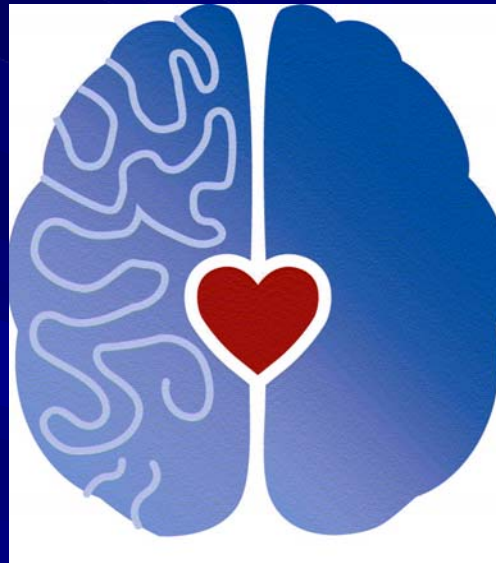


# Eight Year Results of ASD / PFO Closure in an Integrated Neurology-Cardiology Program

What have we learned?



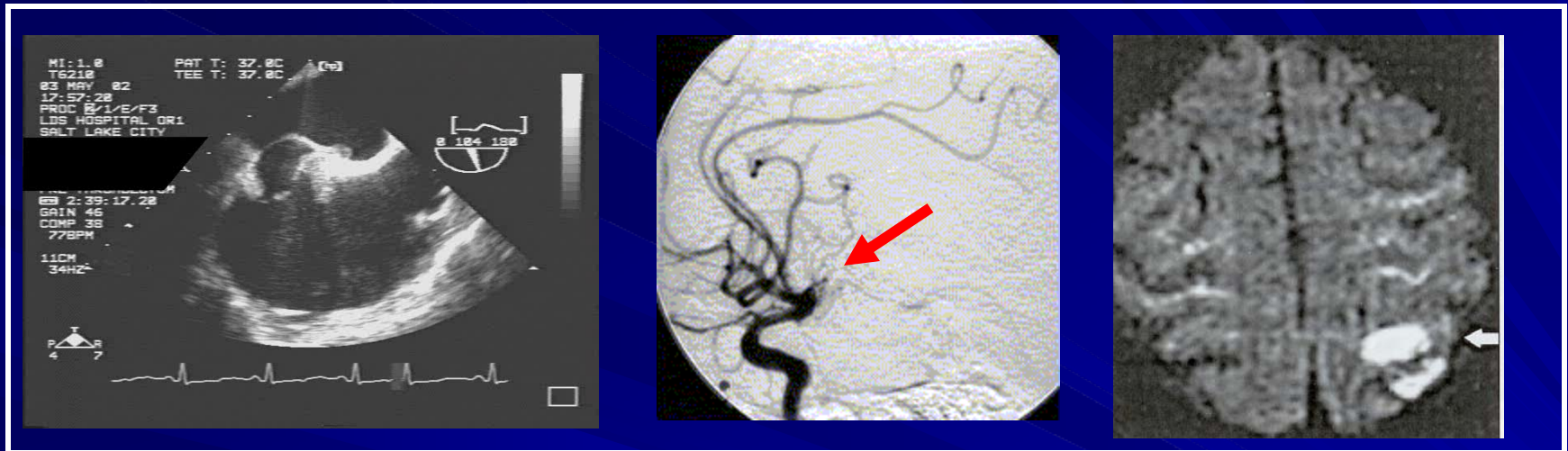
SHERMAN G SORENSEN MD  
SORENSEN CARDIOVASCULAR GROUP

# DISCLOSURE

NOTHING TO DISCLOSE

# PARADOXICAL EMBOLISM DUE TO ATRIAL LEVEL RIGHT-TO-LEFT SHUNT

An uncontested relationship



Paradoxical embolic stroke in adults is unique to RL shunt due to ASD / PFO

Paradoxical embolic materials include thrombus of all sizes, fat, de-saturated blood, platelet aggregates, bubbles, cellular debris, and amniotic fluid.

Paradoxical embolic events are serious as one-half of first strokes are disabling.

The risk of these events is lifelong, unpredictable and is present in health; in illness; and with medical procedures

# ASD / PFO TREATMENT OPTIONS

## Patient Preference



Although all of us love our surgeons,

NOBODY loves surgery!



## ASD SURGICAL REPAIR

- Superior to medical RX ( 1 RCT)
- Inferior to catheter closure (no RCT)
- PFO surgical closure (no RCT)

## PFO MEDICAL THERAPY

- RCT: SPIRIT, WASID,WARSS
- Non RCT (meta + retrospect)  
medical therapy is inferior to mechanical closure for stroke prevention

## RCT (RESPECT, CLOSURE 1)

- > 5 yrs; no risk stratification  
brief follow-up, ? representative



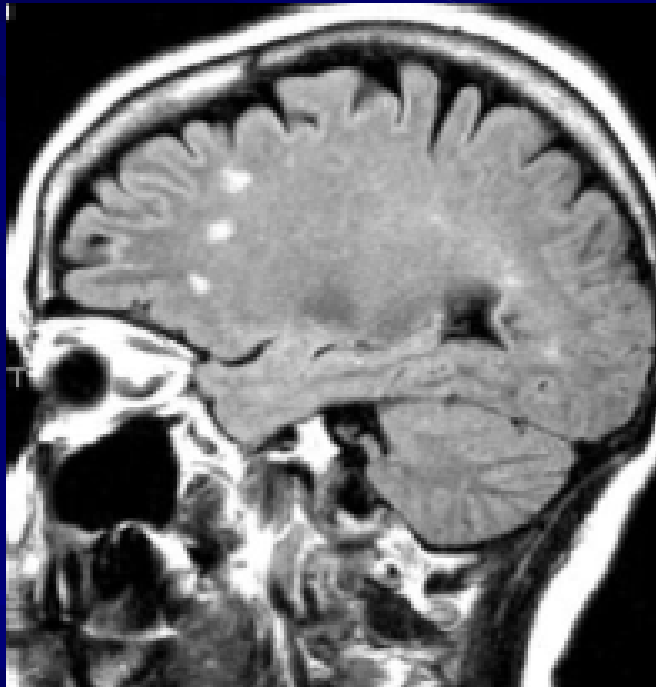
FORMER PRIME MINISTER



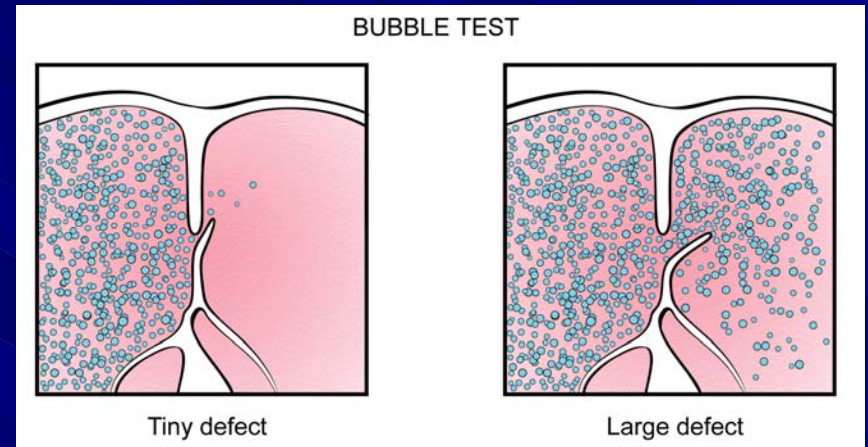
PERCUTANEOUS DEVICE CLOSURE

# EARLY EXPERIENCE: 2001-2002

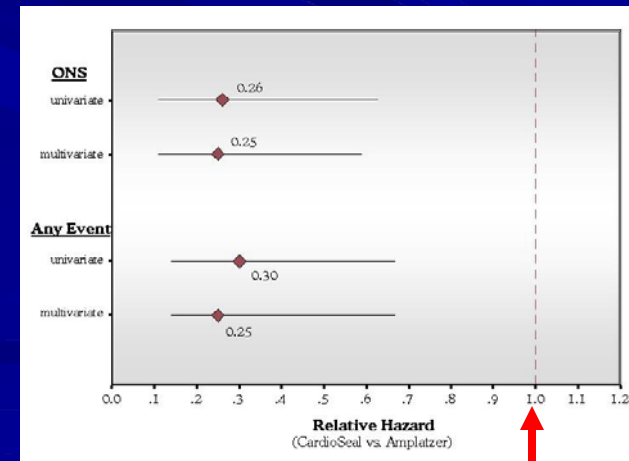
## PHASE 1



THE TROUBLE WITH SPOTS



### TROUBLE WITH BUBBLES



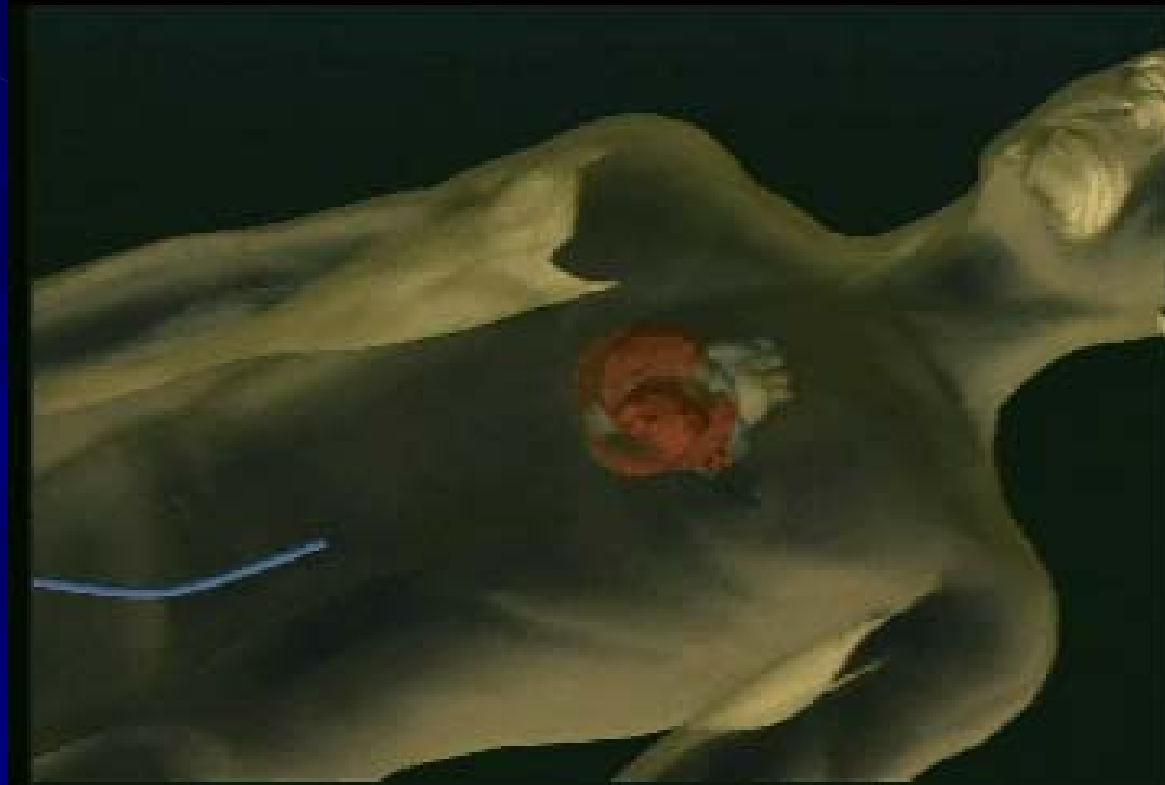
DEVICE DILEMMA

# PHASE 1 CONCLUSIONS

- **COLLABORATIVE, INTEGRATED CARE**  
Although good scientific information exists, the absence of RCT, differing opinions, and patient preference all indicate the need for integrated testing and treatment.
- **DEVICE MANAGEMENT**  
The unique nature of low pressure system treatment, variability of anatomy, and device management all indicate the need for dedicated or committed use rather than “add-on” practice.
- **TESTING**  
The serious nature of brain injury and device placement require neurological and cardiology testing to define high risk patients and to evaluate the effects of therapy

# SEPTAL DEFECT CLOSURE

Improved implant technique and device selection



## PROCEDURAL FEATURES:

CATHETERIZATION LABORATORY PROCEDURE (45 MINUTE)  
VENOUS CATHETERIZATION ONLY; ICE IMAGING + FLUORO  
CONSCIOUS SEDATION; NO GENERAL ANESTHESIA  
NO TRANSESOPHAGEAL ECHO

# PHASE II

The development of a structured, dedicated program.

- **SPECIALTY INTEGRATION**  
WESTERN NEUROLOGICAL ASSOCIATES  
TANNER CLINIC
- **BRAIN IMAGING / NEURO CONSULTATION**  
MRI AND MRA
- **CARDIOVASCULAR TESTING**  
Power M-mode Transcranial Doppler (TCD)  
Contrast Enhanced Echo (CE-TTE)

# PHASE II

Research + patient and physician education programs



HEART & BRAIN

## PHYSICIAN AND PROVIDER PROGRAMS



PFO  
Migraine



LOC



NVI  
Stroke Prevention  
Program



SORENSEN



SPACE



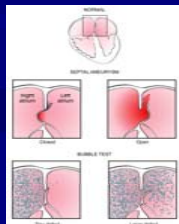
## EDUCATIONAL WEBSITE

[WWW.SORENSENMD.COM](http://WWW.SORENSENMD.COM)

## RESEARCH AND EDUCATION PROGRAMS

STROKE AWARENESS (DR GORDON DIXON)

DATA BASE / PUBLICATION STAFF



JILL RHEAD

## PATIENT INFORMATION

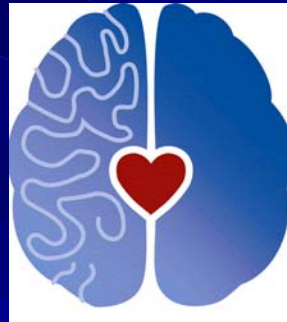
PRINTED INFORMATIONAL BROCHURES

WIRELESS REVIEW OF OWN STUDIES

NEUROVASCULAR COORDINATOR TEACHING

PATIENT INFORMATION  
**PARADOXICAL EMBOLIC STROKE**

ATRIAL SEPTAL DEFECTS (ASD)  
PATENT FORAMEN OVALE (PFO)



**HEART AND BRAIN**

**NEUROVASCULAR STROKE PREVENTION  
PROGRAM**

**SHERMAN G SORENSEN MD, DIRECTOR**

Heather Aguilar RN  
NVI Coordinator

[WWW.SORENSENMD.COM](http://WWW.SORENSENMD.COM)

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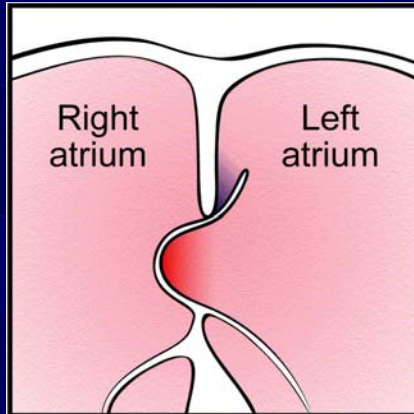
**NEW FIFTH EDITION**  
35 page Brochure

# RISK STRATIFICATION

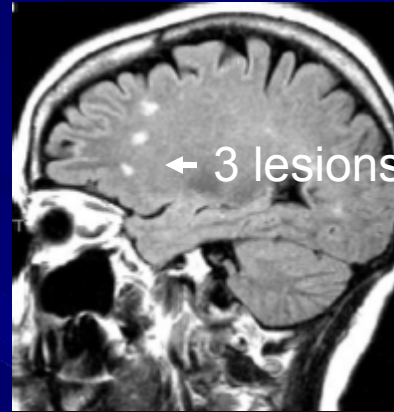
Risk stratification is fundamental to all medical, surgical, and procedural care



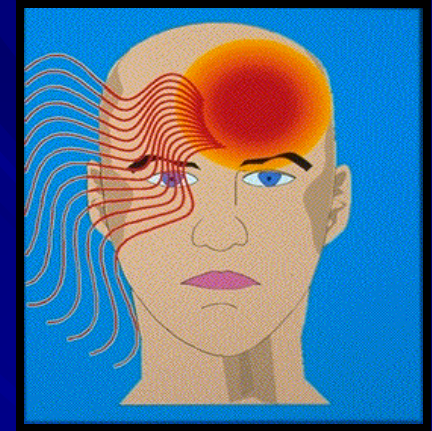
**HIGH FLOW  
REST FLOW**



**"ANEURYSM"**



**BRAIN INJURY**



**MIGRAINE**

**HIGH FLOW:** Valsalva or calibrated respiratory strain Spencer Grade 5 or 5+ or left heart chamber opacification

**REST FLOW:**  $\geq$  TCD Spencer Grade 4 at rest or moderate CE-TTE rest shunt

**SEPTAL ANEURYSM:** Literature-based risk factor; Indicates non-restrictive defect which is directly proportional to flow

**BRAIN INJURY:** 1) Clinical CVA 2) Imaging CVA 3) Multi-focal T2 MRI lesions  
4) Clinical TIA 5) REGARDS III whispering stroke

**MIGRAINE:** Particularly if with aura

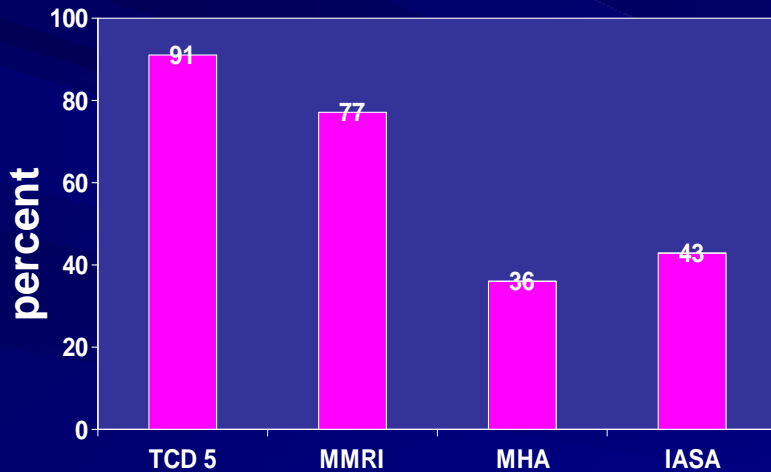
**OTHER:** Sleep apnea, pulmonary HT, Ebstein's, tricuspid regurgitation, scuba diving, DVT, PE, coagulation disorders, high risk RX.

# PHASE II RESULTS

## Patient risk stratification.

Percentage of Program patients with Literature-based risk factors for 2nd stroke

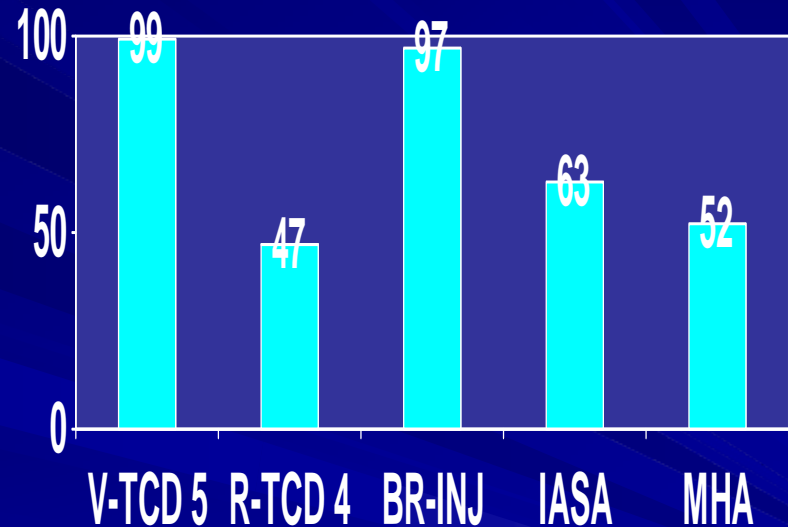
2005



1000 patients w/ catheter closure

Sorensen SG et al; AJC 2005;96:49

RECENT



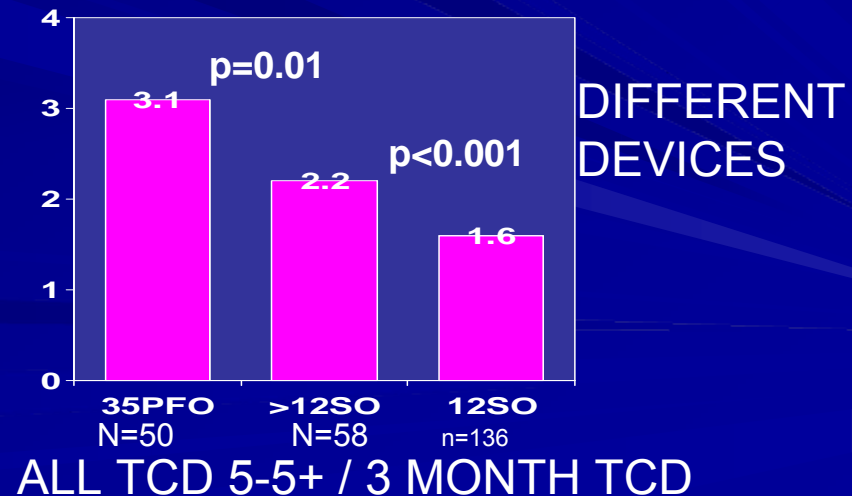
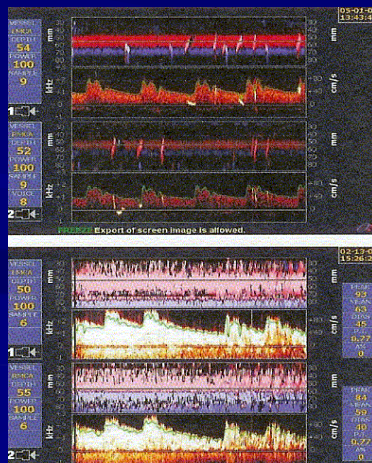
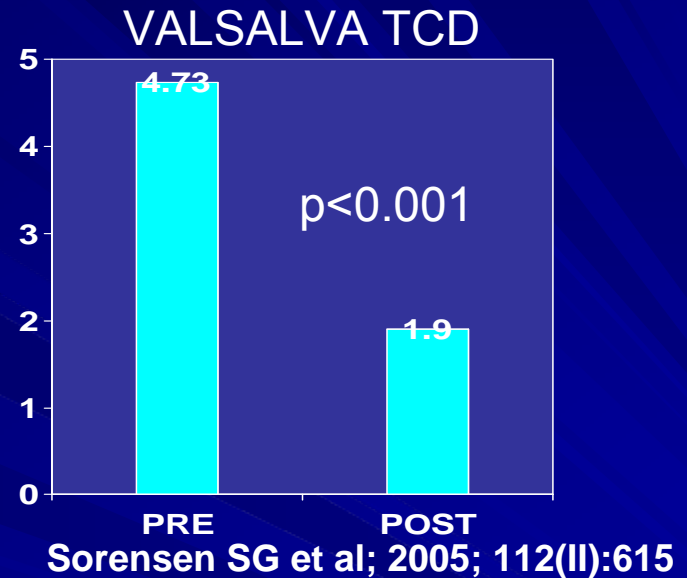
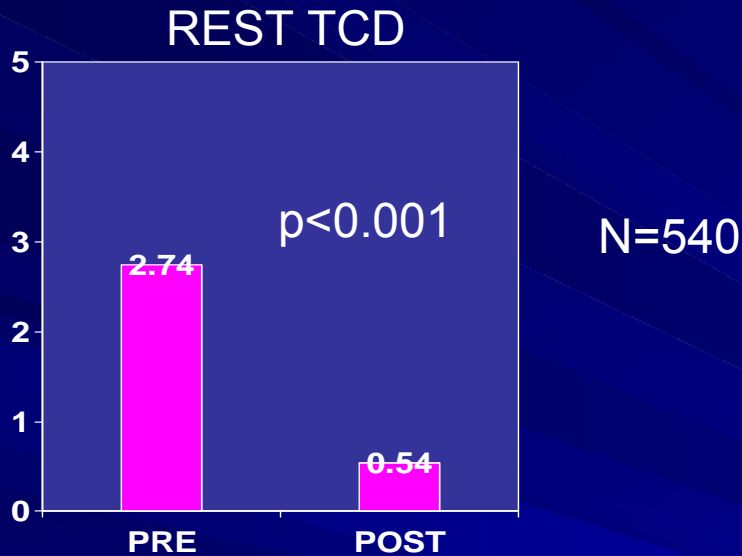
750 patients w/ catheter closure

Great Basin Data Base

NEUROLOGY CONSULTATION 97%

# CLOSURE DEVICE EFFICACY

TCD evaluation of shunt before and 3 months after closure



# RESULTS

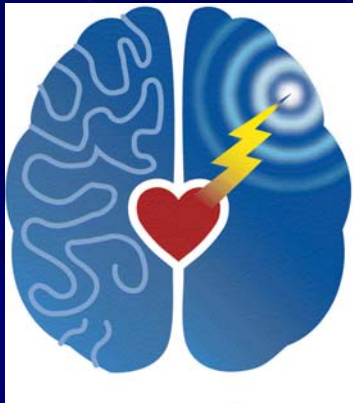
## SERIOUS ADVERSE EVENTS

N = 350	1 – 3 years	#	%
DEATH		0	0
CVA w/residual		0	0
MRI (-) neuro event (TIA)		5	(1.4)
MRI (+) neuro event (CVA)		4*	(1.1)
Device erosion		0	0
Arrhythmia		3	(0.9)
Device removal / dislodge		0	0

\*Annualized relative risk of CVA compared to historical controls = 0.15 (p <0.01)

# PHASE III

What's ahead for septal closure?



PFO MIGRAINE CENTER



COGNITIVE DYSFUNCTION



20 DEVICES IN THE PIPELINE

## GLOBALIZATION

True integration as we all see these patients

Ophthalmology: embolic visual loss / migraine

ENT/Balance: Posterior circulation vertigo and imbalance

Renal: Dialysis micro-bubble embolization

OB/GYN: TIA and Stroke: Hyper-coagulation of pregnancy / migraine

Urgent care: TIA and possibly neurological conditions

Primary care: You see all of it

Neurology: White matter disease

Procedural medicine: Orthopedics, Neurosurgery, In-dwelling lines



END