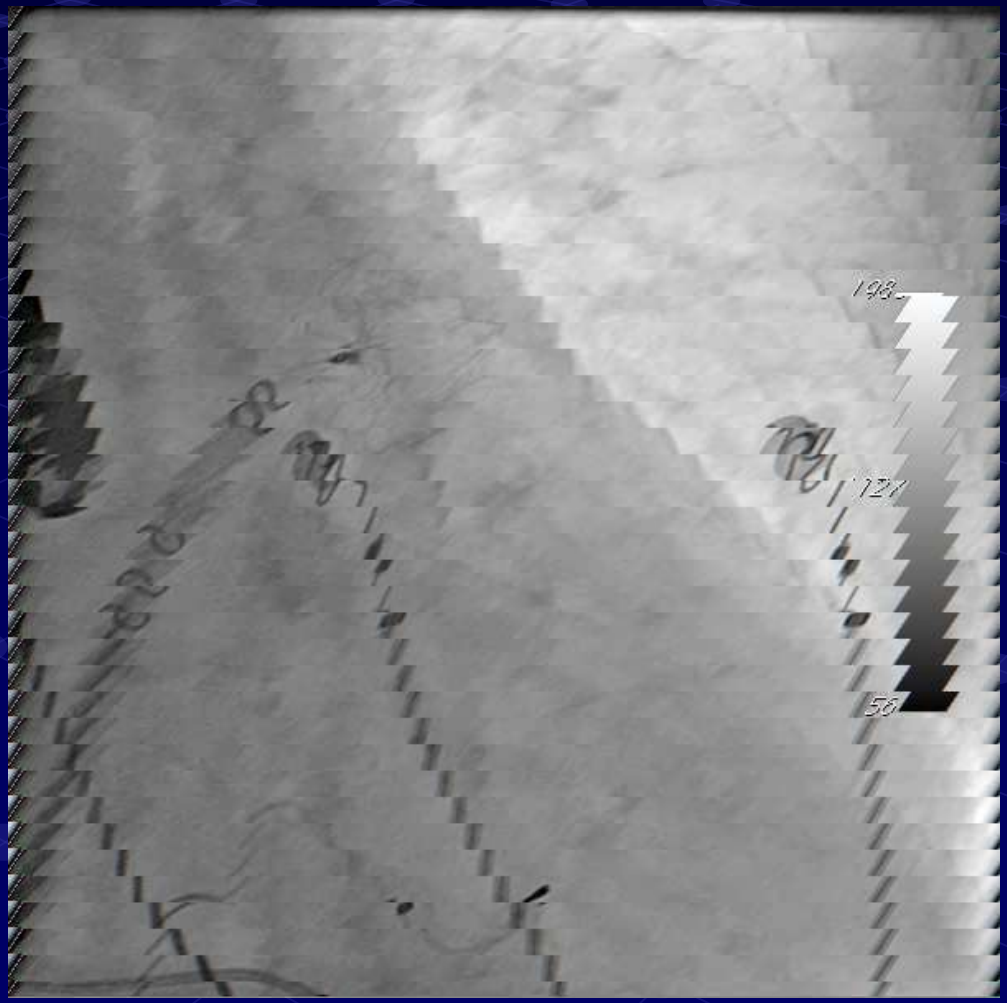
# Orejuela Multilobular

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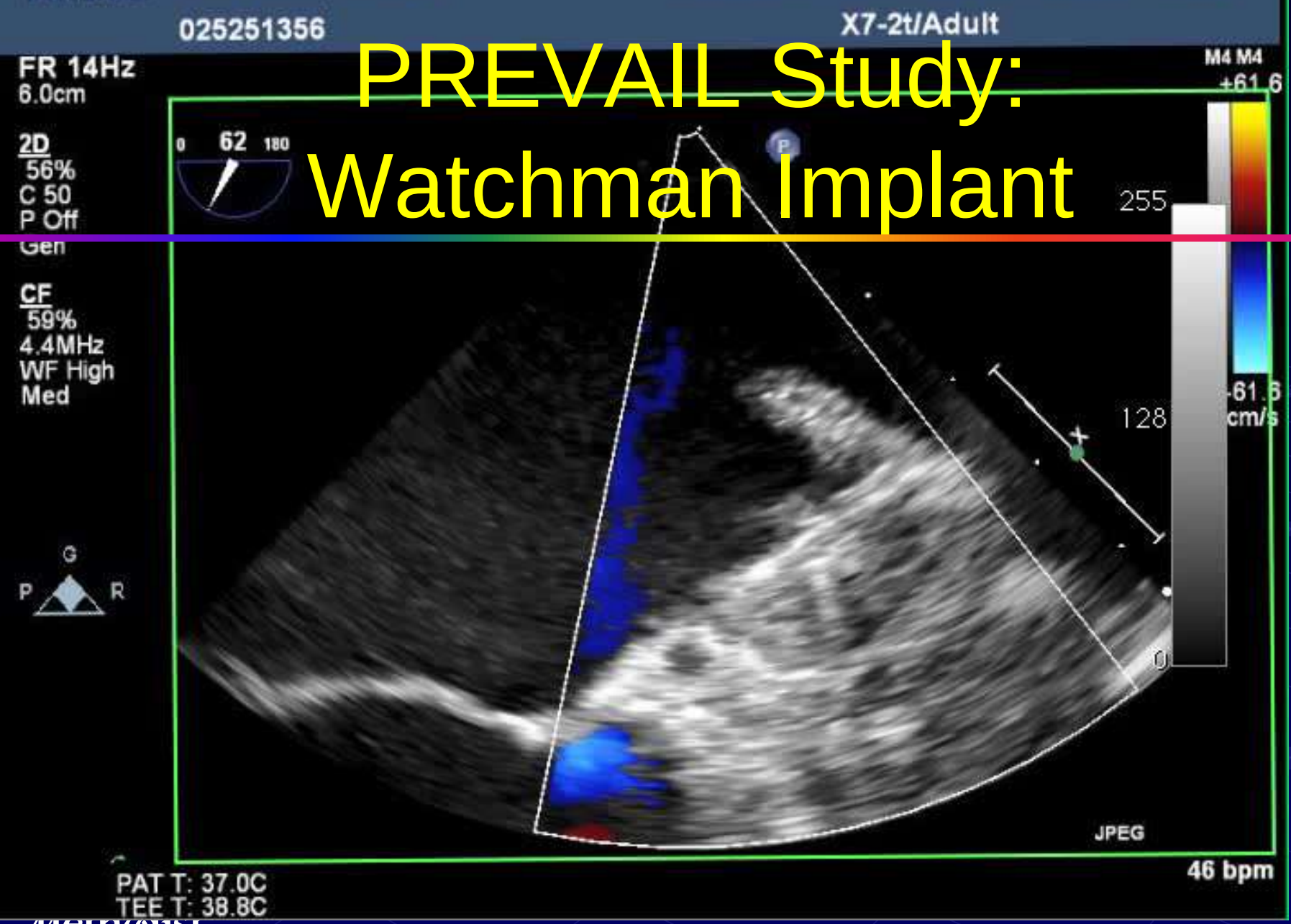
# PREVAIL Study: Watchman Implant

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# PREVAIL Study

- 475 patients
- CHADS2 Score of 2 or more
- 2:1 randomization
- Primary endpoint:
  - Hemorrhagic stroke
  - Ischemic stroke
  - Systemic embolism
  - CV or unexplained death

| PREVAIL Enrollment To Date | |
|---|---|
| Pacific Heart Institute, CA | 18 |
| **Methodist Hospital, Houston, TX** | **13** |
| St. Luke's Hospital, MO | 10 |
| Central Baptist Hospital, KY | 9 |
| Intermountain Medical Center, UT | 8 |
| Arizona Heart Rhythm Research Center | 6 |
| Cedars -Sinai Medical Center, CA | 5 |
| Massachusetts General Hospital | 5 |
| Emory University Hospital | 5 |
| Fletcher Allen, VT | 5 |
| St. John's Mercy Hospital, MO | 3 |
| Baylor Heart & Vascular, TX | 3 |
| Moffitt Heart & Vascular, PA | 3 |
| Mount Sinai School of Medicine, NY | 3 |
| Cardiology Associates of N. Mississippi | 2 |
| FCVMED, La Jolla, CA | 2 |
| Mercy Gilbert Medical Center, AZ | 2 |
| Minneapolis Heart Institute/Abbott NW, MN | 2 |
| Scripps Green, CA | 2 |
| Swedish Medical Center, WA | 2 |
| New York University Hospital, NY | 1 |
| Texas Cardiac Arrhythmia Research, TX | 1 |
| North Shore University, IL | 1 |
| Sanger Heart and Vascular | 1 |
| William Beaumont, MI | 1 |
| Florida Hospital Orlando, FL | 1 |
| **Cleveland Clinic, OH** | **2** |
| Iowa Heart, IA | 1 |
| **TOTAL TO DATE:** | **117** |

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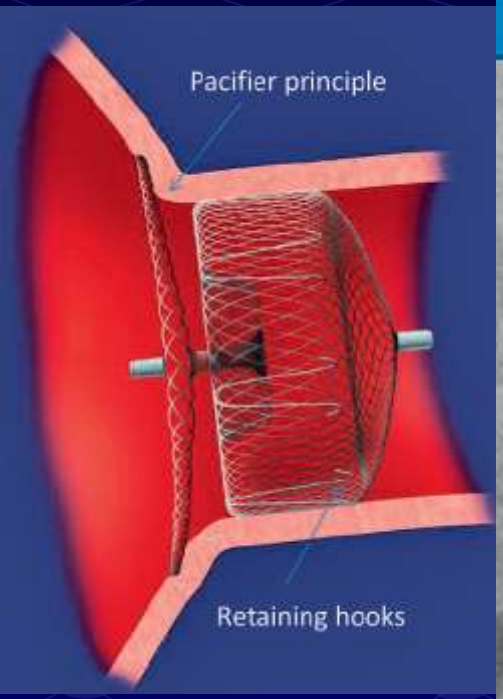
# AGA Cardiac Plug

- Registry data: 96% success in 143 patients.(*Heart* 2011;97:762-765)
- No outcomes data available







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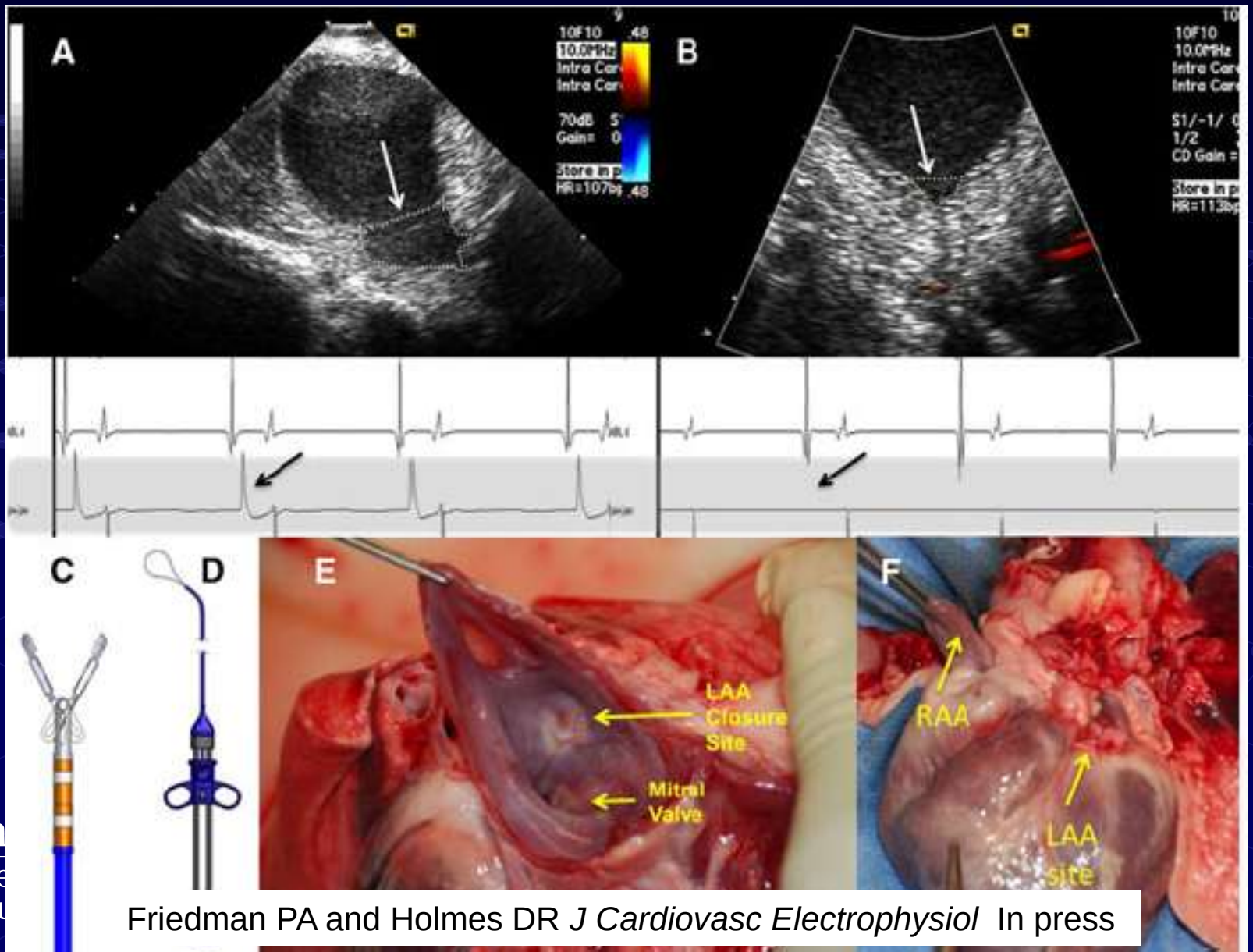
# Transcatheter Patch

## Custom Medical Devices, Inc

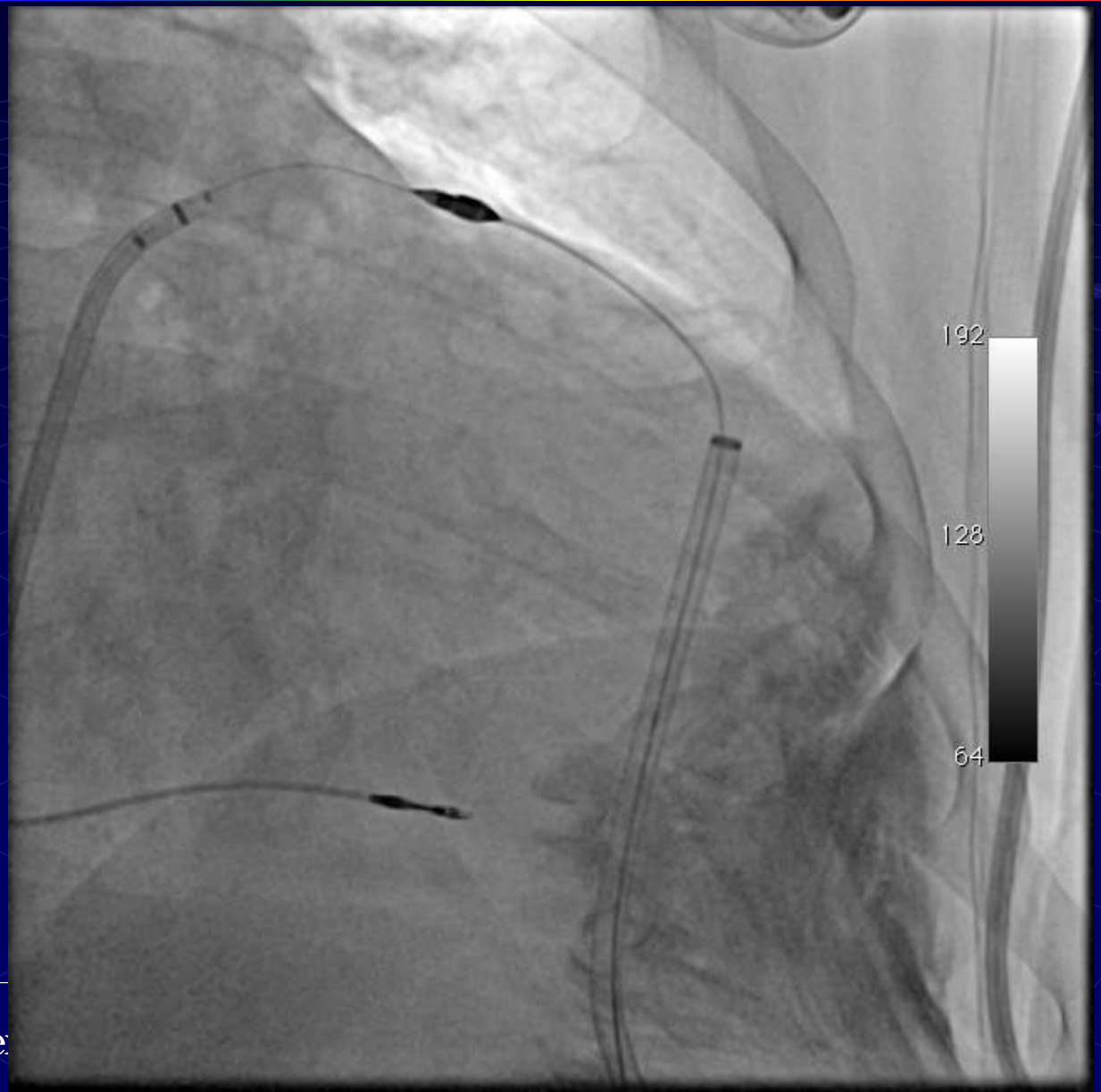

- Parche bio absorbible
- Adherencia al endocardio via fibrina
- Balón para lograr aposición contra el tejido
- ~20 casos en un registro. Sin datos publicados

# Cierre Epicárdico




Friedman PA and Holmes DR *J Cardiovasc Electrophysiol* In press

# Cierre Híbrido: Lariat

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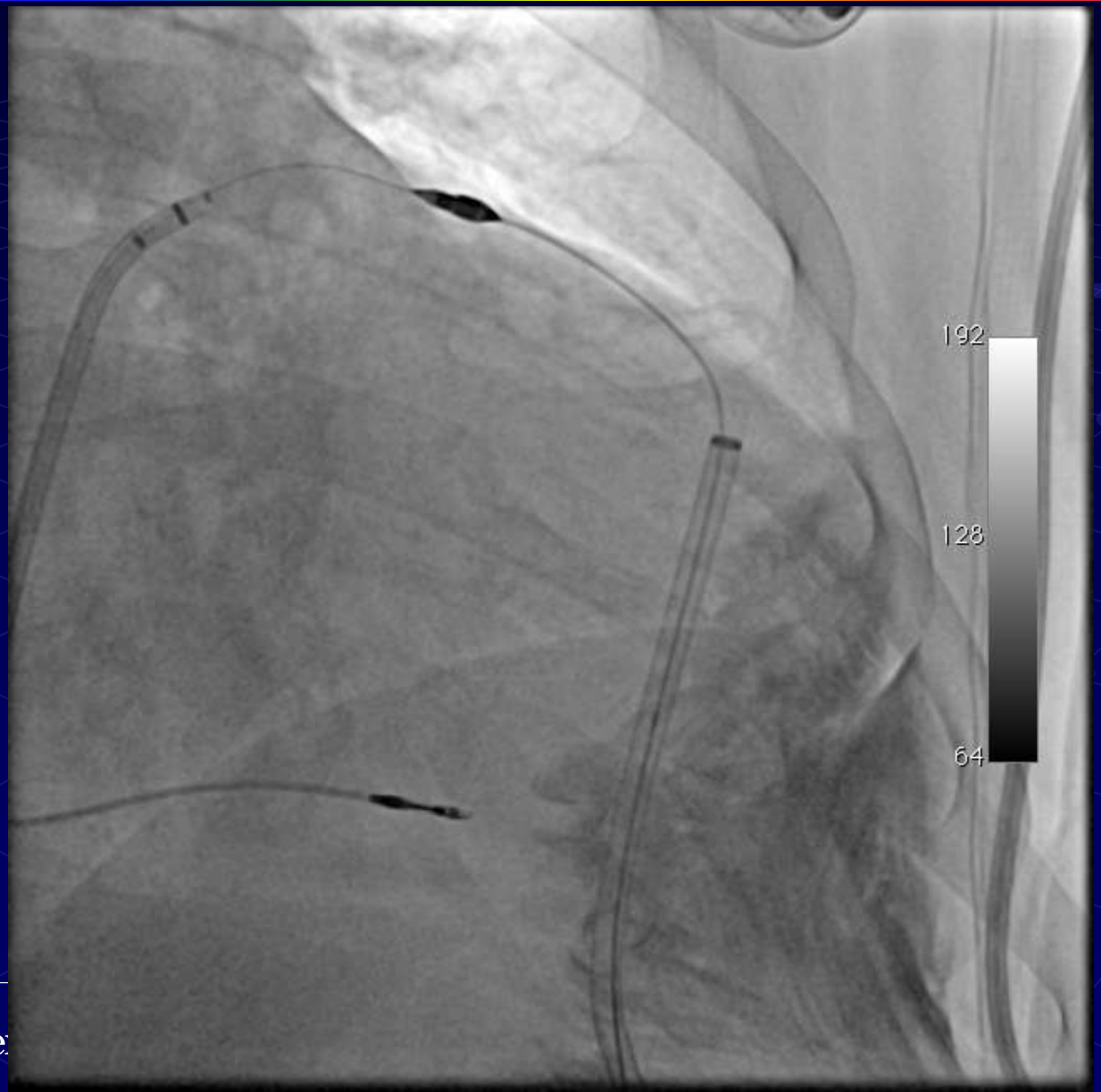


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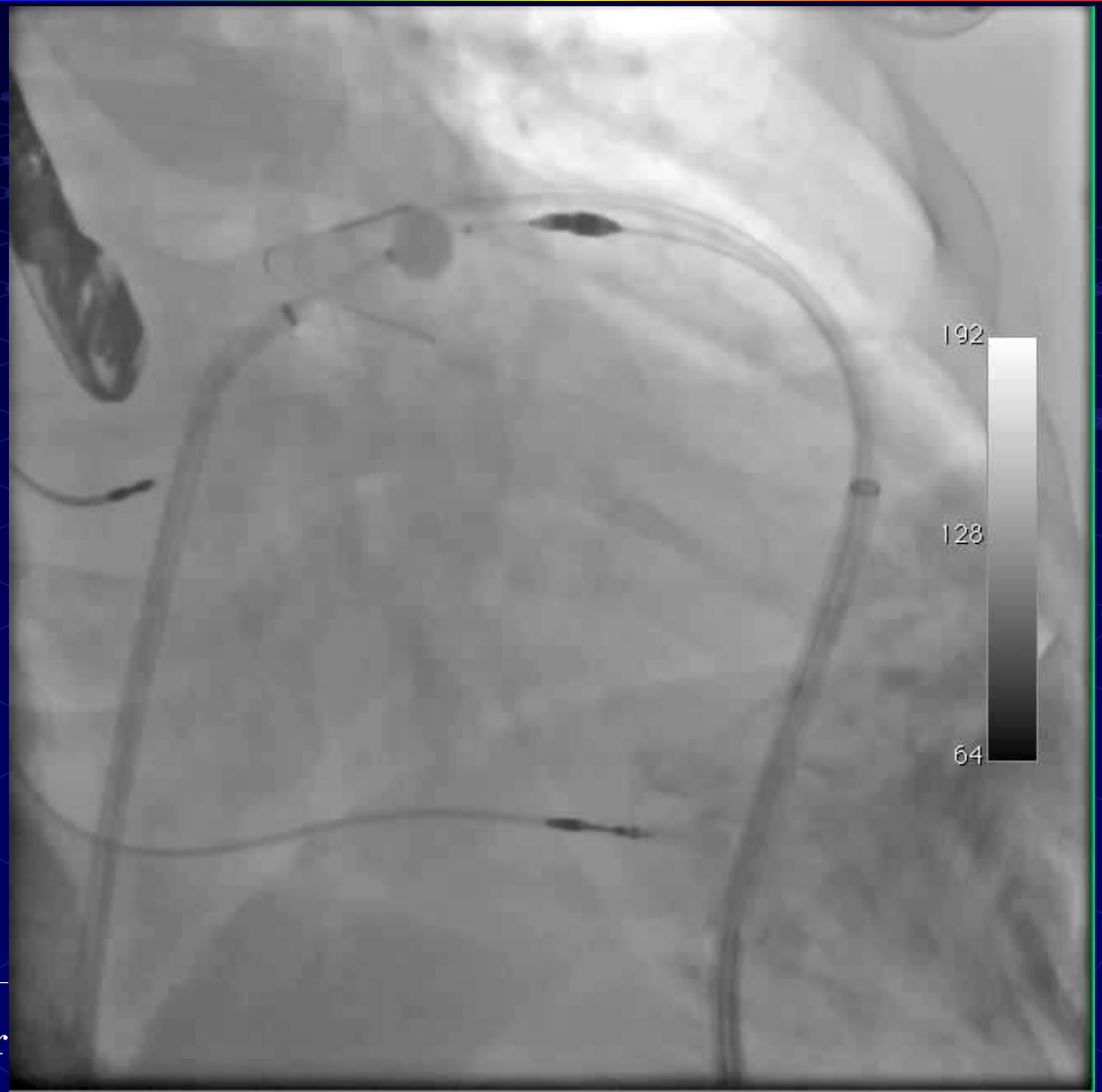


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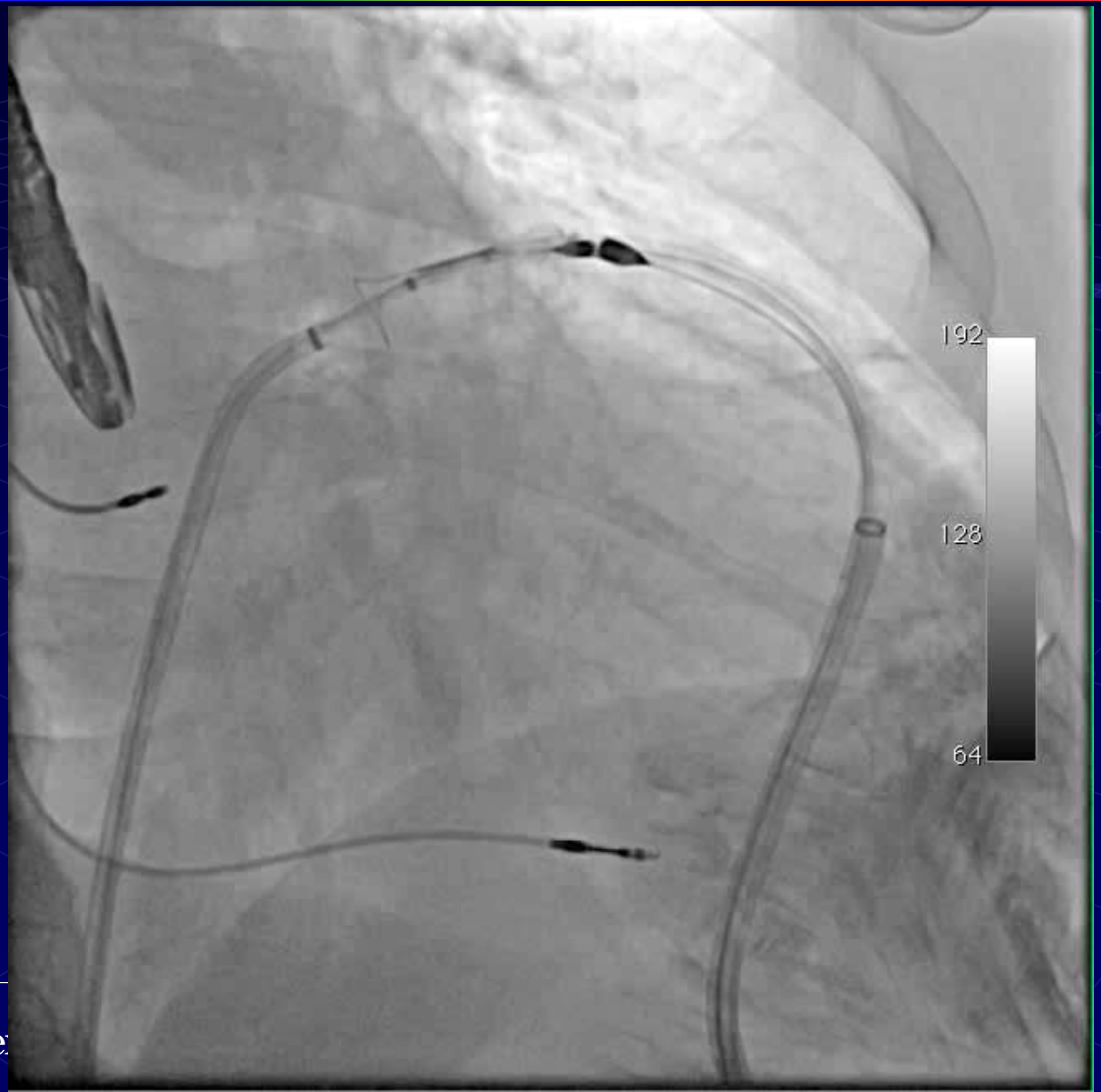


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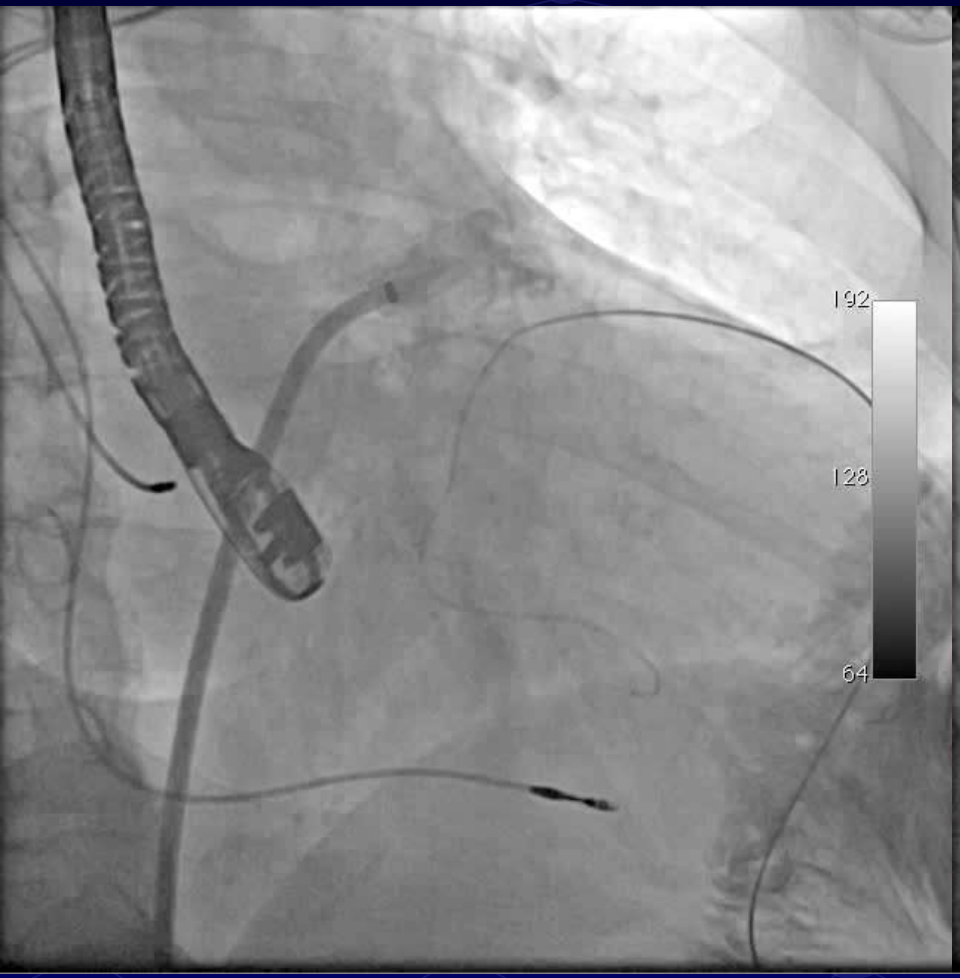
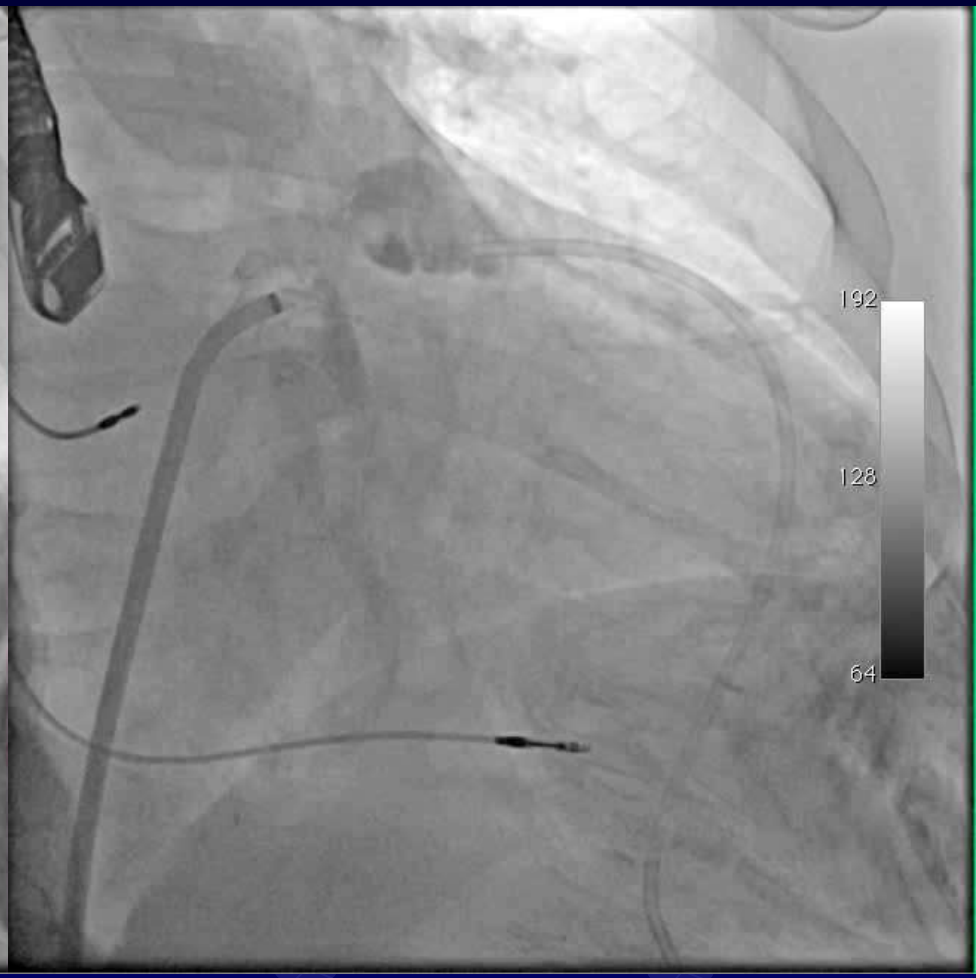
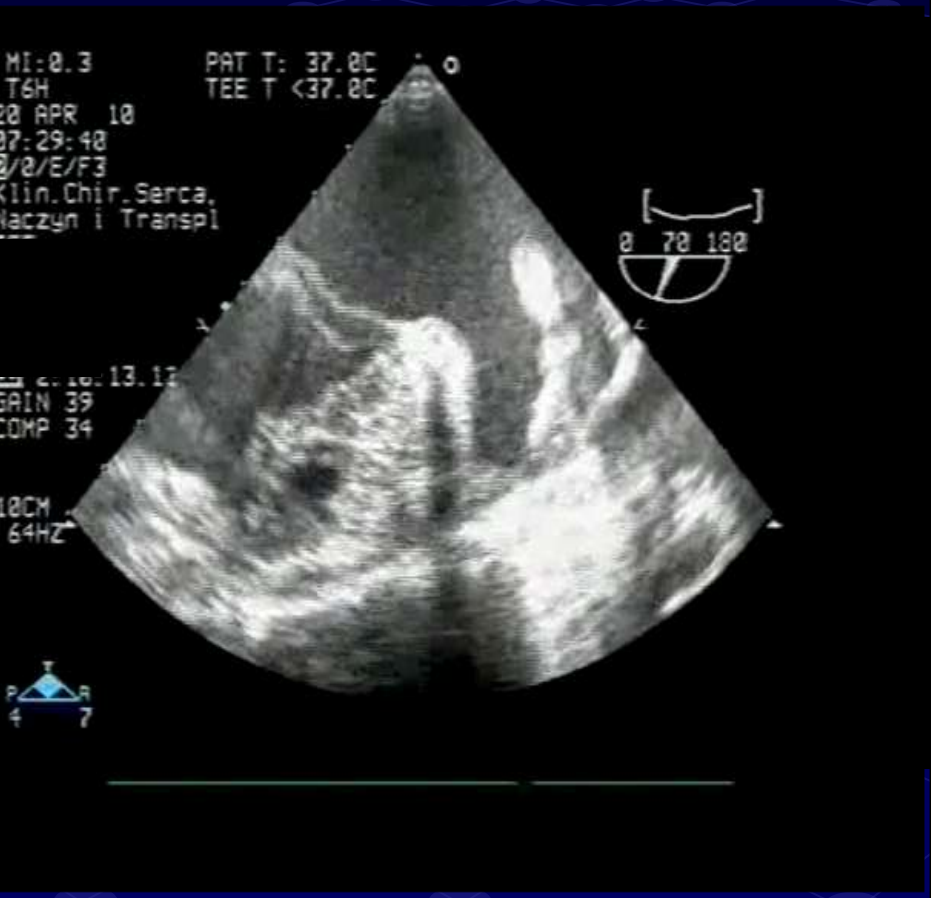


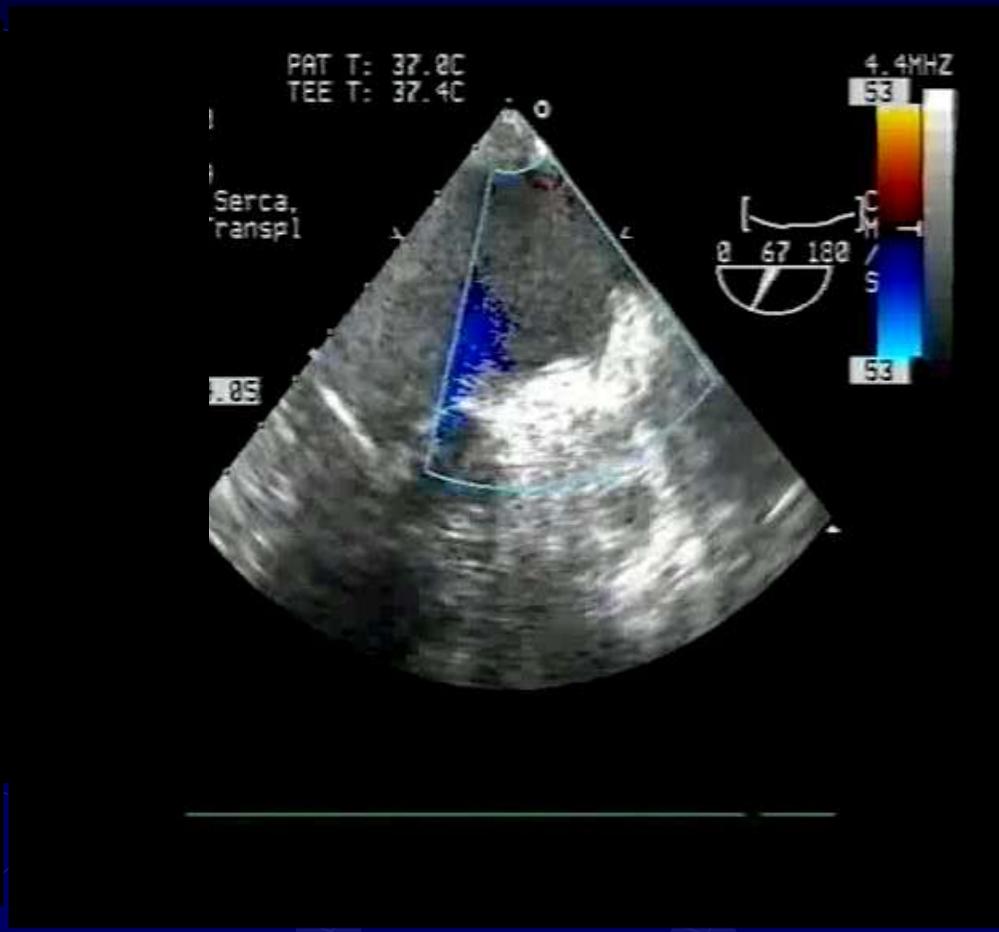



# Cierre Híbrido: Lariat

Antes




Después

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# Resumen

| Device/Method | Advantages | Limitations |
|---|---|---|
| Transseptal device placement | Transseptal technique widely available<br>Available in the setting of previous cardiac surgery<br>Validated as noninferior to warfarin for stroke prevention (Watchman) | Need for procedural and short term anticoagulation and/or antithrombotic regimen until endothelialization occurs<br>Foreign body left in central circulation (small risk of embolization, erosion, dislodgement)<br>Device must be sized to match LAA<br>Previous atrial septal defect closure may preclude transseptal delivery |
| Epicardial | No foreign body left behind<br>No need for procedural anticoagulation because no contact with central circulation and no transseptal puncture (which exposes blood to tissue factor)<br>Adjustable size loop to accommodate variable LAA shape/morphology without need for sizing<br>Pericardial control facilitates management of effusion should one develop | Human experience not yet reported<br>Previous cardiac surgery limits pericardial access and maneuverability<br>Epicardial access techniques less widely available than transseptal puncture |
| Hybrid | No foreign body left behind<br>Pericardial control facilitates management of effusion should one develop | Need for both transseptal and epicardial access with risks of both, and delivery failure if cannot achieve both<br>Superiorly directed LAA, multiple lobes and pectus excavatum may preclude use |

# Conclusiones

- Eficacia demostrable en la oclusión de la orejuela
- Eficacia en la prevención de embolias cerebrales
  - Sólo demostrado en el dispositivo Watchman
- Éxito en la prevención de embolias dependerá de:
  - Características de cada dispositivo y aplicabilidad a cada paciente
    - Cirugía previa / Anatomia de la orejuela
  - Seguridad del procedimiento:
    - Operador-dependiente
    - Competencia en la punción trans-septal y abordaje epicárdico subxifoideo son indispensables

# Preguntas por Responder

- Necesidad de ocluir la orejuela si se hace una ablación efectiva
  - En el mismo procedimiento o en otro subsecuente
- Papel pro-fibrilatorio de la orejuela
- Papel hemodinámico y neuroendocrino de la orejuela
- La formación en estos procedimientos pertenece al curriculum de cardiologia intervencionista o electrofisiología