TCT 2008
Washington, DC, USA, Oct 12-17, 2008

The CARDIOKINETICS Ventricular Implant for LV Aneurysm Partitioning: Early Clinical experiences from the PARACHUTE First-in-Man Trial

Horst Sievert,
Nina Wunderlich, Nico Majunke
CardioVascular Center Frankfurt
Frankfurt, Germany
Washington Hospital Center
Washington, DC

Conflict of Interest Statement

Physician name	Company	Relationship
Horst Sievert	Abbott, Access Closure, AGA, Angiomed, Ardian, Avinger, Boston,Bridgepoint, CardioKinetix, CardioMEMS, Coherex, Cordis, CSI, Edwards, EndoCross, EndoTex, ev3, FlowCardia, Gore, Guidant, Invatec, Lumen Biomedical, Kensey Nash, NDC, NMT, OAS, Occlutech, Osprey, Ovalis, Pathway, pfm, PendraCare Percardia, Remon, Rox Medical, Sadra, Sorin, Spectranetics, SqareOne, St. Jude, Terumo, Topspin, Velocimed, Xtent	Consulting fees, Travel expenses, Study honoraria
	Cardiokinetix, Access Closure, Velocimed, CoAptus, Lumen Biomedical	Stock options, Stocks

Concept of Technology

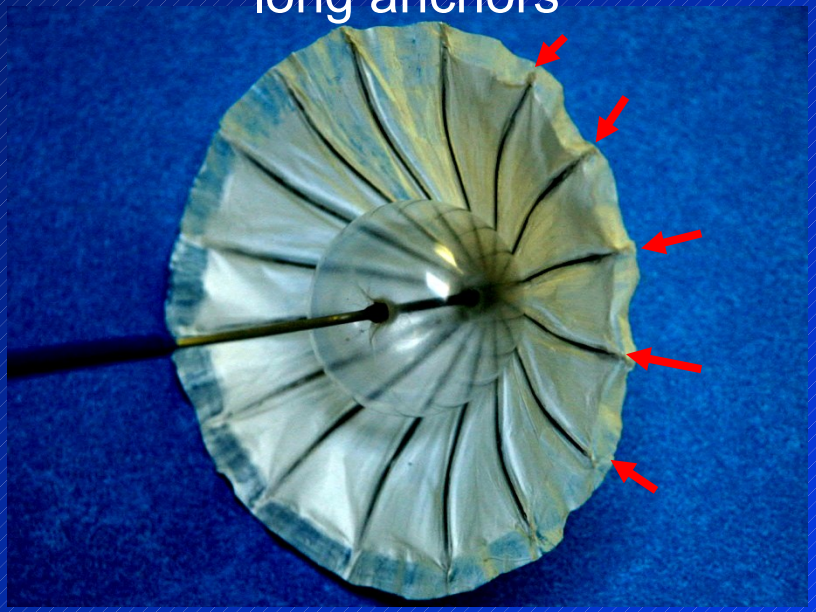
- LV “partitioning” in LV akinesia or aneurysms due to ischemic heart disease
- Replicates surgical techniques of ventricular restoration (Dor procedure)

VPD Implant Procedure

VPD-Implant

- First device designed to treat LV wall abnormalities by catheter techniques
- Umbrella-like occlusive membrane with a nitinol frame
- 2 mm long anchors
- Two sizes (75/85mm)
- Introduced through a 14 F sheath

16 struts with 2mm long anchors

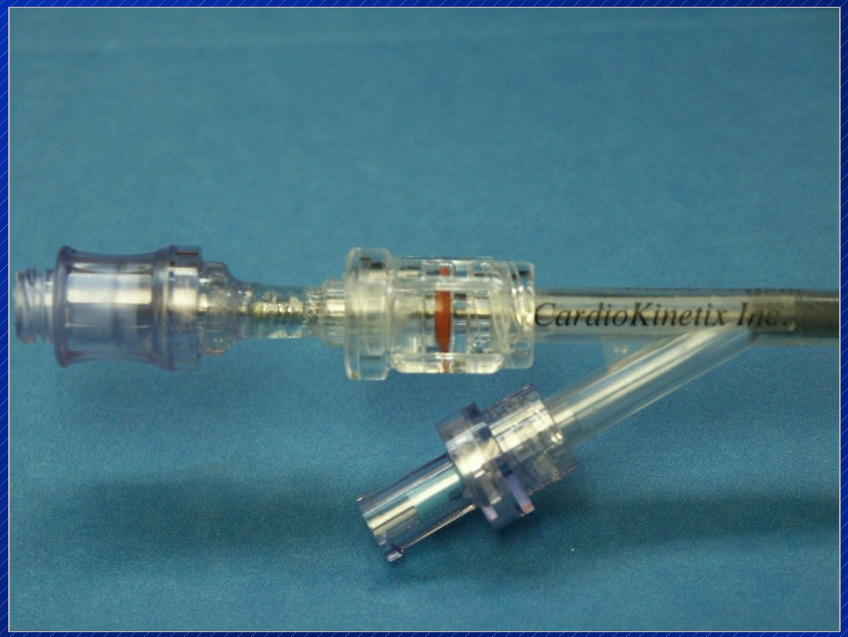


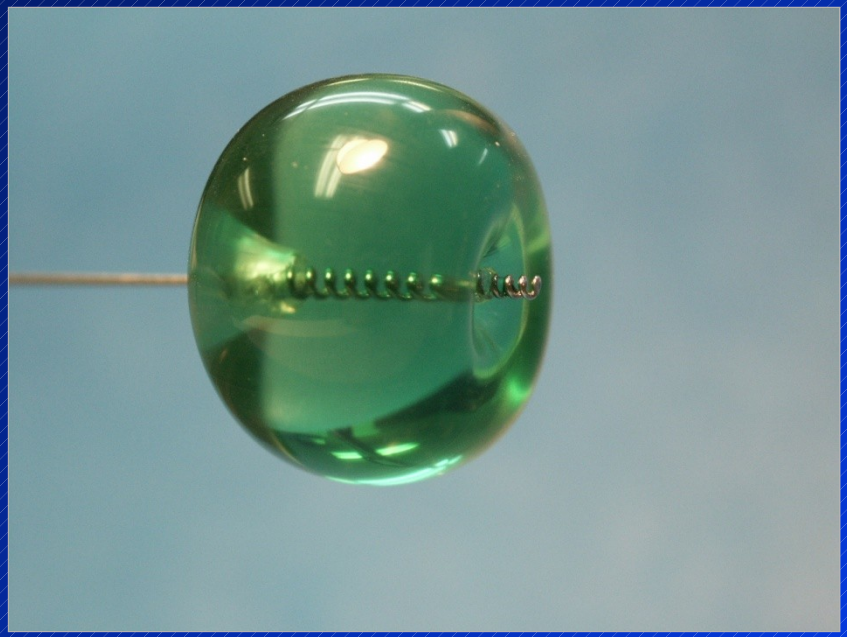
Access system

1- Guide catheter
2- Dilator
accommodates a 6-7 Fr pigtail

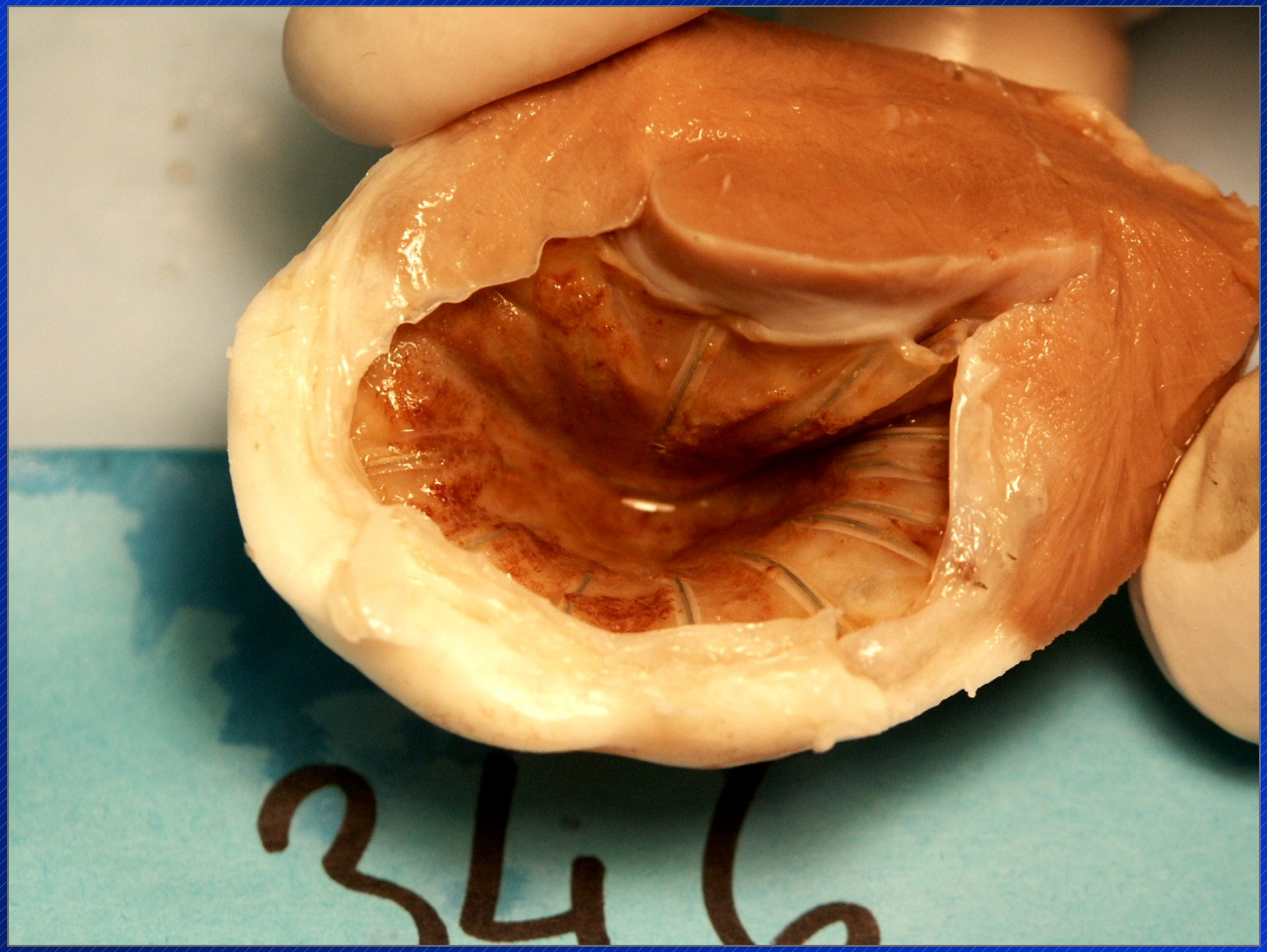
Delivery Catheter

- Balloon inflation port
- Proximal injection port
- Implant detachment knob
- Distal balloon

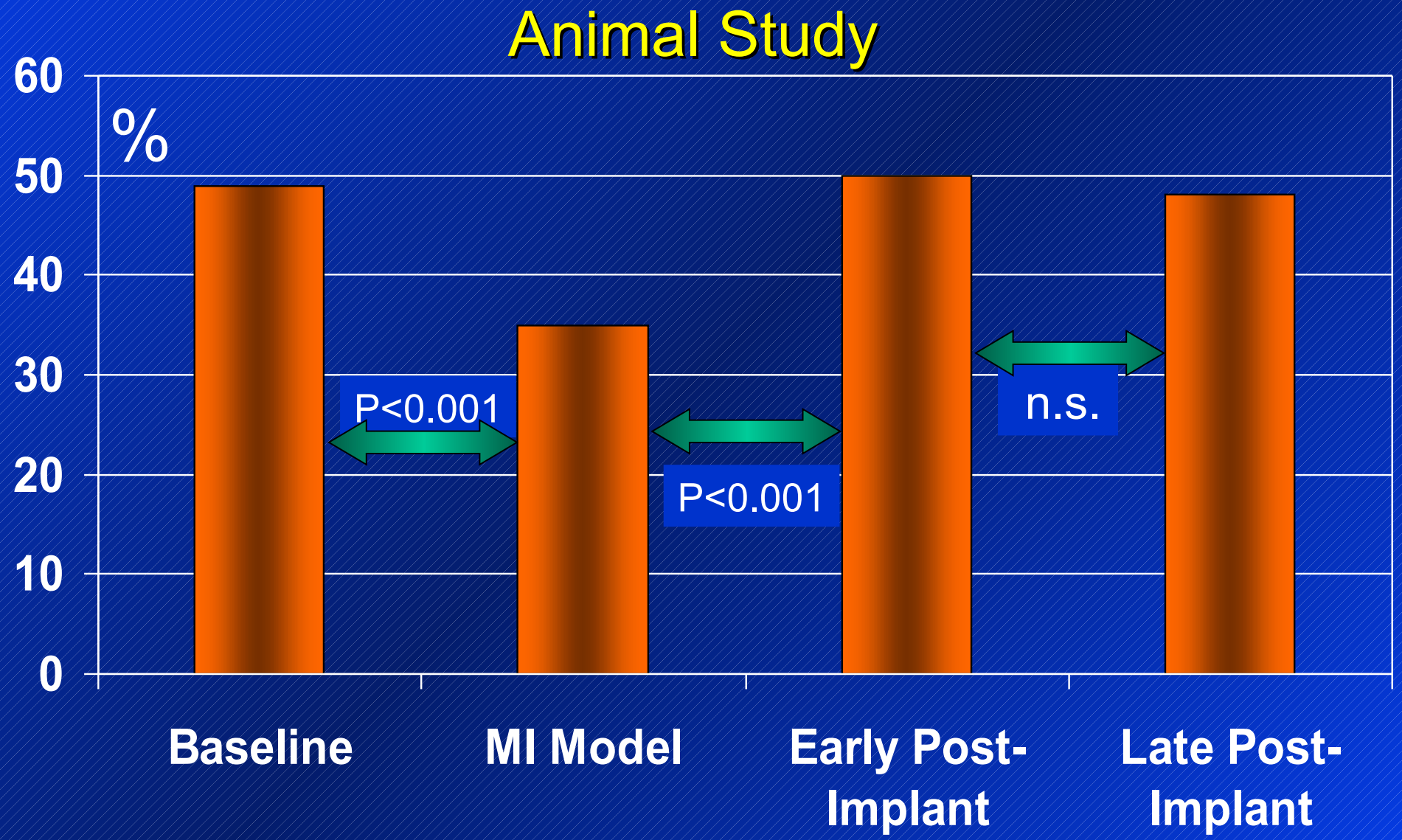




VPD Implant: GLP Animal Study
Tissue In-Growth 3 Weeks Post Implant



Ejection Fraction



This device …

- … is currently evaluated in a (pivitol) US feasibility trial
  - 7 centers
  - 7 patients are included (Sep 2008)
- … is investigational
- … is not available in the US
- … does not have CE mark

Parachute OUS Clinical Trial

Prospective, non-randomized, multi-center first in man trial

Primary Endpoint (Safety):

- Successful device delivery without MACE through discharge

Secondary Endpoints (Effectiveness):

- Change in LV Volumes, Heart Failure symptoms, exercise tolerance

Study Centers/Investigators

- Dedinje Cardiovascular Institute, Belgrade, Serbia
  - D Sagic, P Otasevic, S Gradinac
- Heart Center Bad Nauheim, Germany
  - A Elsässer, C Hamm
- CardioVascular Center Frankfurt, Germany
  - H Sievert, N Majunke, N Wunderlich

Methods

- Device implantation under local anesthesia
- 14 F transfemoral sheath
- Follow-up:
  - TTE @1,3,6,9,12 months and then yearly to 5 years
  - LVgram @ 6 months
- Aspirin and Clopidogrel for 6 months
  - Anticoagulation optional

Main Inclusion Criteria

- Dilated left ventricle, EF ≤40%
- Apical wall hypo-/akinesia
- NYHA II-IV

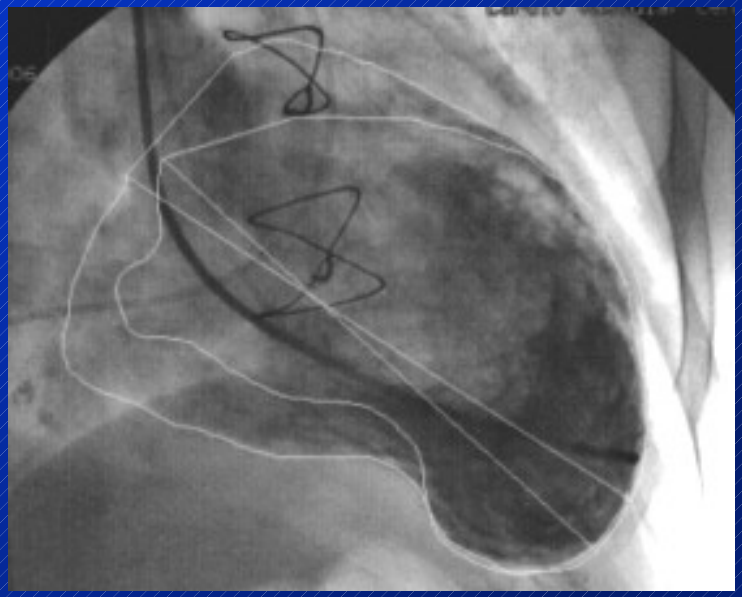
Main Exlusion Criteria

- MI last 30 days
- PCI/CABG last 30 days
- ICD/CRT last 30/90 days
- Significant valve disease
- LV Thrombus

Case Report

- 70 y.o. male
  - AMI in 1998, CABG in 1999
- Left ventricular aneurysm, EF 38%
- On Aspirin, Carvedilol, Ramipril, Nitro, Lasix
- NYHA III

Case Report



DEVICE IN APICAL POSITION

Case Report

BALLOON INFLATION TO EXPAND DEVICE

FULL DEPLOYMENT

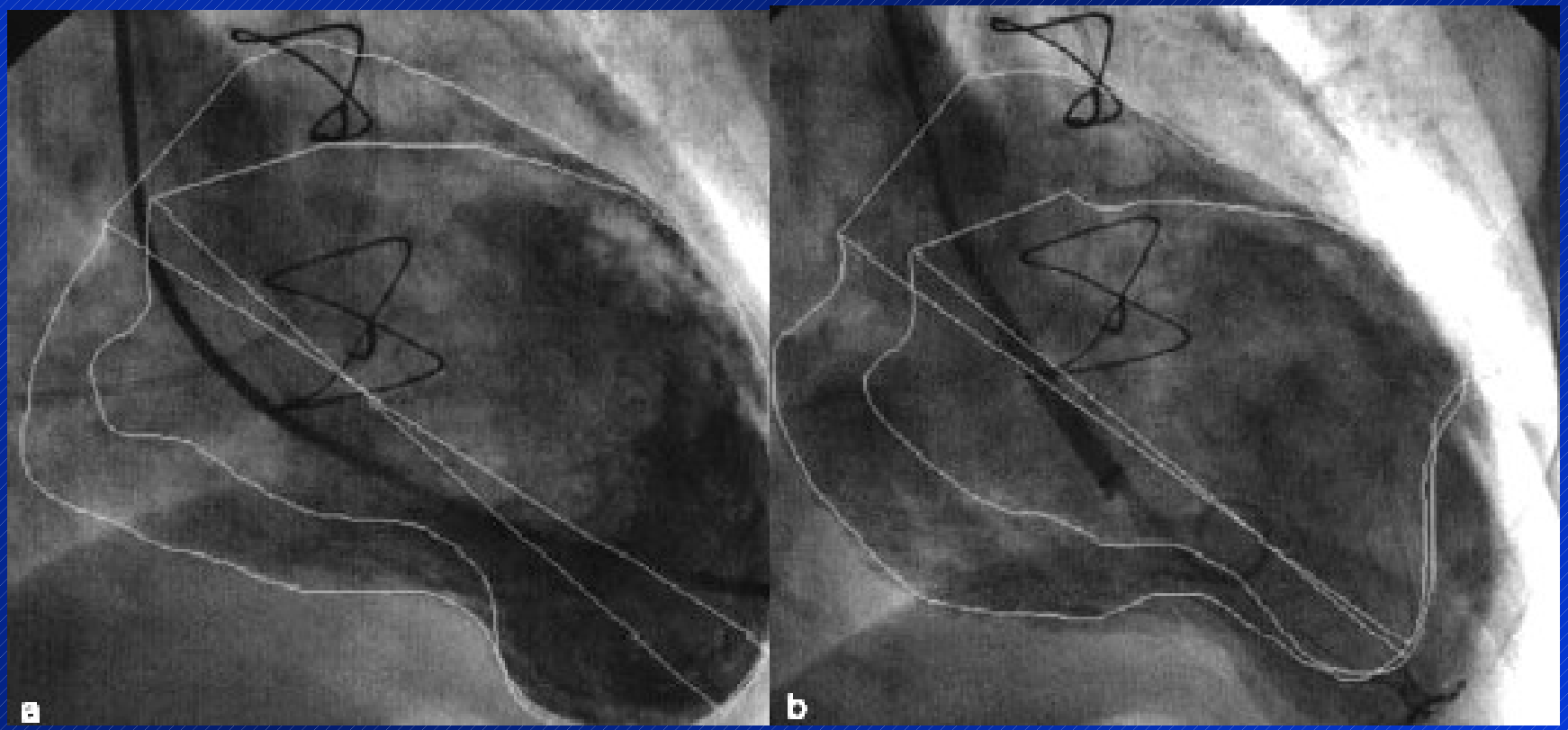
Case Report

FINAL ANGIO

Case Report

PRE IMPLANT EF: 38%

POST IMPLANT EF: 52%



PLAN TO ATTEND

09

12 th International Congress

July 9 – 11, 2009
Frankfurt, Germany

CSI
Congenital &
Structural
Interventions

Take a look at CSI LIVE on www.csi-congress.org

July 08, 2009
Frankfurt, Germany

IMAGING IN
CARDIOVASCULAR
INTERVENTIONS

ici-Focus 2009:

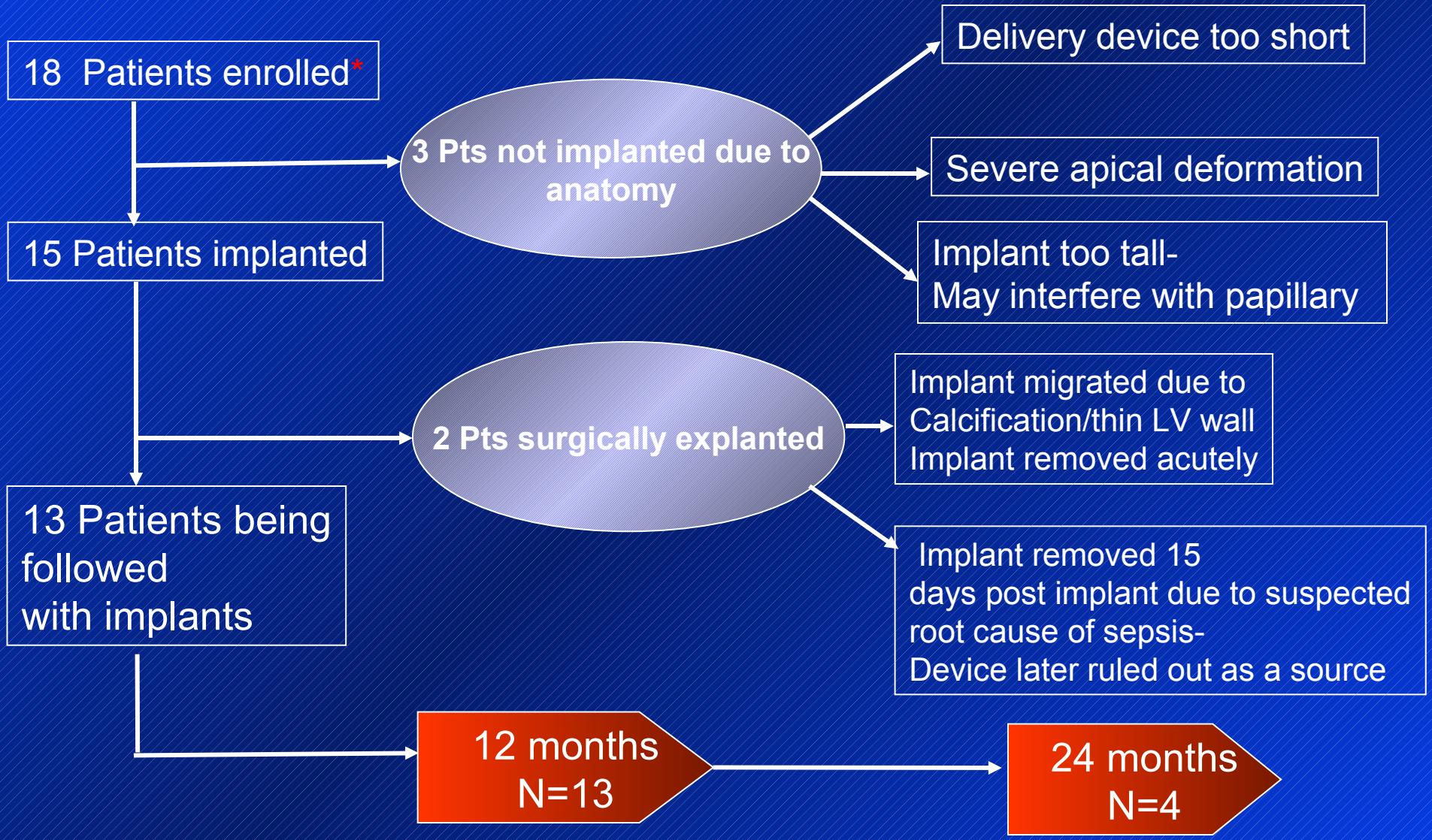
INTERVENTIONAL IMAGING, A KEY ROLE FOR SUCCESS

09

iCi 2009
ahead of
CSI 2009
July 9–11

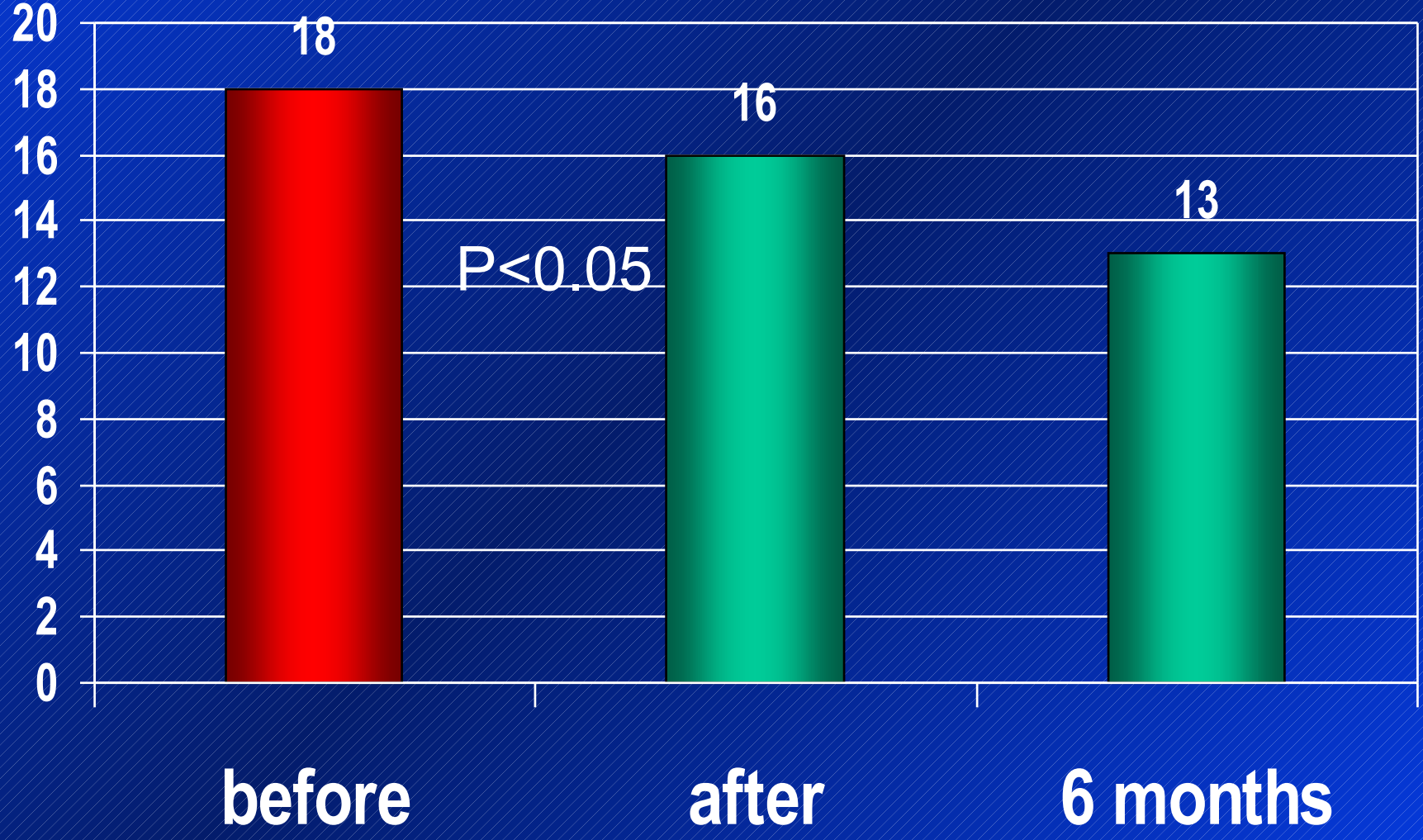
www.ici-congress.org

Results OUS Parachute Trial
Phase I- 12/07



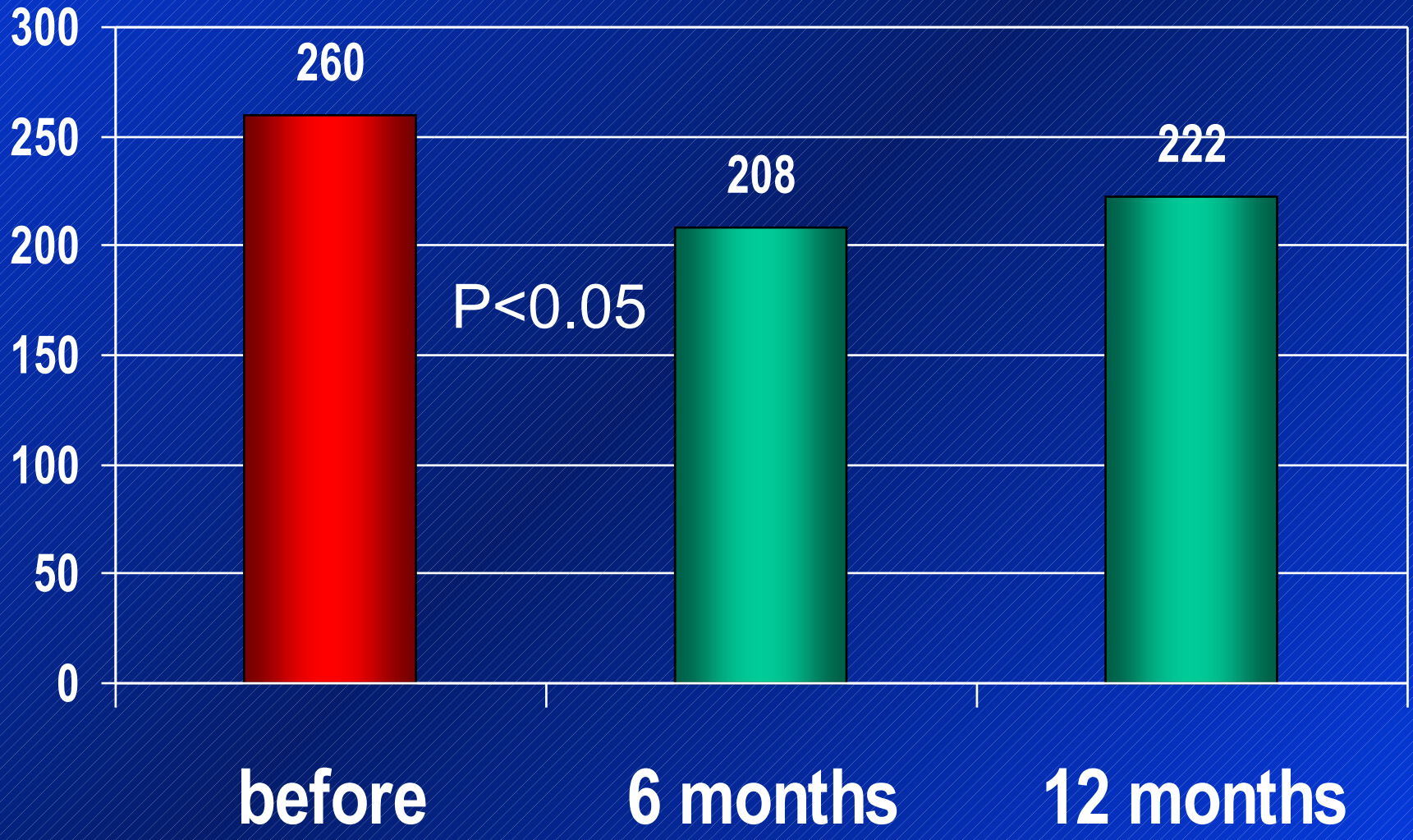
* 1 extra-patient enrolled under a revised protocol

LVEDP



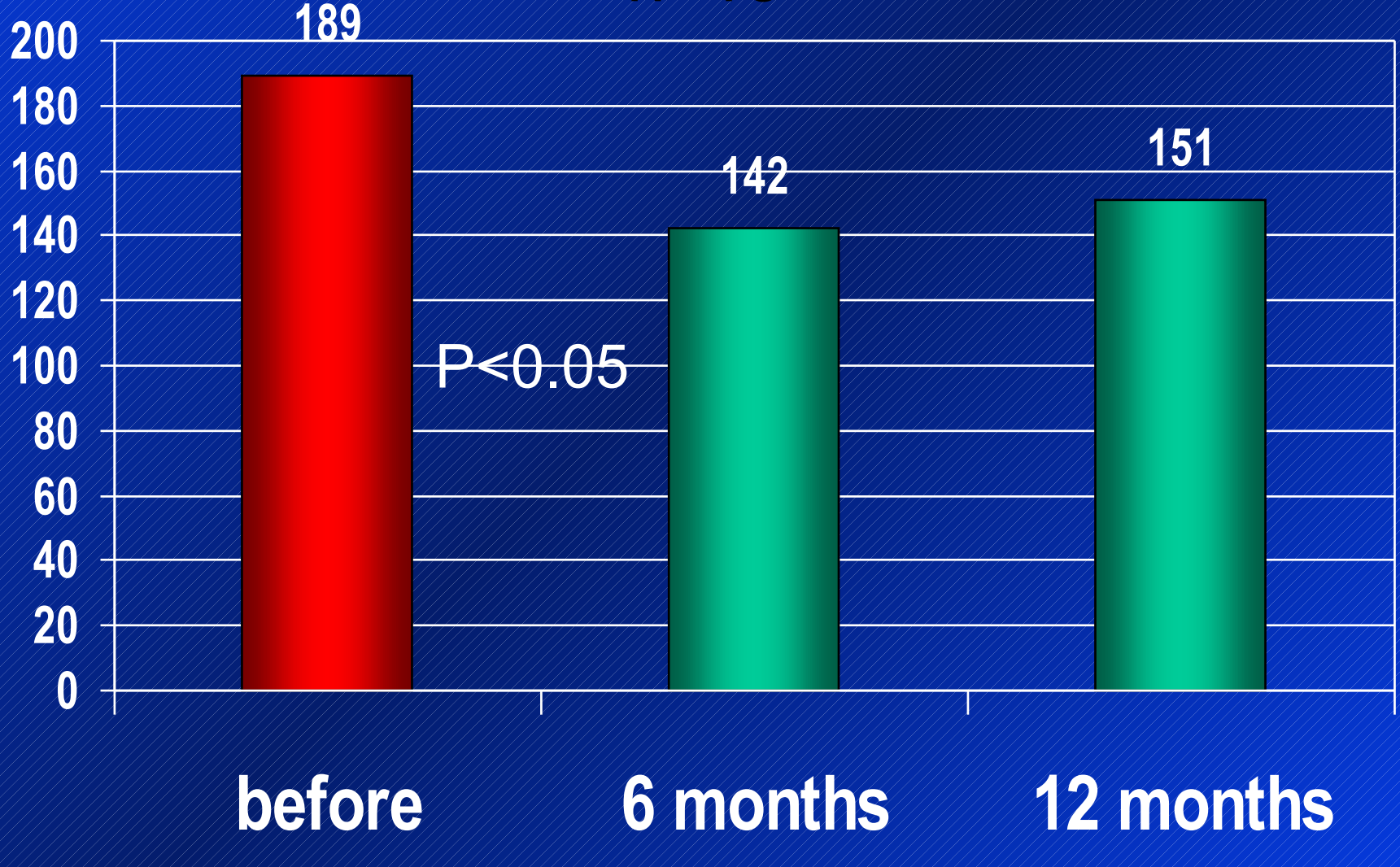
LVEDI - Echo (ml/m^2)

n=13



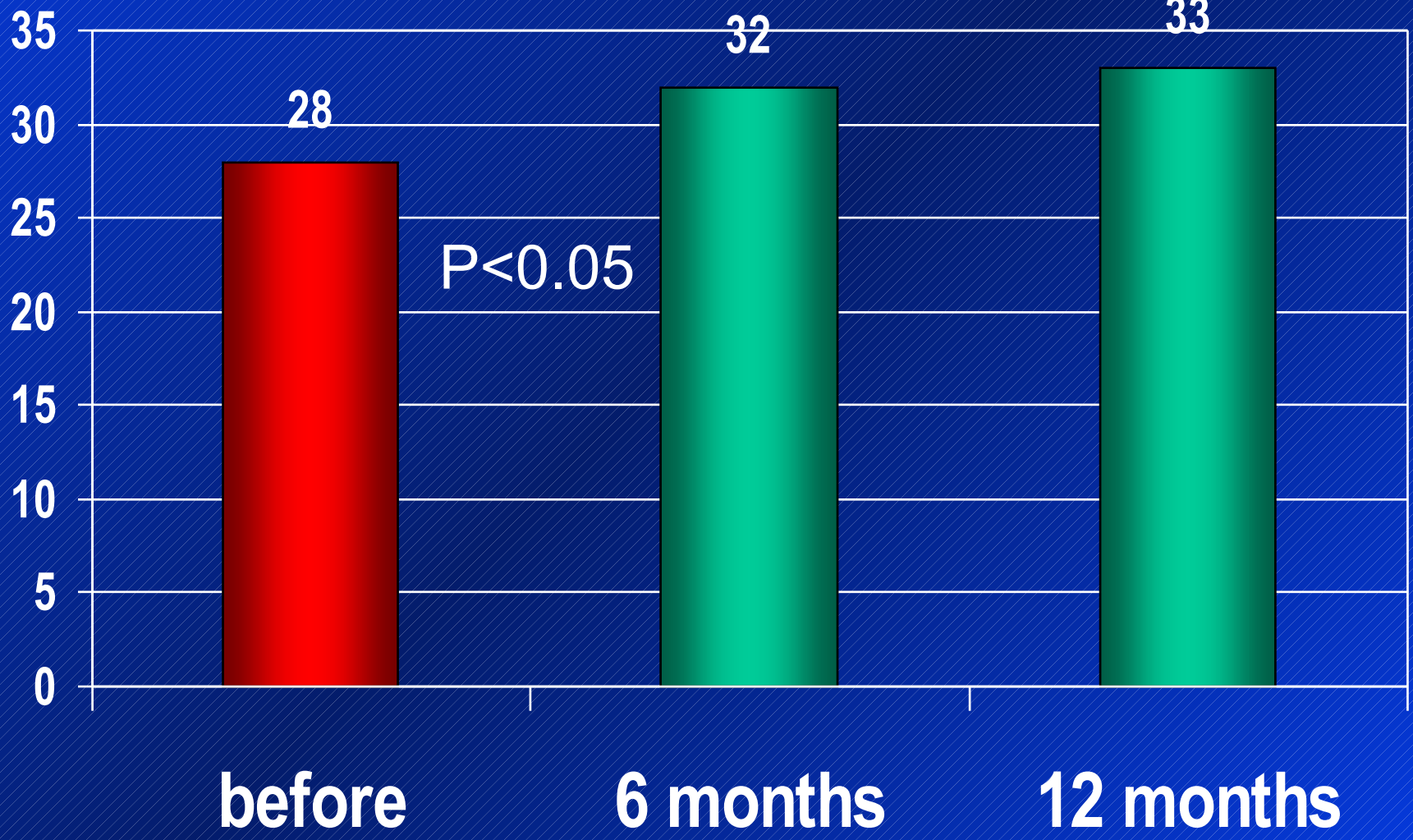
LVESI - Echo (ml/m^2)

n=13

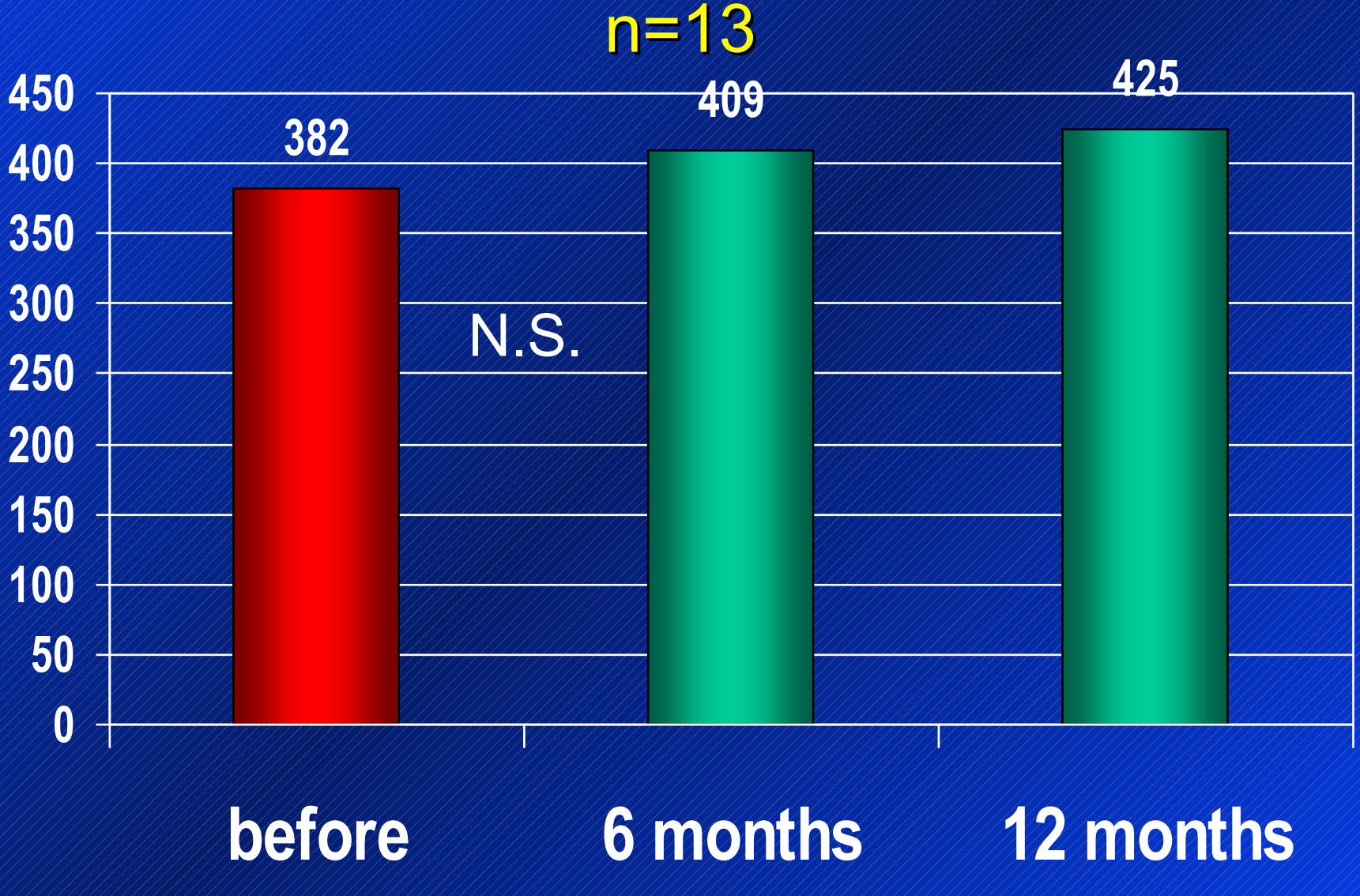


EF - Echo (%)

n=13

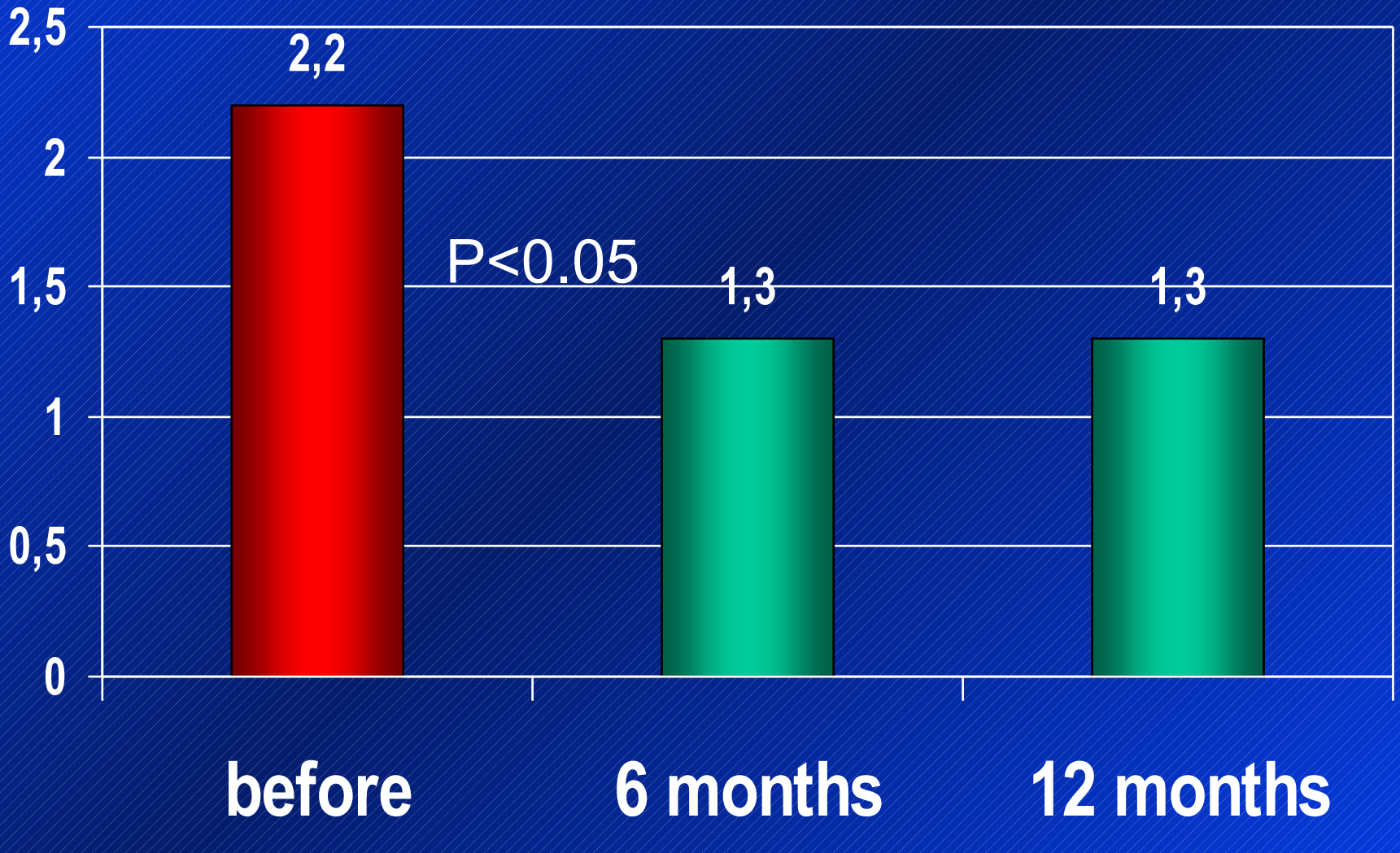


6 min Walk Test (m)



NYHA Class

n=13



Serious Adverse Events

- 1 Early death
  - Sepsis from undiagnosed peri-anal abscess
  - Device removed - culture negative for infection
  - Myocardial infarction, non-device related
- Device misplacement requiring surgical removal
  - Calcifications of the septal wall
  - Surgery uneventful
- Groin complications
  - 1 femoral artery pseudo-aneurysm surgically repaired
  - 1 bleeding requiring re-hospitalization

Serious Adverse Events

- Minor stroke, 14 months post-implant
  - Bilateral carotid artery disease
  - Full recovery
- TIA, 9 months post-implant
  - Paroxysmal AF
- Worsening Heart Failure after14 months
  - hospitalization and therapy re-adjustment
- Hospitalization for syncope, after 2 years
  - II degree heart block, Ventricular Dyssynchrony and Intermittent AF

Catheter Isolation of LV Aneurysms

- VPD is the first catheter-based system to treat LV wall motion abnormalities
- Implant procedure seems to be safe
- 6 and 12 month data show improved functional and hemodynamic outcome
- The US feasibility trial is ongoing