

# Neuromechanics and Neurosurgery -Inseparable!

James M. Drake FRCSC

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The Hospital for Sick Children  
University of Toronto, Canada

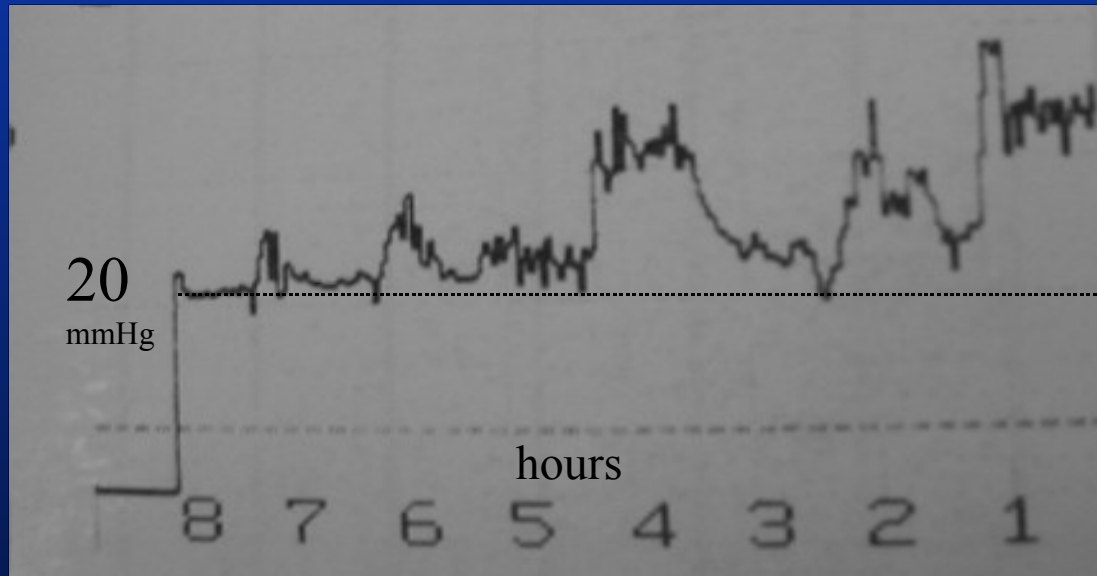
**SickKids**



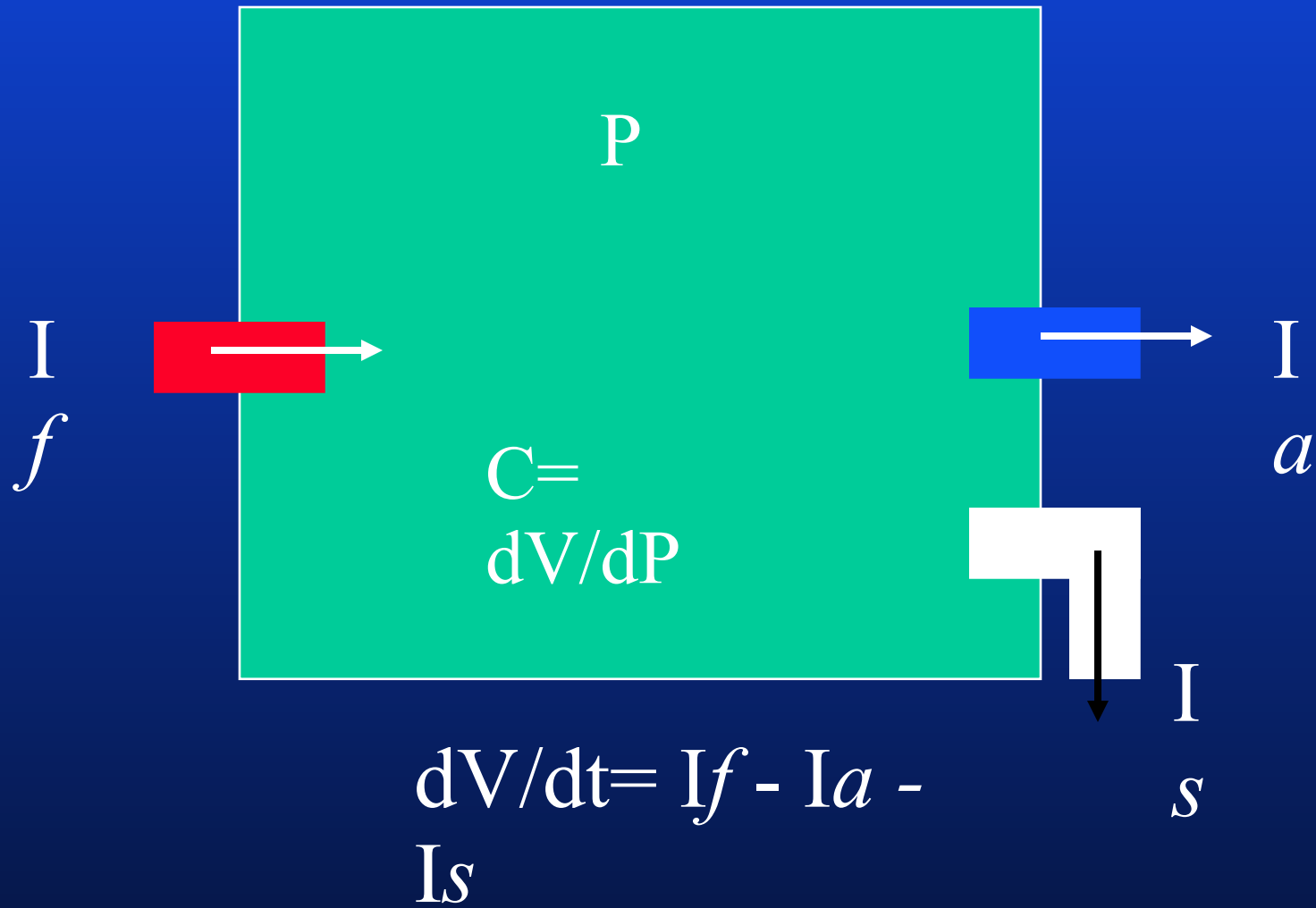
# Outline

- Where have we been ?
- What have we accomplished?
- What remains unknown ?
- Where to we go from here ?

# Intracranial Pressure



# Compartment Models



# Compartment Models of the Brain

$$C(P) \frac{dP}{dt} + \frac{1}{R_d} (P - P_d) = I_f$$

P is pressure

C is compliance

R is resistance to absorption

I if CSF formation

Typically choose 4 parameters

Po – opening pressure

Rd – resistance to absorption

Pd- saggital sinus pressure

If – CSF formation rate

\* Riccati Equation, 18th century

# Compartment Models of the Brain

$$C(P) \frac{dP}{dt} + \frac{1}{R_d} (P - P_d) = I_f$$

## Model

$C(P) = C_0$

$= ae^{-bP}$

$= 1/kP$

$= 1/(k_1P + k_2)$

## Reference

Guinane, 1972

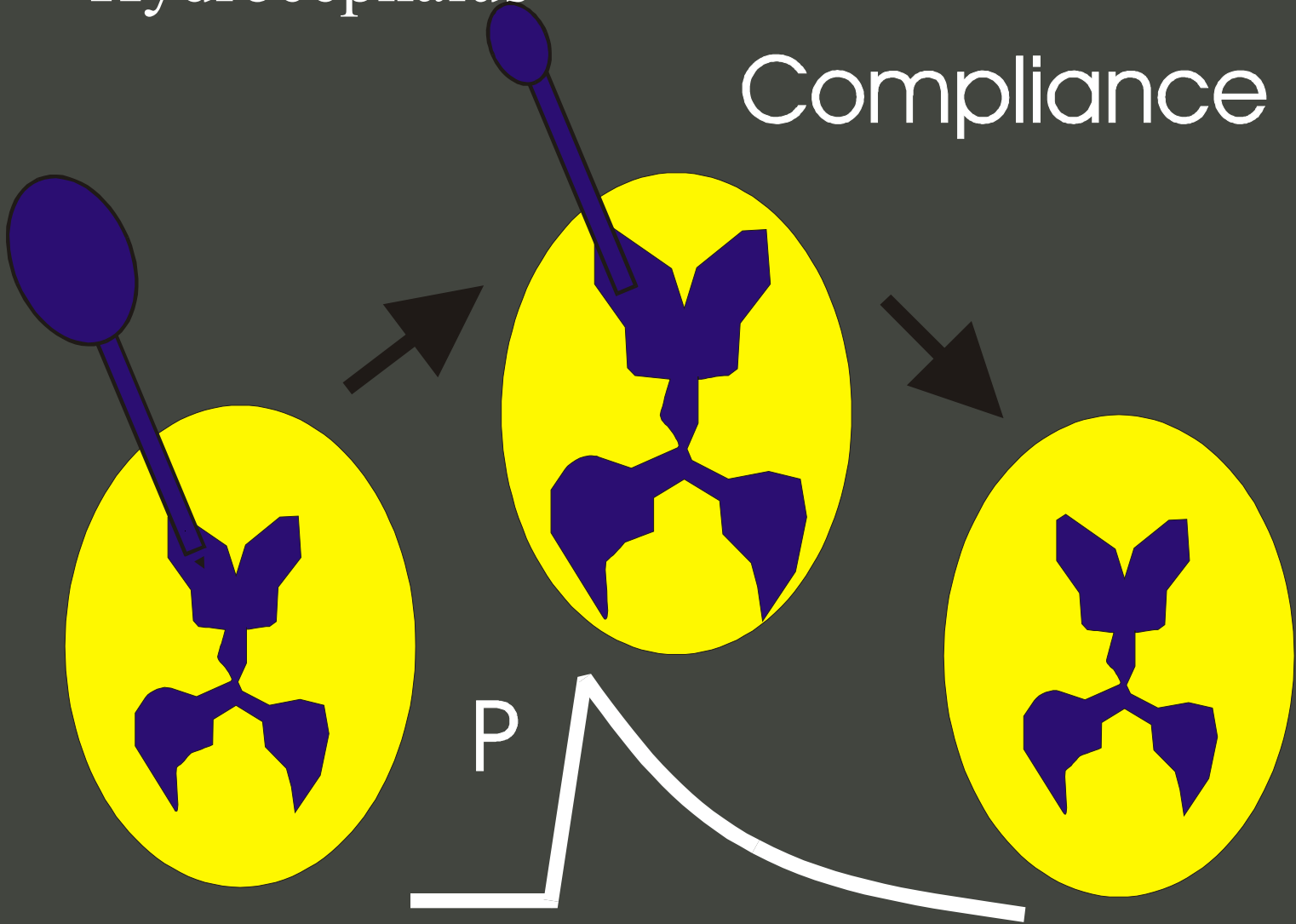
Lim, 1973

Marmarou, 1978 (pressure volume index)

Sklar, 1977

# Mathematical Models of Hydrocephalus

Compliance



# Compartment Models

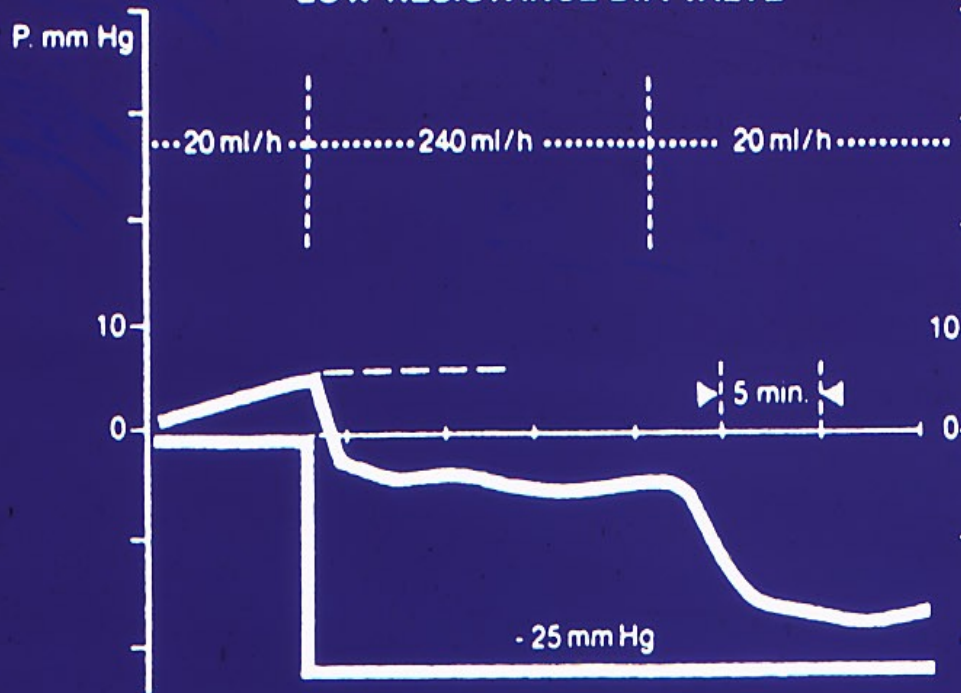
- Explain
  - Transient response to bolus injection
  - CSF accumulation
  - CSF shunt performance
  
  - BUT
    - Have to fit 4 parameters
    - Infinite number of models



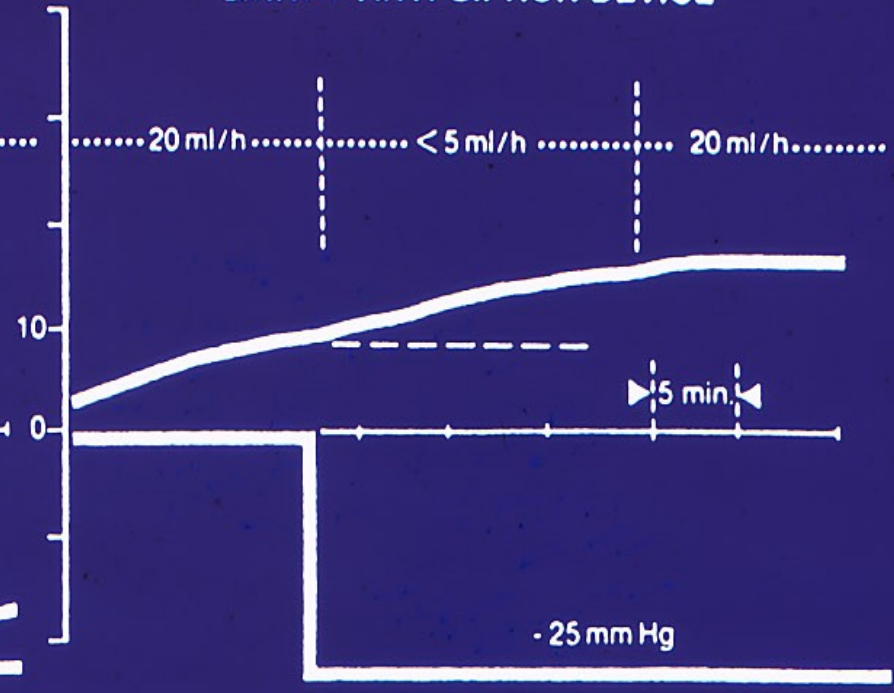
Drake (1998)



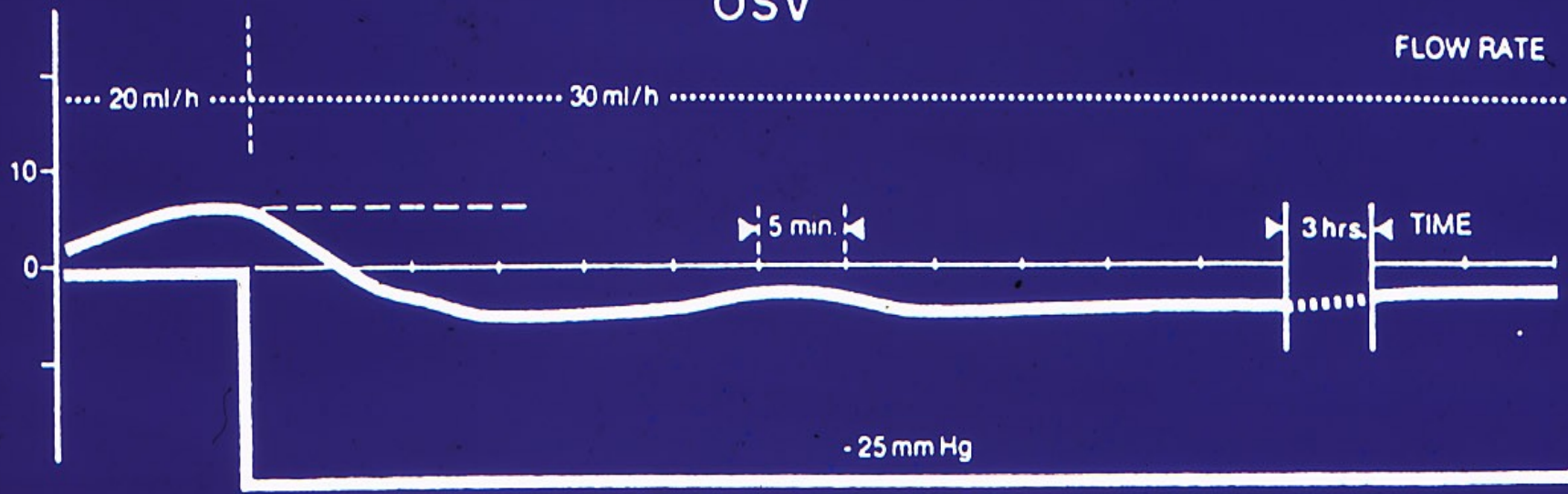
### LOW RESISTANCE D.P. VALVE

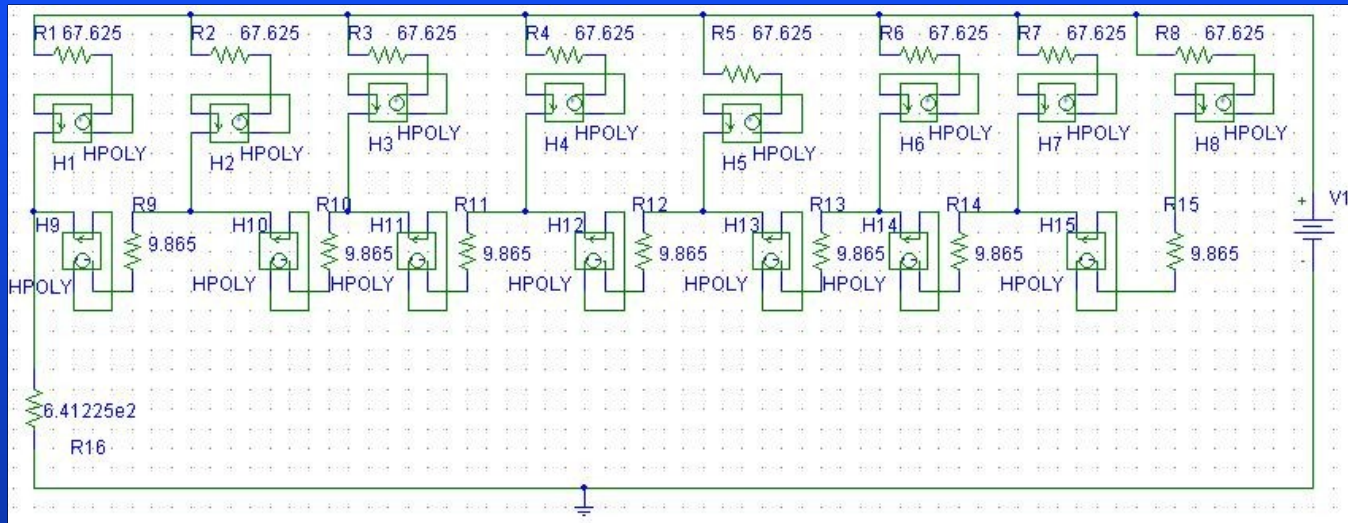


### L.R.V. + ANTI-SIPHON DEVICE



### OSV

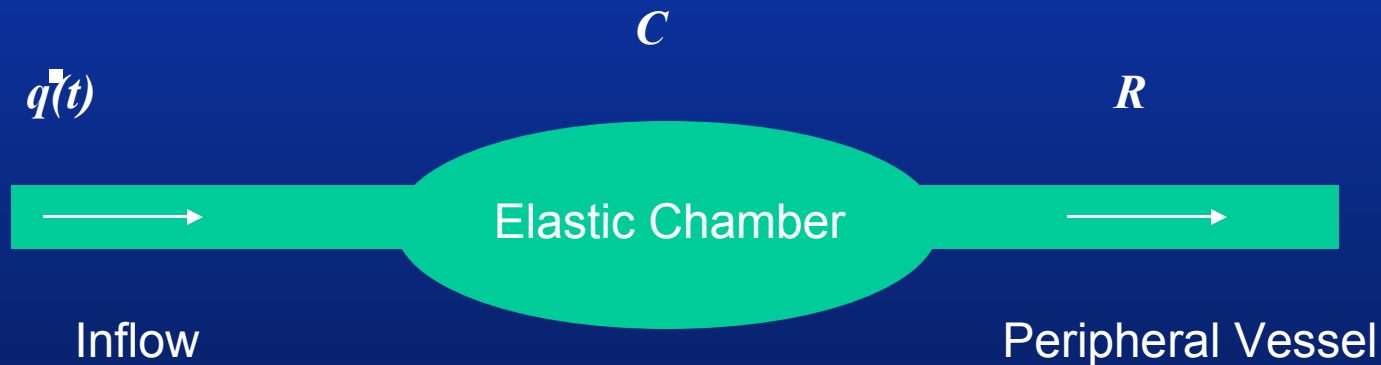




# Windkessel

Otto Frank (1899)

$$C \frac{dp}{dt} + \frac{1}{R} p = \dot{q}(t),$$



e.g.

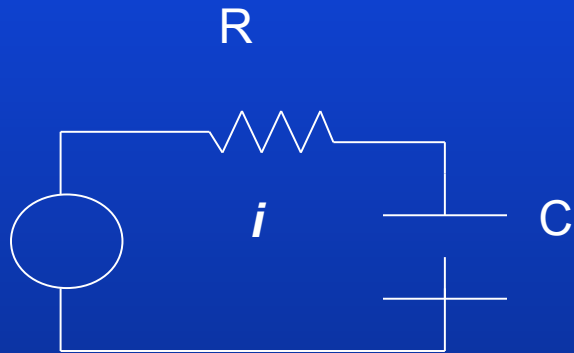
# Pulsatility vs Convection

$I_f = I_0$  CSf formation constant  Many authors

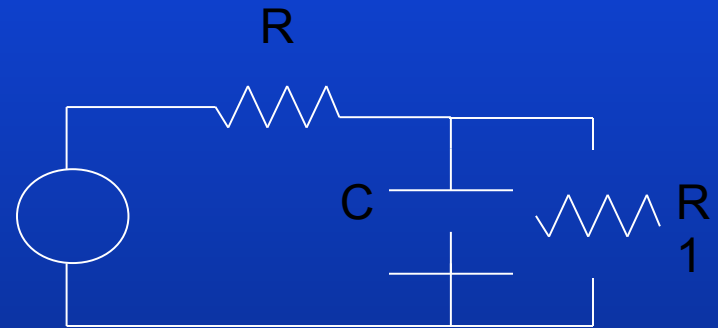
$I_f = H_0$  Bolus injection  Marmarou

$I_f = q_0 \sin^2$   
 $\bar{\omega}t$  Egnor

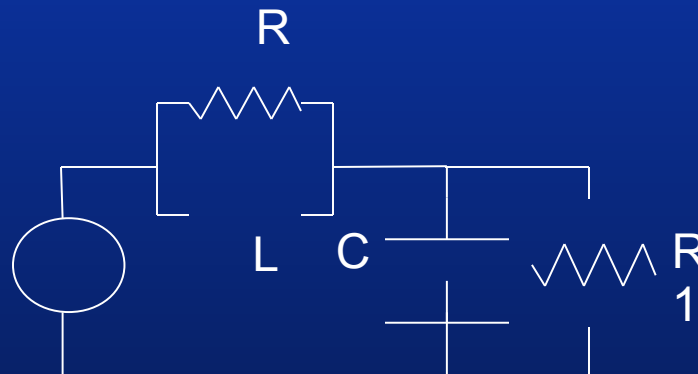
# Windkessel Electrical Analogs



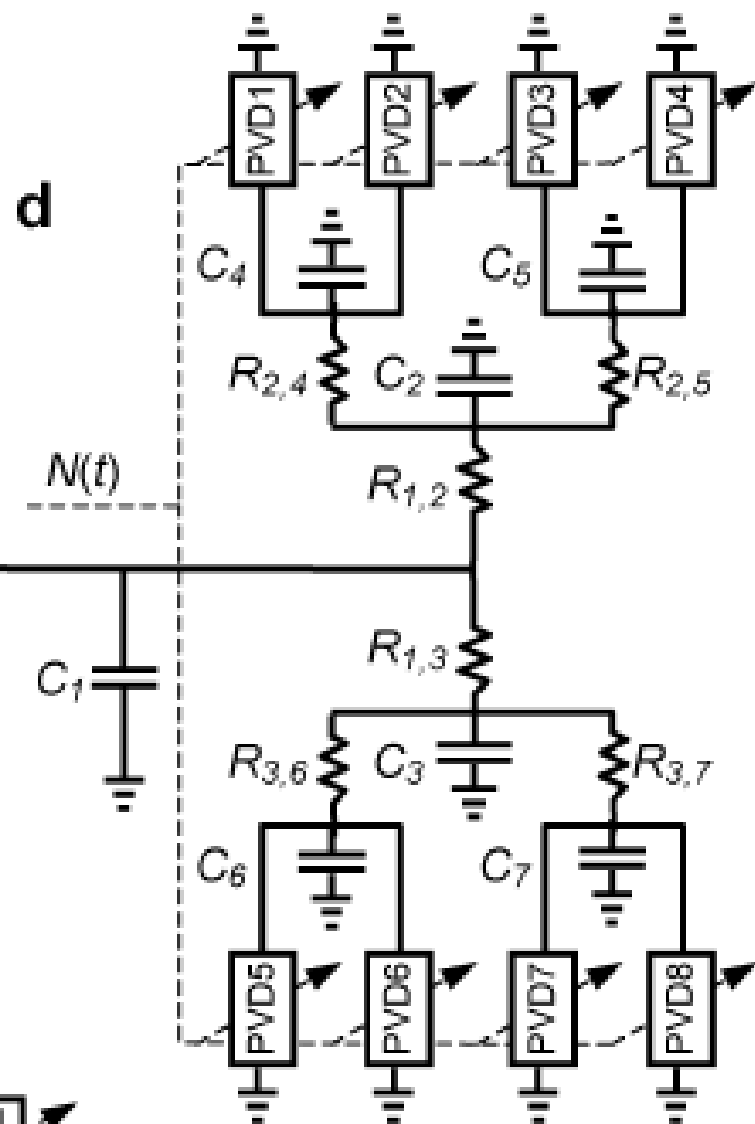
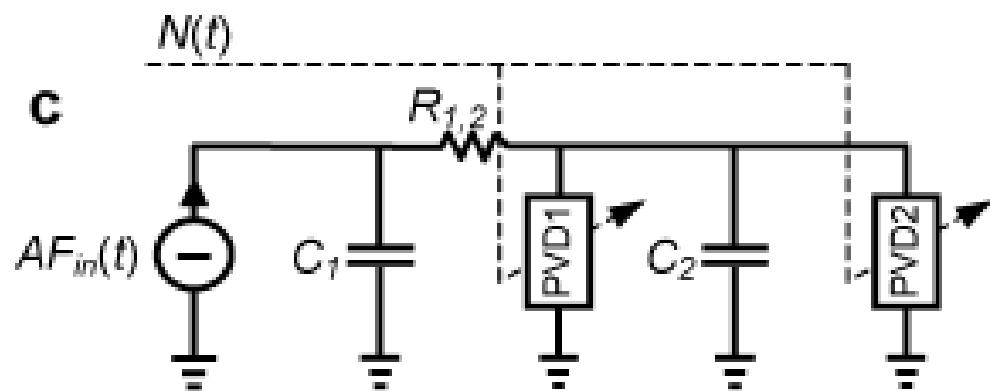
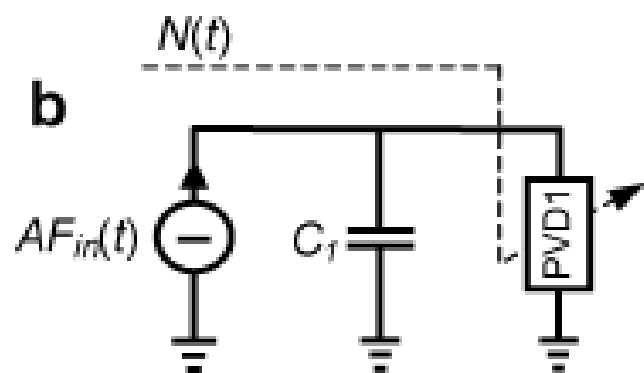
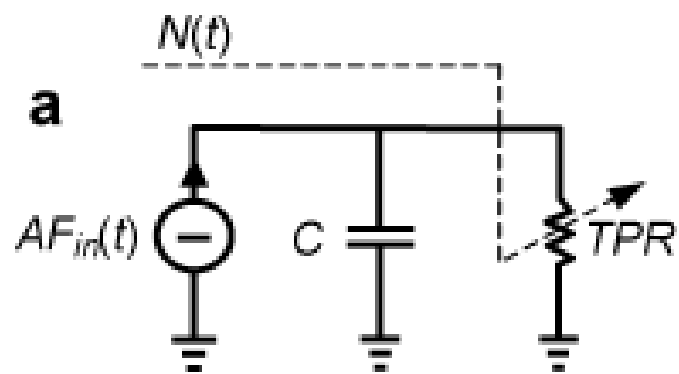
Two element



Three element



Four element



# Pulsation Model

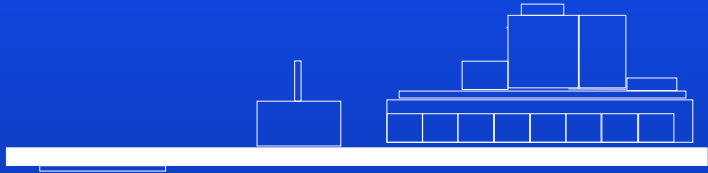
testing by approximation/orders of magnitude

- Windkessel and Resonance ?
- Biomechanical properties of brain must be a function of heart rate to maintain resonance
- Changes in flow velocity as a function of heart rate several orders of magnitude greater than MRI data
- Forces on CSF smaller by several orders of magnitude than anticipated
- Pulsation might be quite important, but none of models have elucidated any mechanism

# Problems common to all Compartment Models

- Brain is basically a balloon
- Parameters fit to anticipated result
- Little insight to pathologic process
- No “spatial” information on pressure, stress, strain, or “pulsation”





Medos Valve

Nulsen and Spitz -  
Original Ball Valve



Delta Valve

Diaphragm valve



Orbis Sigma



Horizontal Vertical  
Valve

Anti-siphon  
device

# 750 Hydrocephalus Valves Tested in Vitro and a Review on 691 Tests Reported in Literature

Aschoff A, Benesch C, Biedermann D, El Tajeh, Fruh K, Hashemi B, Klank A,  
Ludwig J, Oikonomou J,

## Conclusions

1. There are at least **1448** independently tested valves; unfortunately many studies seem to be unknown to most neurosurgeons and even the authors of "Shunt-Books".

The quality of methods and reliability ranges between class I - III. An increasing number of tests meets class I, in the last decade > 50%.

There is no major review, metaanalysis, Cochrane-study or data-bank of results. However, the publications of the U.K. Shunt Evaluation Group and own papers may be first steps (Aschoff 95).

2. Official tests (ASTM, ISO, shunt companies) are too short, ignore common potentially disturbing factors and include failures in test methodology (ASTM = class III, ISO = class II).

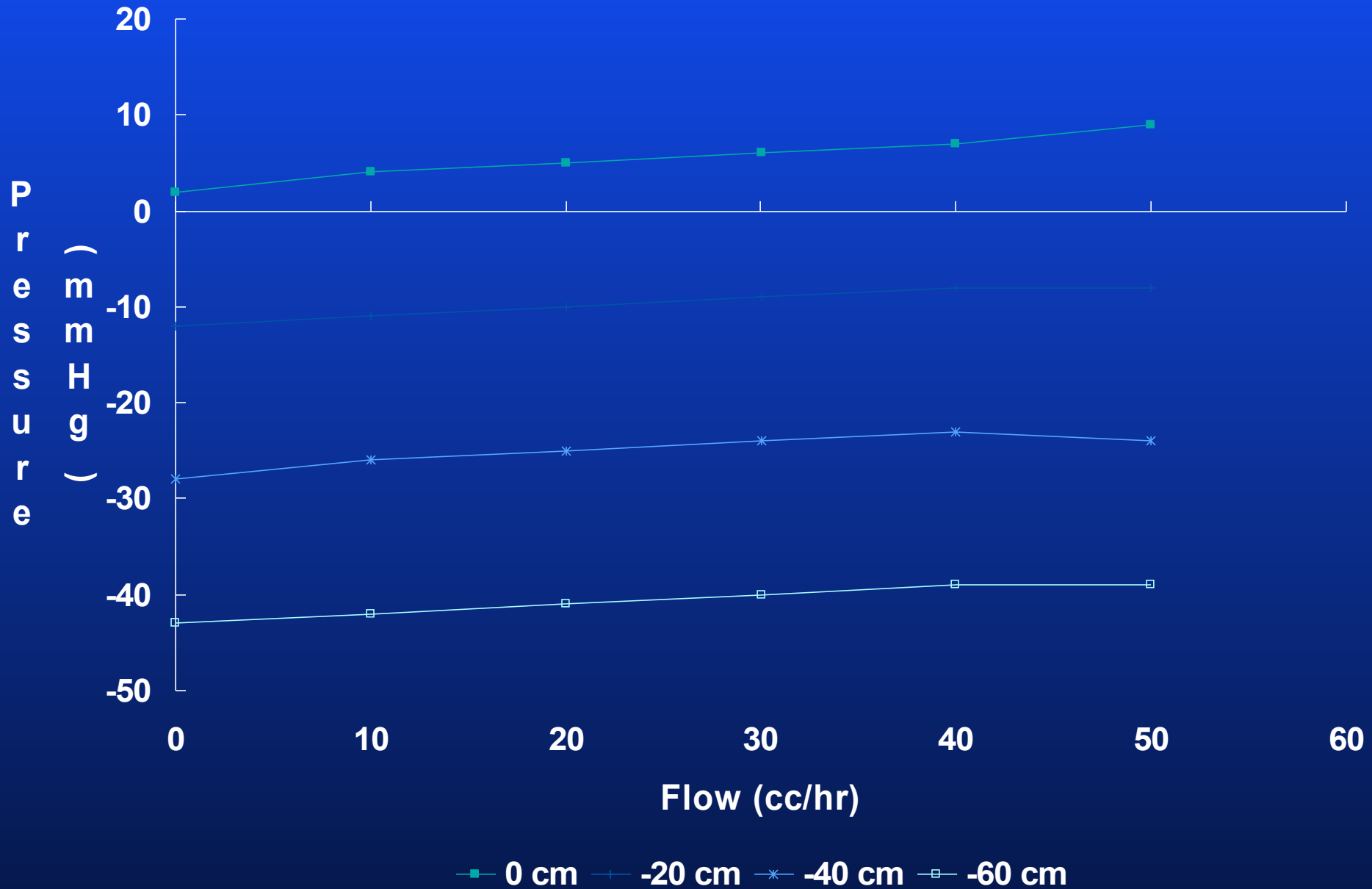
3. Of 148 valves on the world market **10** are well-investigated (statistically sufficient sample size, class I-, long-term-, safety tests). Approx. 40% have **never** been tested independently, in 50% we have only anecdotal data.

4. Many valves showed deficits in accuracy, long-term-stability, and safety, the vast majority presented adequate flow-rates in either the upright or horizontal positions only, not in both.

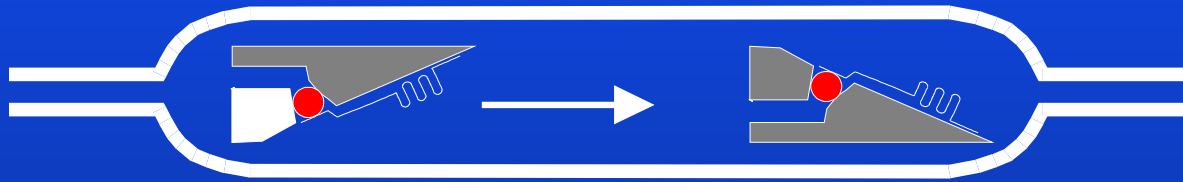
5. The evident clinical success in approx. 80% of cases, despite poor shunt technology, may be attributed to the enormous adaptability of the patients and not to valves.

6. "Smart" shunts are not a "Mission Impossible", but up to now ignored by most neurosurgeons and even shunt experts.

# CSF Shunt Tubing

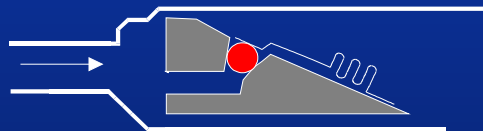


# Standard Differential Pressure Valve

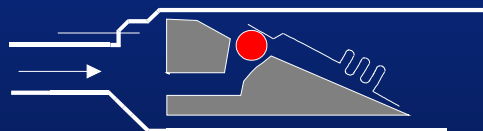


## Mechanism

### Spring-Ball Valve

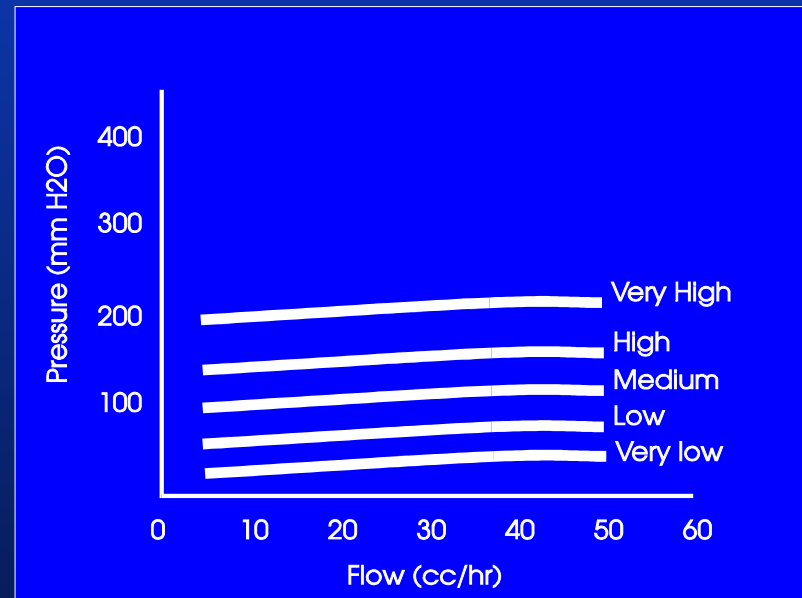


Valve Closed



Valve Open

## Pressure Flow Characteristics



mobile  
diaphragm



## LOW RESISTANCE

External Pressure -  
Atmospheric  
Internal Pressure - Positive

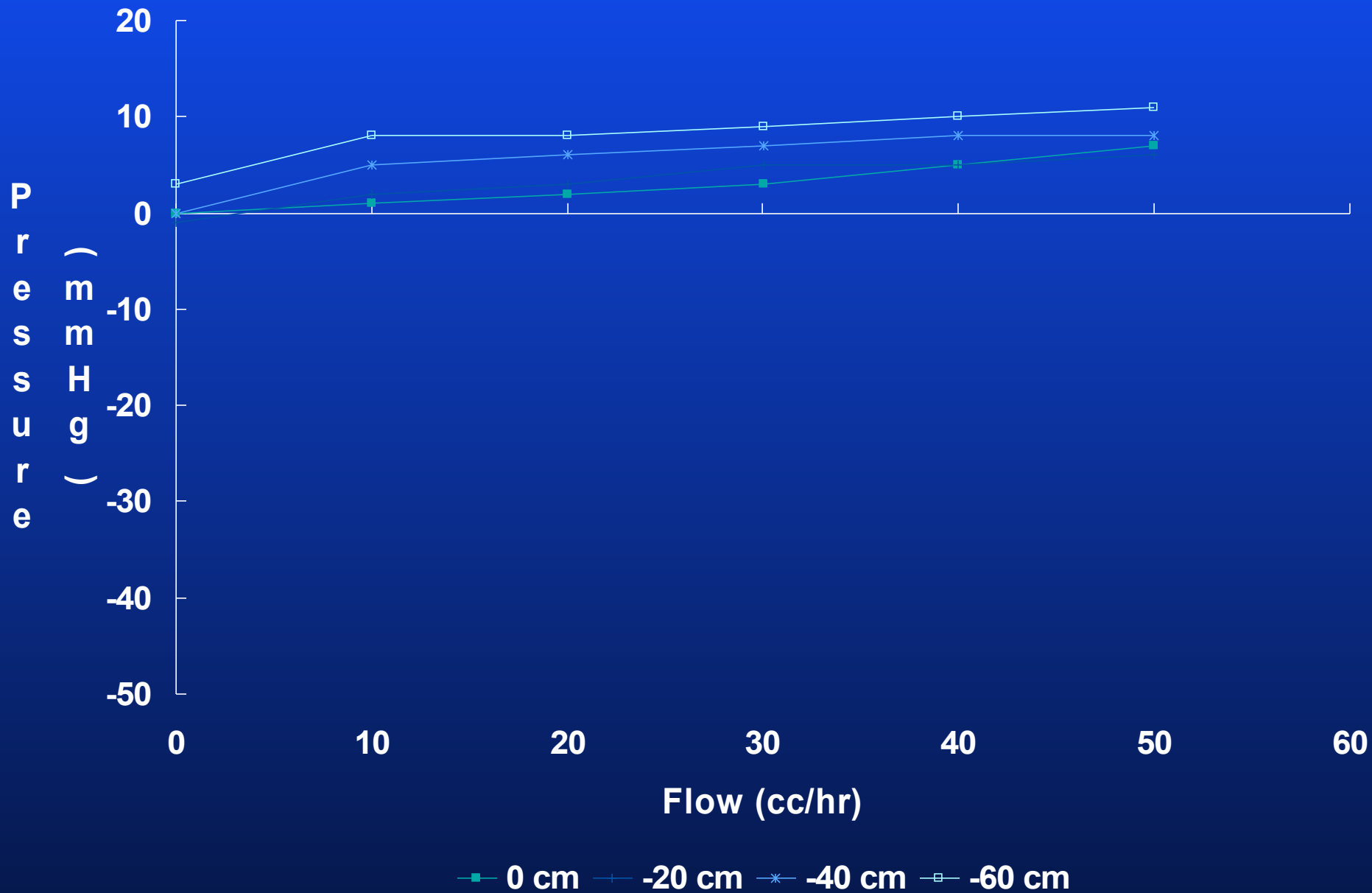
## HIGH RESISTANCE

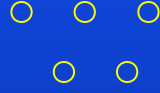
External Pressure - Atmospheric  
Internal Pressure - Negative  
(siphoning)

## HIGH RESISTANCE

External Pressure - Positive (Tissue  
Capsule)

# PS Medical ASD

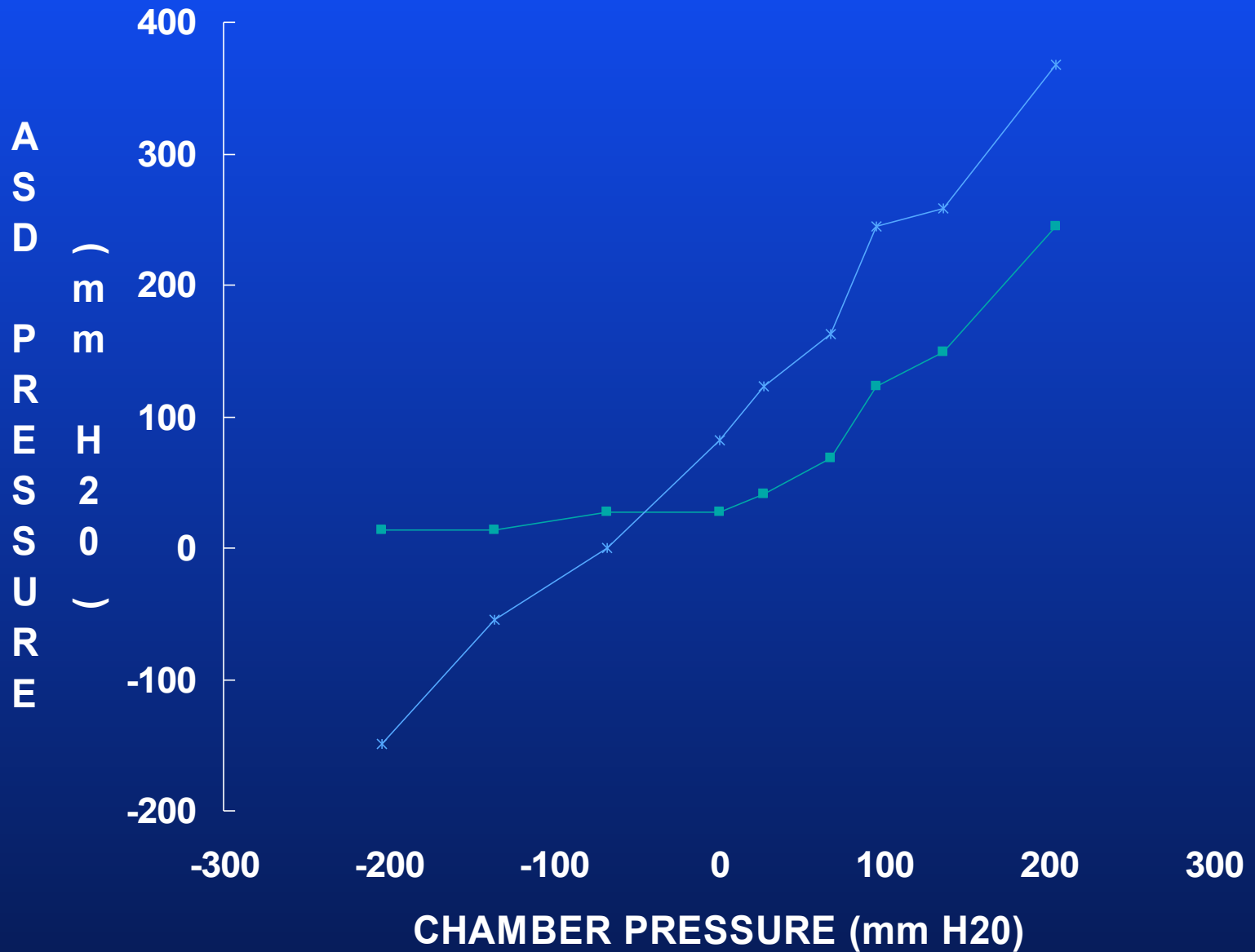




P  
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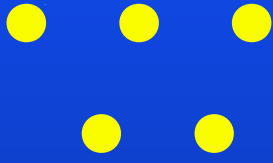
0 2 0 4 0 3 0

# ASD PRESSURE vs CHAMBER



(Flow Rate = 10)





— r t e p o c s o — — c o o  
e r e s e r p

o e 0 4 0 2 C

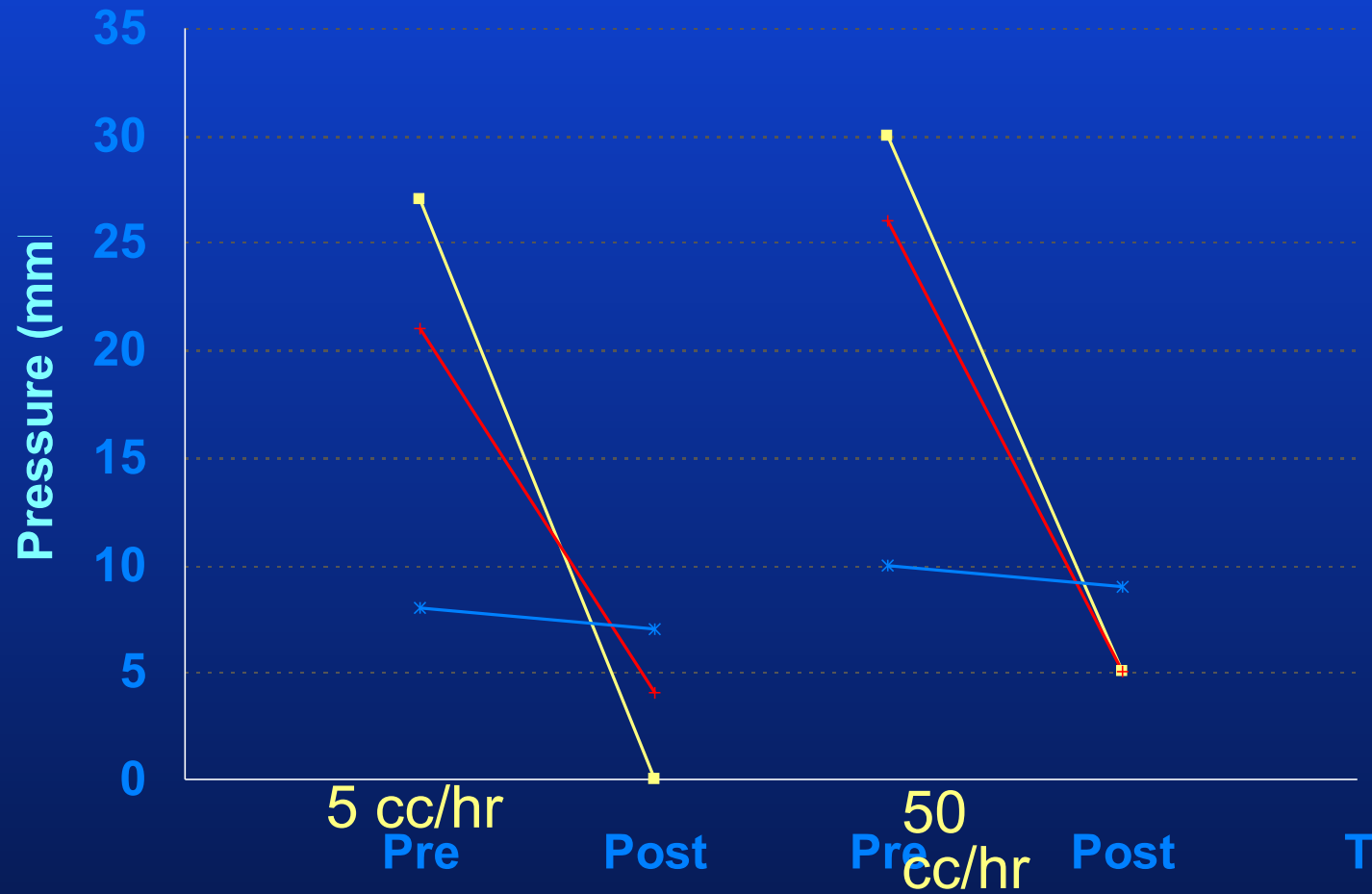
c c n c n c

# Average Change Infusion Pressure Post ASD Implantation



# Anti-siphon Device Pressure

Pre and Post Capsule Release

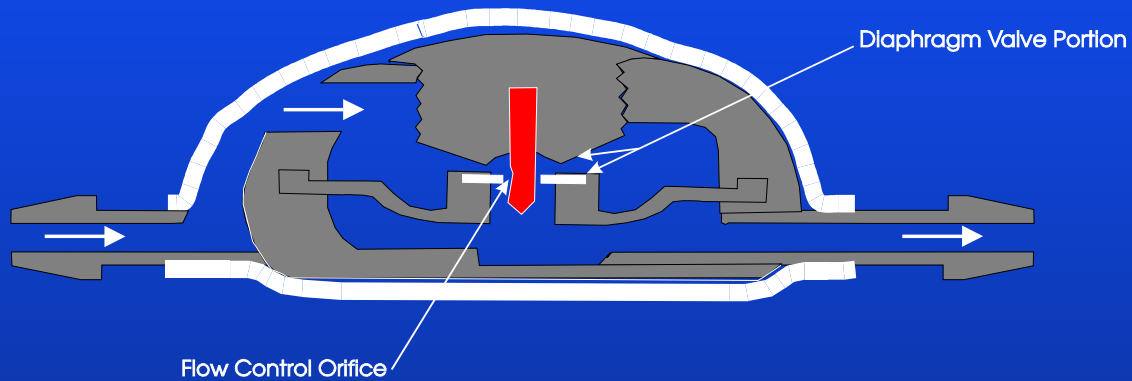


# Tonsillar herniation: the rule rather than the exception after lumboperitoneal shunting in the pediatric population

**PAUL D. CHUMAS, M.B., F.R.C.S.(ED), DEREK C. ARMSTRONG, M.D., F.R.C.P.(C),  
JAMES M. DRAKE, M.B.,B.CH., F.R.C.S.(C), ABHAYA V. KULKARNI,  
HAROLD J. HOFFMAN, M.D., F.R.C.S.(C), ROBIN P. HUMPHREYS, M.D., F.R.C.S.(C),  
JAMES T. RUTKA, M.D., F.R.C.S.(C), AND E. BRUCE HENDRICK, M.D., F.R.C.S.(C)**

*Divisions of Neurosurgery and Neuroradiology, The Hospital for Sick Children, University of Toronto,  
Toronto, Ontario, Canada*

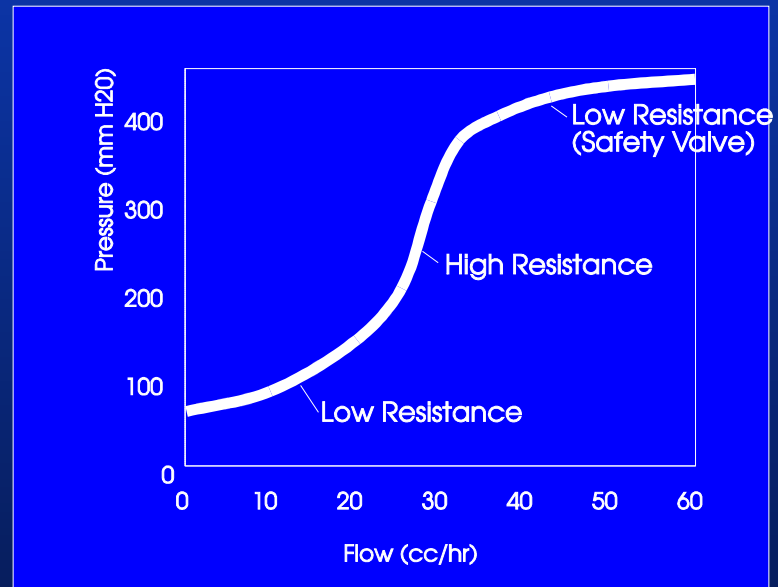
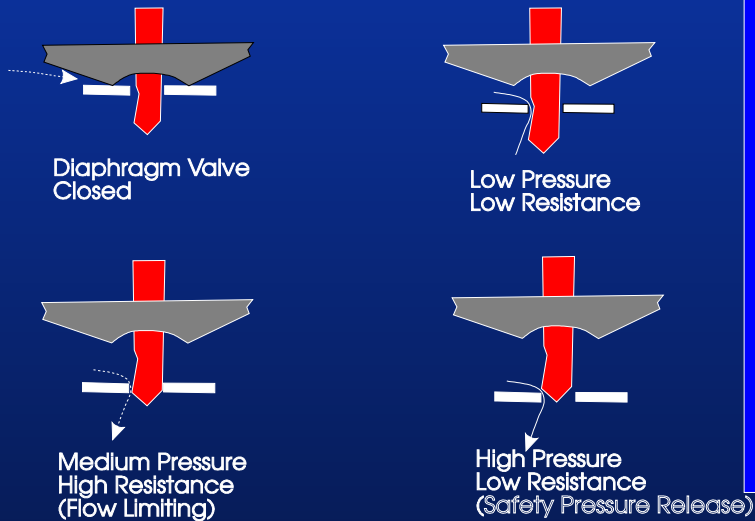
# Cordis Orbis Sigma



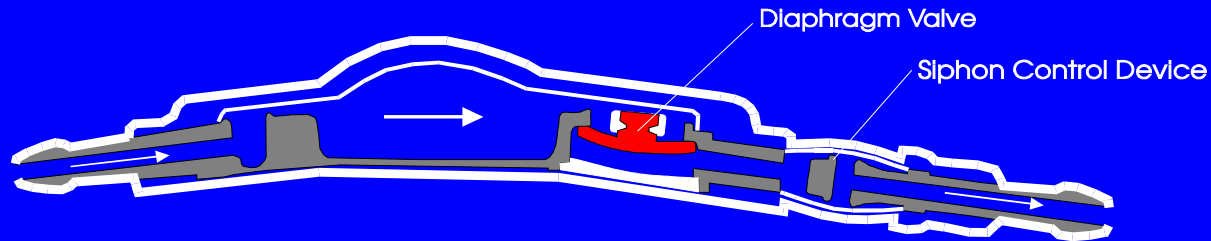
## Mechanism

## Pressure Flow Characteristics

### Variable Resistance Valve

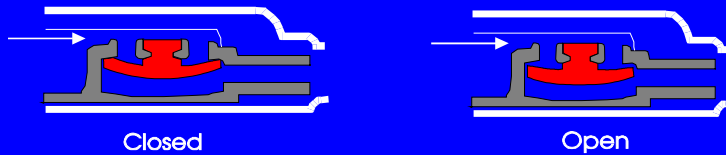


# PS Medical Delta Valve



## Mechanism

### Diaphragm Valve



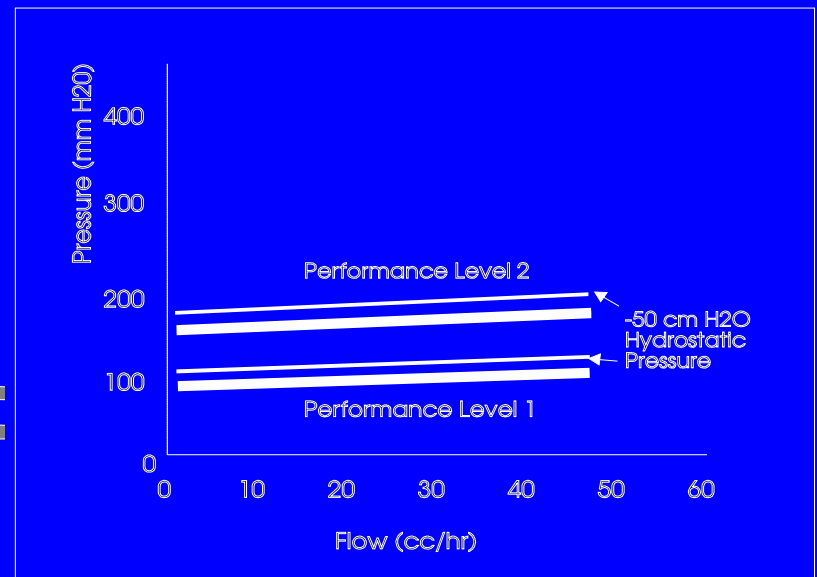
### Siphon Control Device (SCD)



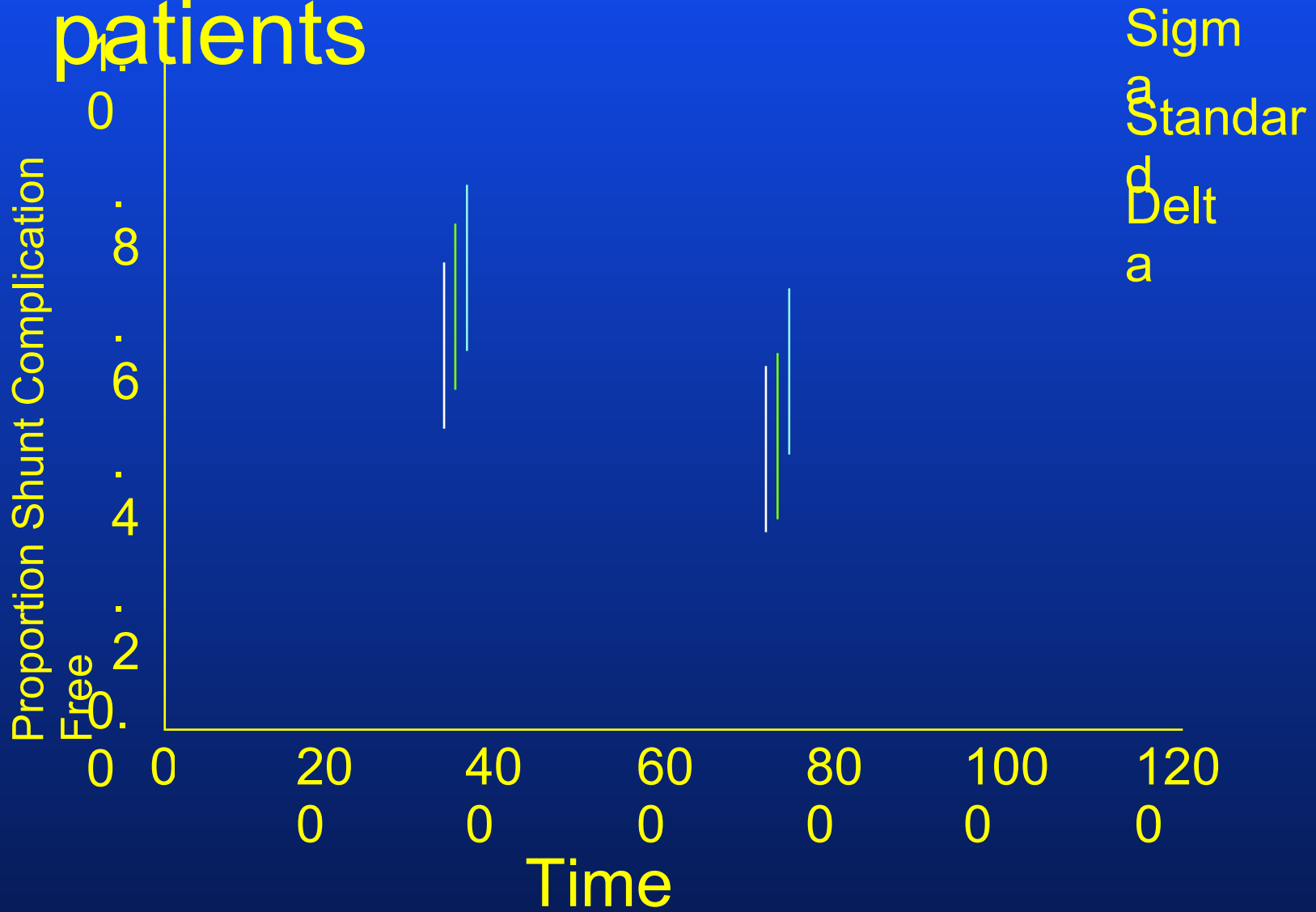
Positive Pressure  
Diaphragm Open  
Low resistance

Negative Pressure  
Diaphragm Closed  
High Resistance

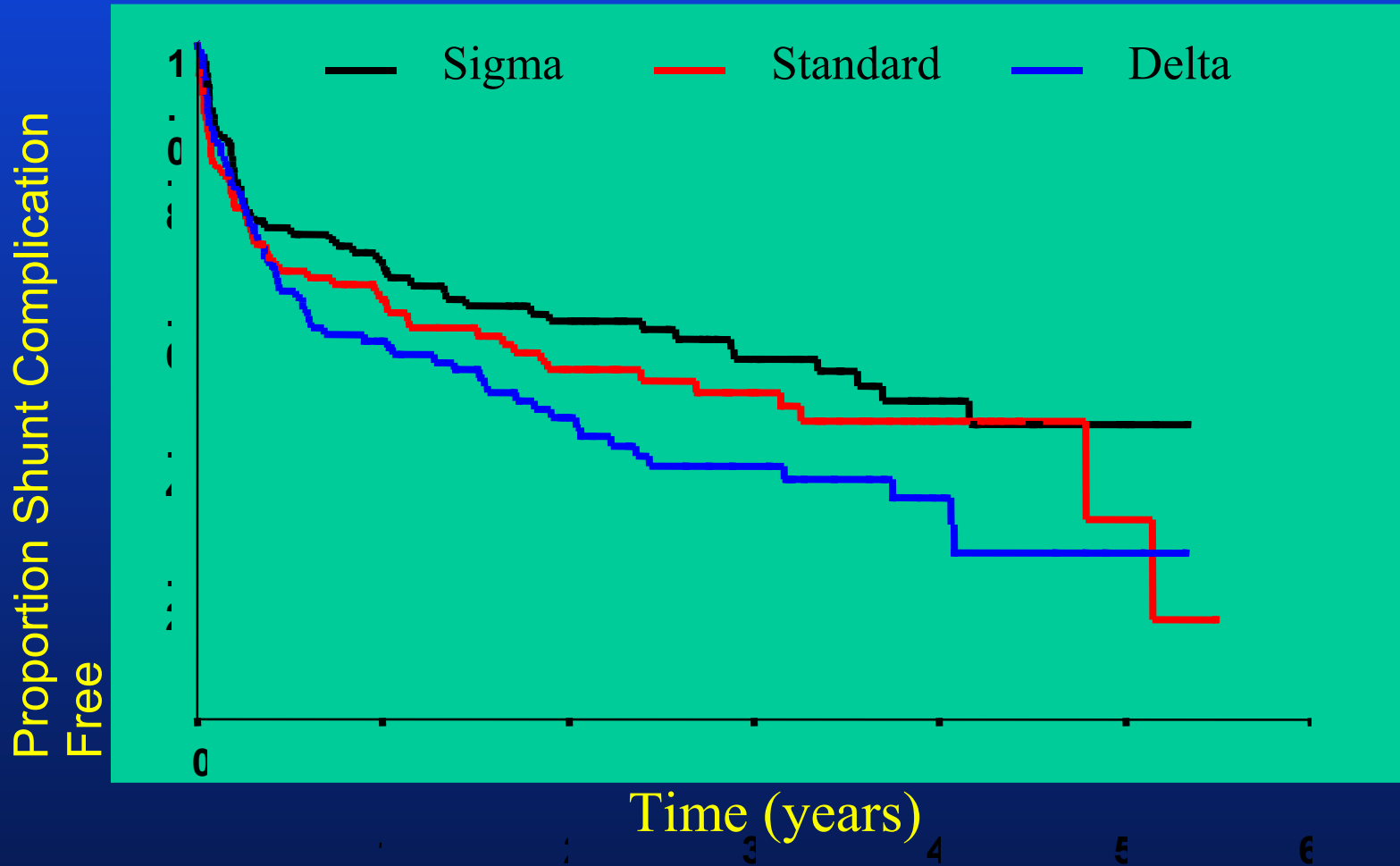
## Pressure Flow Characteristics



# Shunt Design Trial - 344 patients



# Shunt Design Trial - Long term follow up





## Secondary outcomes: location of obstruction

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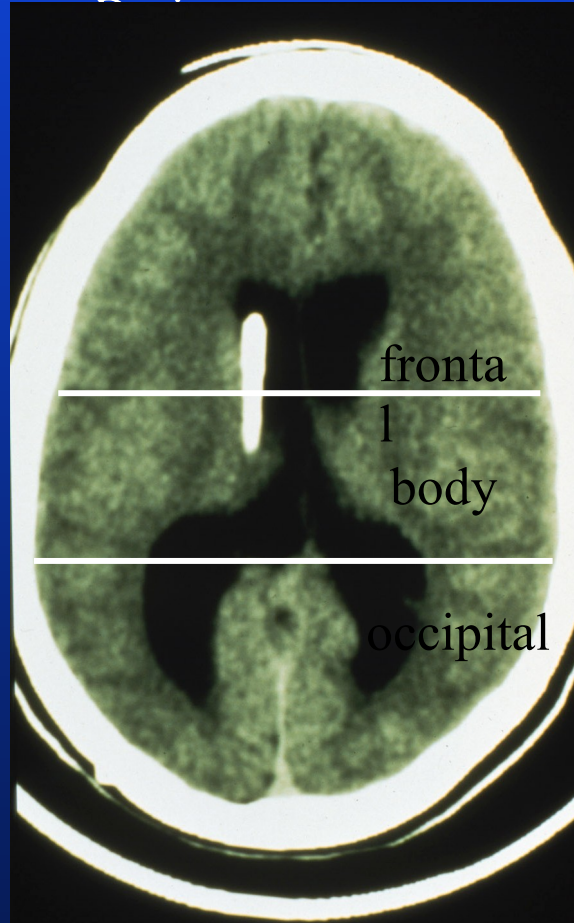
	<b>Delta (38)</b>	<b>Standard (39)</b>	<b>Sigma (31)</b>
<b>Ventricular catheter</b>	<b>16</b>	<b>18</b>	<b>2</b>
<b>Valve</b>	<b>2</b>	<b>5</b>	<b>8</b>
<b>Distal</b>	<b>2</b>	<b>1</b>	<b>5</b>
<b>Peritoneal catheter</b>	<b>5</b>	<b>2</b>	<b>2</b>
<b>Migration, Disconnection, Fracture</b>	<b>3</b>	<b>7</b>	<b>7</b>
<b>Unknown</b>	<b>10</b>	<b>6</b>	<b>7</b>

# Imaging Analysis Shunt Design Trial

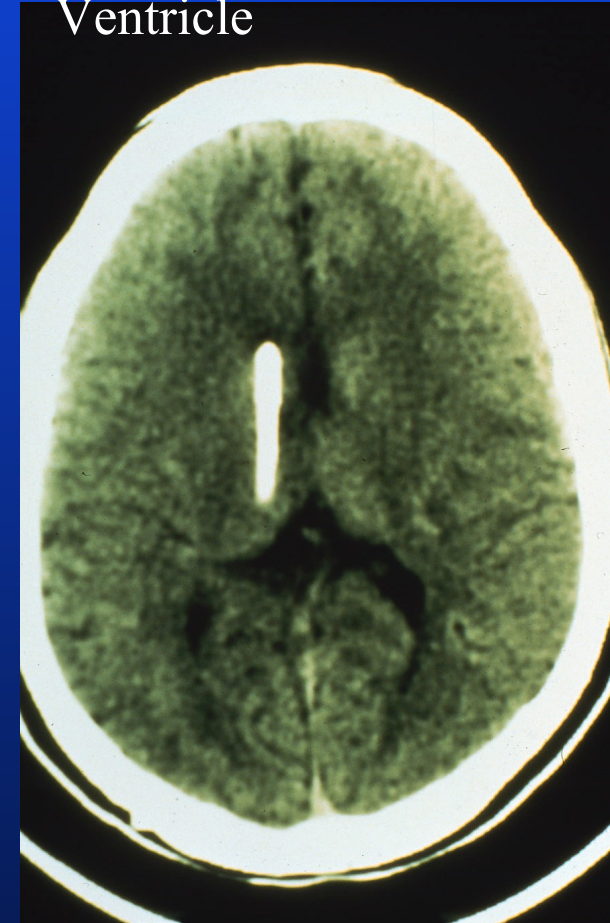
Surrounded by  
CSF



Touching



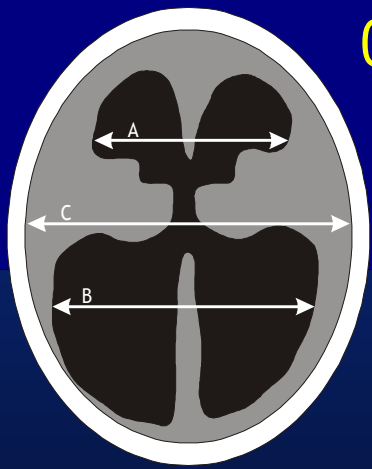
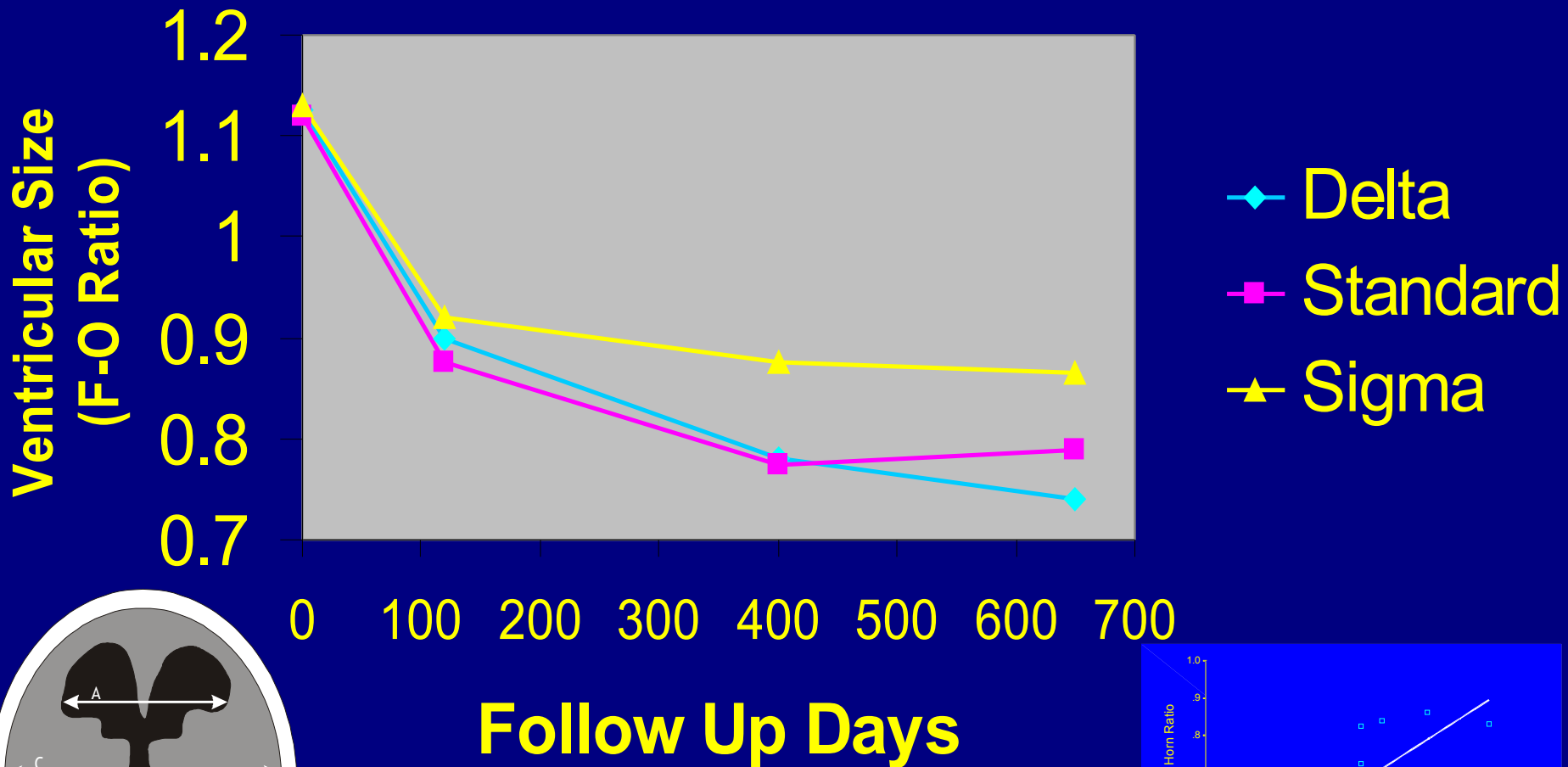
Surrounded by  
Ventricle



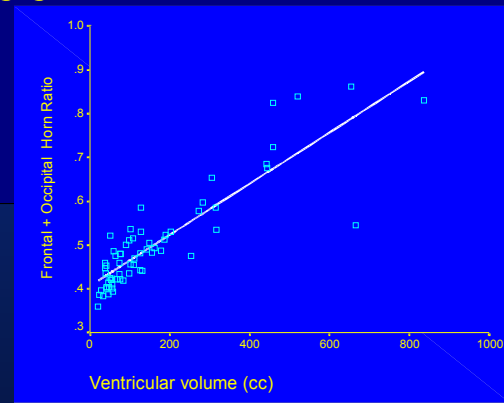
\* Failure scans

1 1 1

# Ventricular Size By Valve



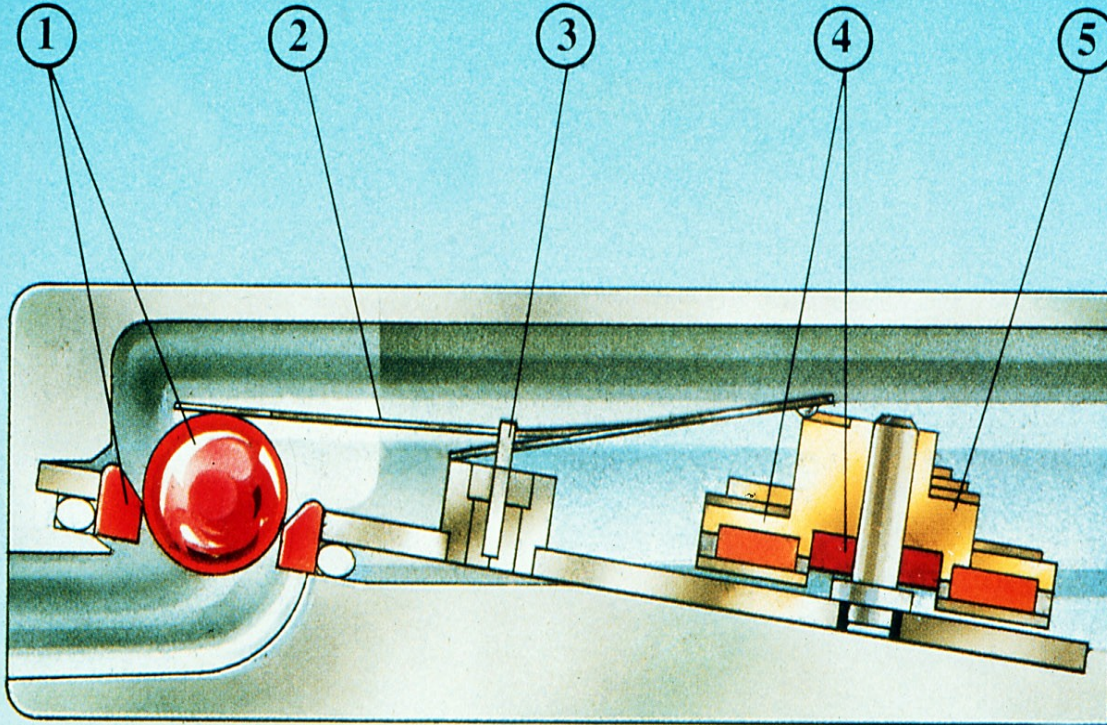
$$F-O \text{ Ratio} = (A+B)/2C$$



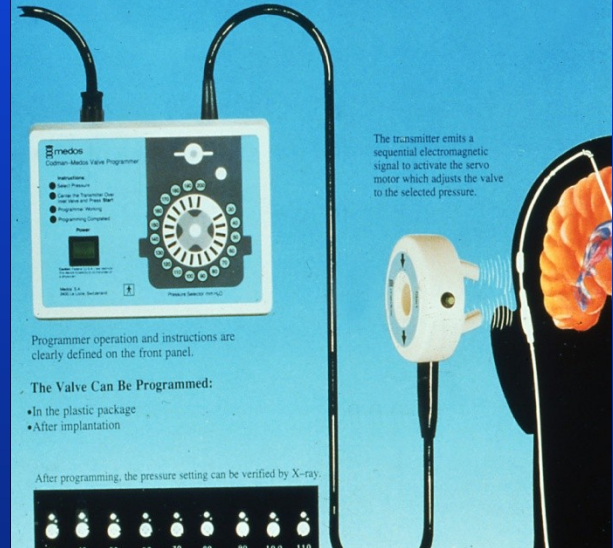
Bench Testing  $\cong$  In Vivo Performance

Bench Testing  $\neq$  Clinical  
Outcome

# Medos Adjustable (programmable) valve



Noninvasive Programmability plus the Reliability of the Hakim Mechanism.



The transmitter emits a sequential electromagnetic signal to activate the servo motor which adjusts the valve to the selected pressure.

Programmer operation and instructions are clearly defined on the front panel.

The Valve Can Be Programmed:

- In the plastic package
- After implantation

After programming, the pressure setting can be verified by X-ray.

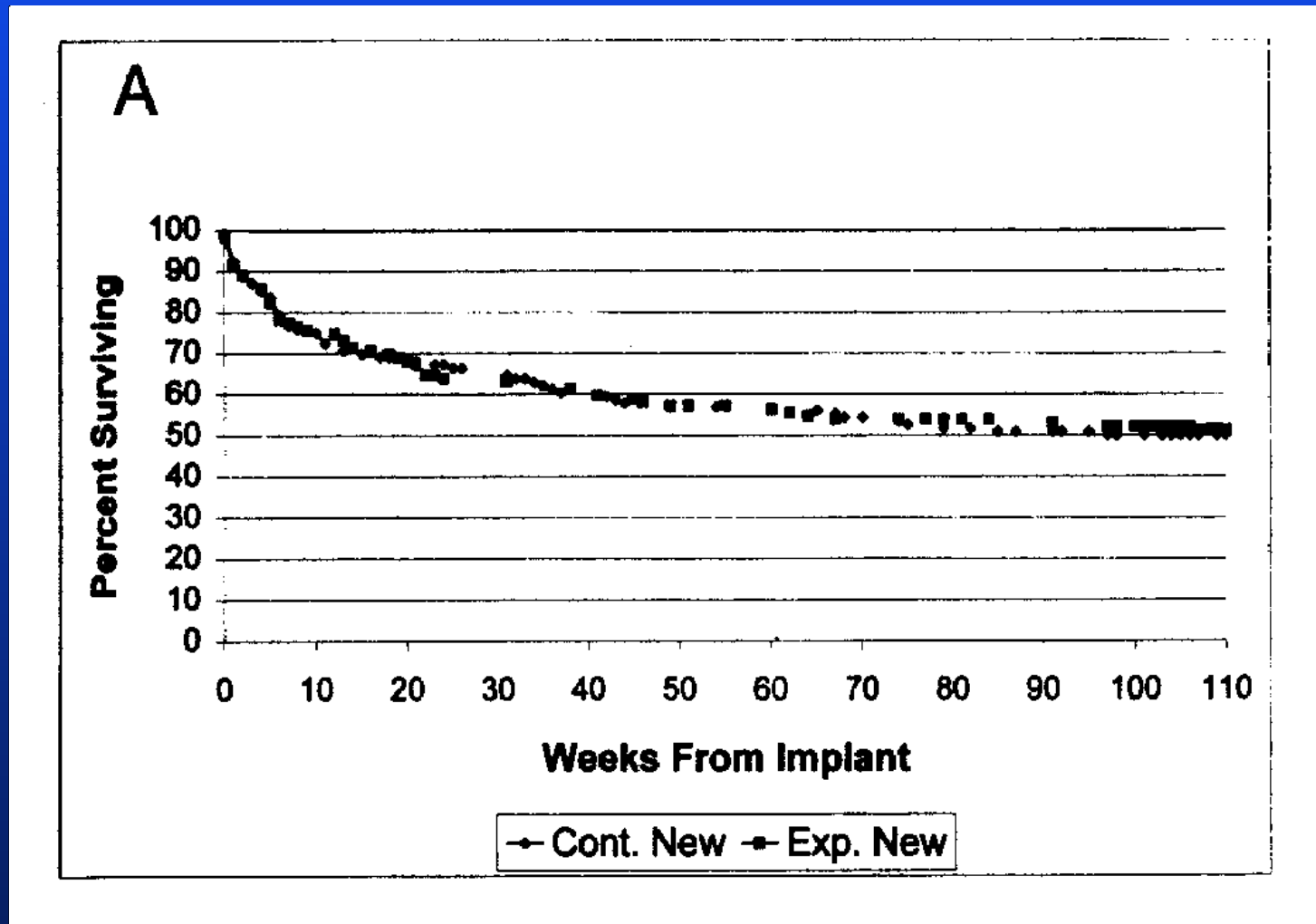


X-rays of the meter valve illustrate the sequence of the of the cam, indicating the programmed pressure setting mm of H<sub>2</sub>O.



Procedure for adjusting valve

# Medos Trial - Prospective, randomized, 377 patients

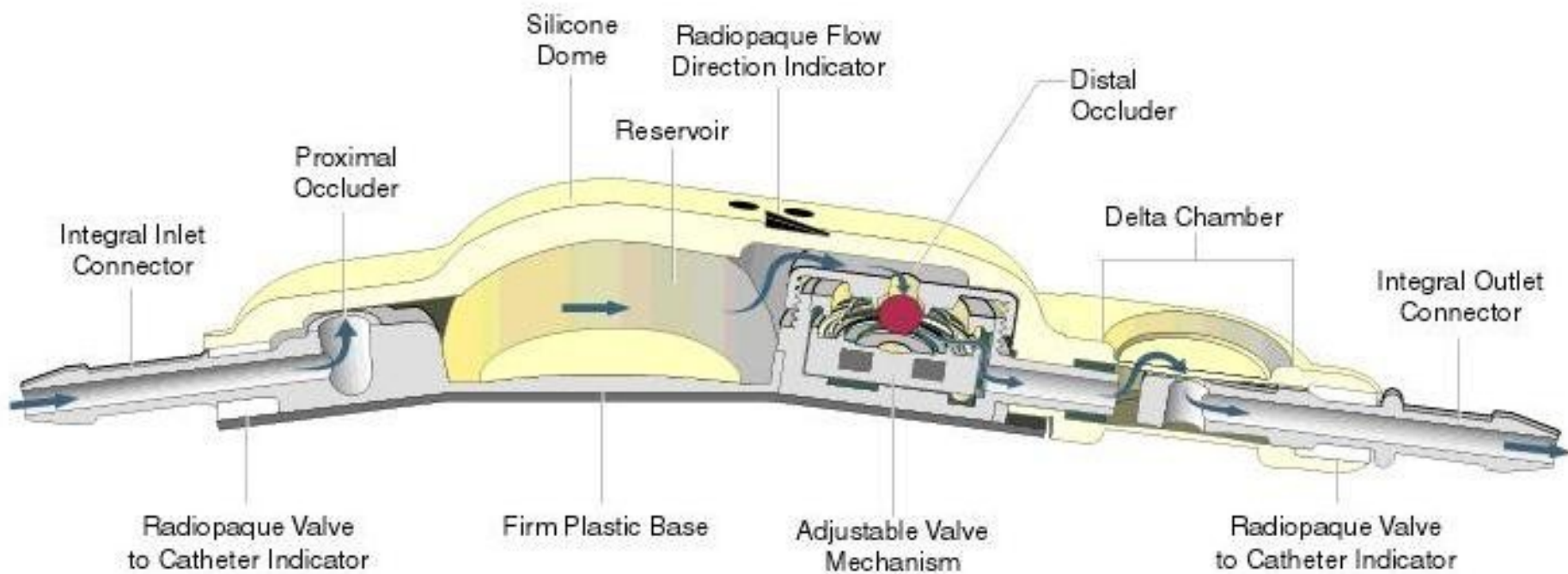
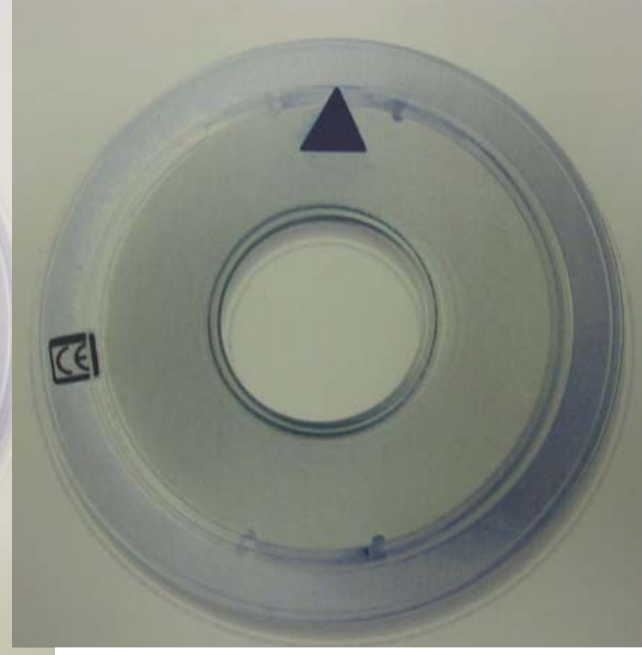


# Alteration of the pressure setting of a Codman-Hakim programmable valve by a television.

Utsuki S, Shimizu S, Oka H, Suzuki S, Fujii K.

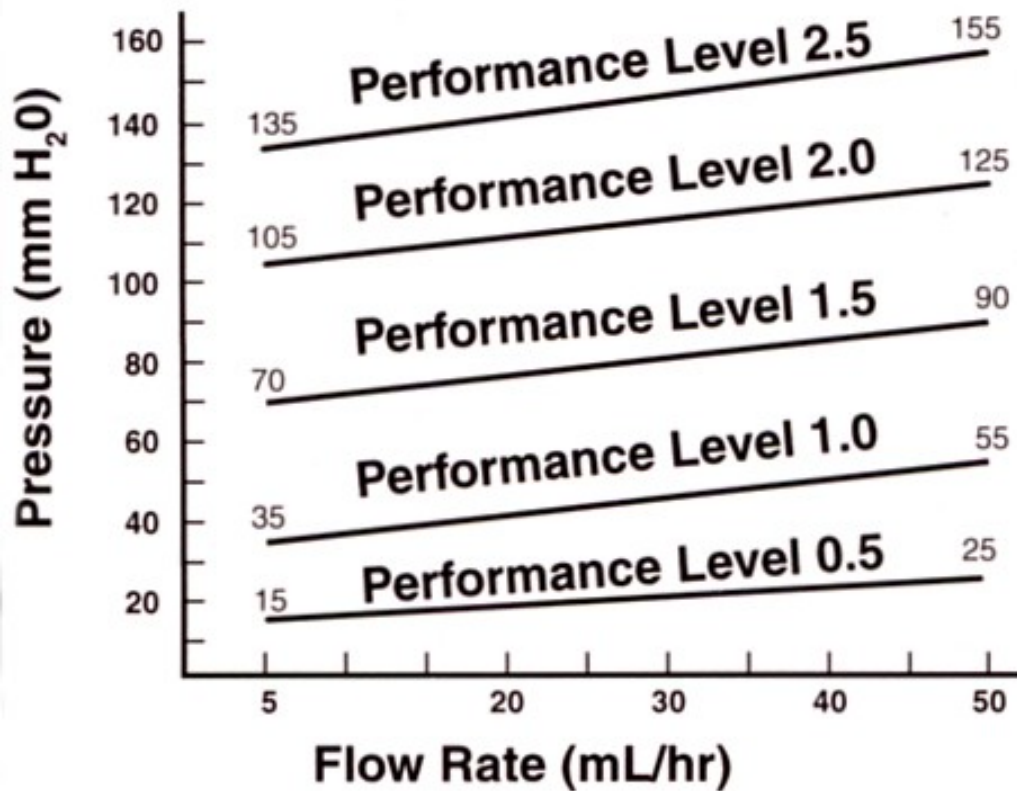
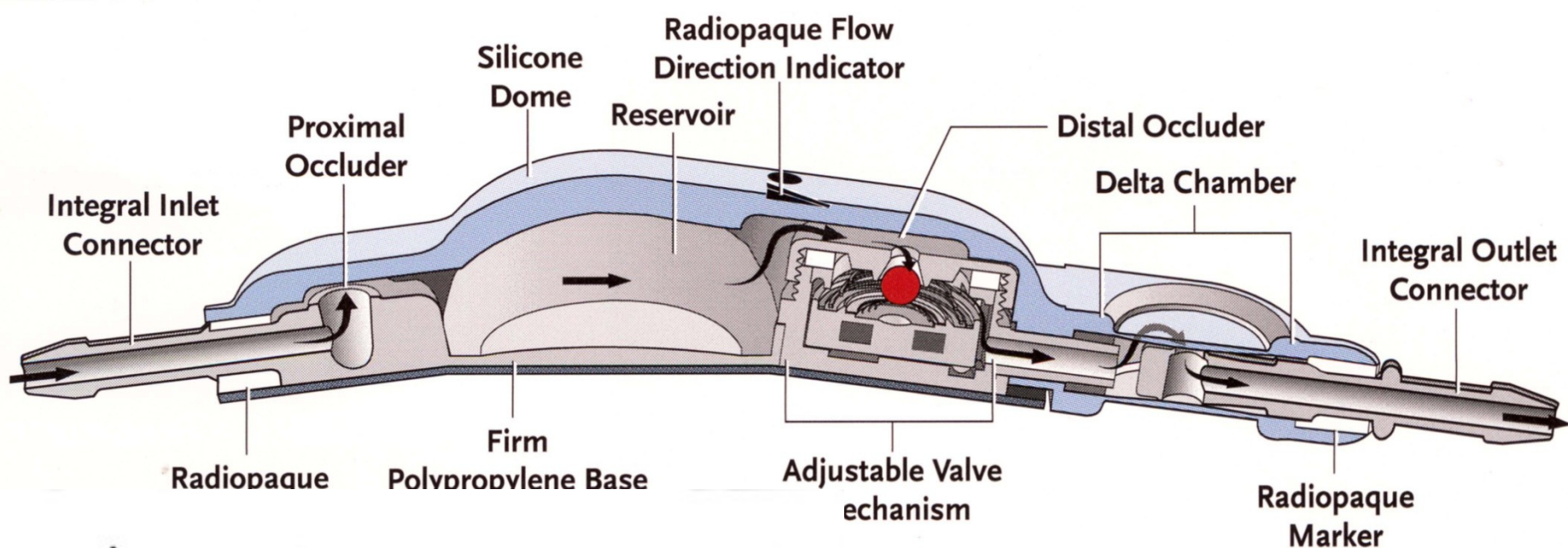
A 7-year-old girl presented in semicomatose condition. She had received a ventriculoperitoneal shunt using a Codman-Hakim programmable valve. Head computed tomography demonstrated hydrocephalus and head radiography showed that the pressure setting of the shunt valve had changed to 60 mmH(2)O from 40 mmH(2)O. The pressure setting was returned to 40 mmH(2)O, and she was discharged because her clinical symptoms and hydrocephalus improved. One month later, she lost consciousness again and was transported to our hospital. Hydrocephalus and shunt valve pressure of 50 mmH(2)O were noted, and the pressure setting was returned to 40 mmH(2)O again. She was discharged without complications. We suspected that the valve pressure was caused by close contact with a television, because the patient tended to touch a television with her head during play. The valve pressure did not change after the television was placed on a high stand out of reach. We should recognize that there are many sources of weak magnetic fields that may influence a programmable valve in everyday life.

Neurol Med Chir (Tokyo). 2006 Aug;46(8):405-7







STRATA Adjustable Valve





# Shunt survival – Core group Strata Valve



-  Sigma
-  Differential pressure
-  Codman Hakim programmable
-  Delta

**Adjustment and malfunction of a programmable valve after exposure to toy magnets. Case report.**

**Anderson RC, Walker ML, Viner JM, Kestle JR.**

Inadvertent adjustments and malfunctions of programmable valves have been reported in cases in which patients have encountered powerful electromagnetic fields such as those involved in magnetic resonance imaging, but the effects of small magnetic fields are not well known. The authors present a case in which a child playing with a collection of commercially available toy magnets altered the pressure setting of an implanted valve and may have caused its permanent malfunction.

J Neurosurg. 2004 Nov;101(2 Suppl):222-5

# The Diamond & Diamond II Valve



**Finally,**  
**a flow regulating shunt designed to restore physiologic balance of CSF flow and pressure.**

- ▶ Works to control flow in conjunction with CSF production
- ▶ Flow begins at low pressures and is maintained within physiologic limits over a broad range of pressures
- ▶ Provides physiologic pressure regulation regardless of patient position or activity

### Featuring...

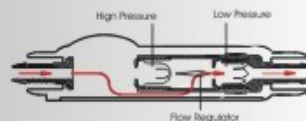
**Flow Regulation: the physiologic answer to CSF shunting**

*Non-metal parts which eliminate artifacts when using today's modern imaging technology*

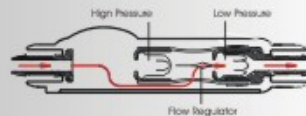
*Calibration of valves with pulsed fluid to more closely replicate in-vivo physiologic conditions*

*Two physiologic flow rates suitable for adult or pediatric patients.*

At low pressure (20 - 60 mm) the performance of the valve is controlled by the low pressure valve.



In the mid range (60 to 170 standard or 60 to 220 "A" model) the flow regulating mechanism responds to pressure to control flow.



At high pressures (170 + standard or 220 "A" model) the high pressure valve provides progressive pressure relief to prevent hypertension.



P.O. Box 80390  
 Valley Forge, PA 19484  
 610 539-9300 800 462-2563 Fax: 610 539-9333  
 Email: [sales@vygonus.com](mailto:sales@vygonus.com)  
 web page: <http://www.vygonneuro.com>

**Laboratory evaluation of the phoenix CRx diamond valve. Czosnyka ZH, Czosnyka M, Richards HK, Pickard JD. Neurosurgery. 2001 Mar;48(3):689-93; discussion 693-4. Links United Kingdom Shunt Evaluation Laboratory, Academic Neurosurgical Unit, Addenbrooke's Hospital, Cambridge, England. zc200@medschl.cam.ac.uk**

OBJECTIVE: To assess the long-term hydrodynamic properties of a new cerebrospinal fluid flow-regulating hydrocephalus shunt called the CRx Diamond valve (Phoenix Biomedical Corp., Valley Forge, PA). METHODS: Three samples of a Diamond valve were tested in the United Kingdom Shunt Evaluation Laboratory during a 40-day period. Tests were performed for long-term pressure-flow performance, overdrainage, susceptibility to ambient temperature changes, external pressure, reflux, presence of small particles in the reagent, mechanical durability, and magnetic resonance imaging compatibility. RESULTS: Tests demonstrated that the Diamond valve stabilized flow within the range of 0.36 to 0.62 ml/min when pressure varied from 14 to 23 mm Hg. Hydrodynamic resistance demonstrated pressure-dependent variability from 20 to 78 mm Hg/(ml/min). The time drift of hydrodynamic parameters was significant ( $P < 0.001$ ). The valve was insensitive to changes in temperature, external pressure, rapid fluctuations of differential pressure, small particles in fluid, and reflux. CONCLUSION: The Diamond valve demonstrated the intended variable resistance, which increased as the pressure increased. This property may help it limit overdrainage related to body posture as well as nocturnal vasogenic waves. Flow through the valve stabilizes within a wide range, which may contribute to the prevention of excessive pressure buildup after implantation. However, shunt placement should be avoided in patients who present with normal baseline intracranial pressure but an increased incidence of high vasogenic intracranial pressure waves.

**A new self-adjusting flow-regulating device for shunting of CSF. Paes N.  
Clinica de Coluna, University of Mogi das Cruzes, Tatuape, Sao Paulo, Brazil.  
Childs Nerv Syst. 1996 Oct;12(10):619-25.**

Traditional shunts were primarily designed to manage hydrocephalus by regulating intracranial pressure. However, in some circumstances, their performance characteristics can cause them to underdrain or overdrain CSF. Overdrainage has been linked with clinical complications such as valve-dependent shunt syndrome, cranial stenosis, slit-ventricle syndrome, and subdural hematomas, and it may contribute to ventricular catheter occlusion. In addition to complications associated with hypertension and ventriculomegaly, underdrainage has been linked with residual brain edema, and subcutaneous CSF effusion has been observed at the site of cranial perforation, mainly in pediatric patients. Newer designs attempt to reduce these complications, but fall short for various reasons. The author presents a new shunt design, which utilizes variable aperture technology (patent pending) that results in the physiologic regulation of CSF flow under both positive and negative pressure conditions. This new design offers encouragement for the management of hydrocephalus and the prevention of complications due to overdrainage.

# The Shunt “Rep”

## Most Telling Comment

- Me “your child needs a shunt for failed third ventriculostomy, post infectious hydrocephalus”
- Rep “Just don’t put in any of that junk that (company they formally worked for) makes”

# Miethke Dual Switch Valve

DualSwitch-Valve - Microsoft Internet Explorer

File Edit View Favorites Tools Help



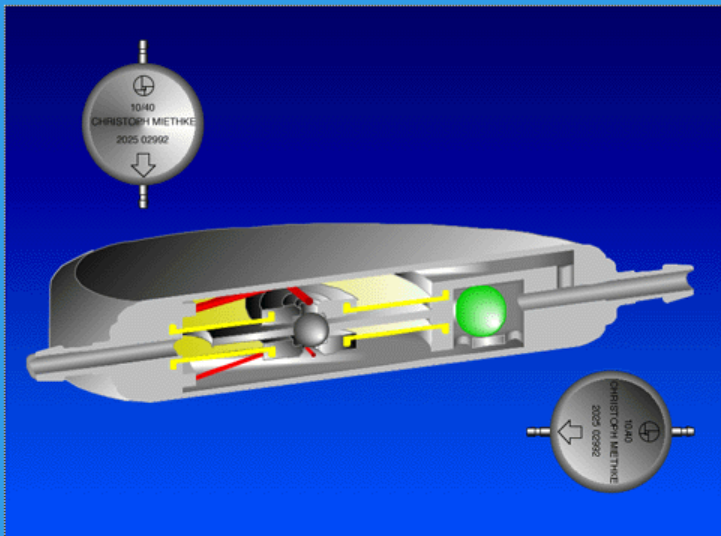
Address [http://www.miethke.com/Products/DSV\\_P1/dsv\\_p1.html](http://www.miethke.com/Products/DSV_P1/dsv_p1.html) Go Links



## DUALSWITCH-VALVE

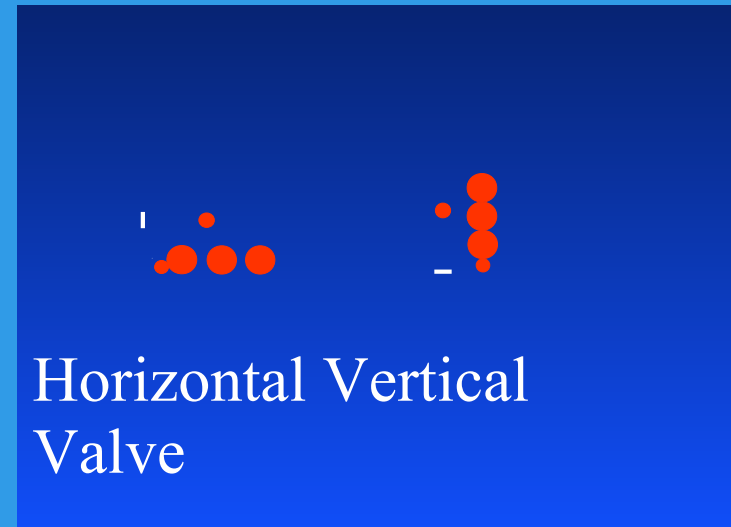
For the Treatment of Hydrocephalus

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=



Horizontal Vertical  
Valve

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for **DSV-Patients Handbook** this button





# Evaluation of three new models of hydrocephalus shunts.

Czosnyka ZH, Czosnyka M, Richards HK, Pickard JD.

Academic Neurosurgical Unit, Addenbrooke's Hospital, Cambridge, UK.

**OBJECTIVE:** To assess the hydrodynamic properties of three new types of hydrocephalus valve.

**METHODS:** Three new constructions have been recently tested in the UK shunt Evaluation Laboratory: the magnetically adjustable **Strata Valve** (Medtronic PS Medical), the gravitational **Miethke Dual-Switch Valve** (Aesculap) and the ventriculo-sinus **SinuShunt** (CSF Dynamics). Pressure-flow performance curves were assessed in a minimum of three samples of each valve to study their longterm variability, influence of temperature, negative outlet pressure, external pressure, presence of pressure pulsations, etc. **RESULTS:** The operating pressure of the Strata Valve can be adjusted magnetically in five steps. This Shunt prevents 'siphoning' but is sensitive to external pressure. The Dual Switch Miethke Valve is a system of two fixed-pressure ball-on-spring valves with a lower opening pressure operating in a horizontal body position and higher when vertical. This function is designed to cancel the effect of siphoning related to body posture. Both Strata and DSV valves have a low hydrodynamic resistance (less than 3 mm Hg/ml/min), and hence they cannot prevent overdrainage related to nocturnal vasomotor waves. The SinuShunt has a higher resistance (9 mm Hg/(ml/min)) and a lower opening pressure. The valve is intended to drain CSF from ventricles to the transverse sinus. **CONCLUSION:** New shunt technology continues to evolve. Laboratory evaluation independent of the manufacturer forms an important link between R&D laboratories and clinical practice.

Acta Neurochir Suppl. 2005;95:223-7

## Miethke Dual Switch Valve – Pub Med 22 refs

1. Meier U, Kiefer M, Neumann U, Lemcke J. Related Articles, Links  
On the optimal opening pressure of hydrostatic valves in cases of idiopathic normal-pressure hydrocephalus: a prospective randomized study with 123 patients. *Acta Neurochir Suppl.* 2006;96:358-63.
- 2: Sprung C, Miethke C, Schlosser HG, Brock M  
The enigma of underdrainage in shunting with hydrostatic valves and possible solutions. *Acta Neurochir Suppl.* 2005;95:229-35.
- 3: Czosnyka ZH, Czosnyka M, Richards HK, Pickard JD. Related Articles, Links  
Evaluation of three new models of hydrocephalus shunts. *Acta Neurochir Suppl.* 2005;95:223-7.
- 4: Meier U. Gravity valves for idiopathic normal-pressure hydrocephalus: a prospective study with 60 patients. *Acta Neurochir Suppl.* 2005;95:201-5.
- 5: Lindner D, Preul C, Trantakis C, Moeller H, Meixensberger J.  
Effect of 3T MRI on the function of shunt valves--evaluation of Paedi GAV, Dual Switch and proGAV. *Eur J Radiol.* 2005 Oct;56(1):56-9.

# The Polaris® Valve



# Dutch Normal-Pressure Hydrocephalus Study: randomized comparison of low- and medium-pressure shunts

Boon AJ, Tans JT, Delwel EJ, Egeler-Peerdeman SM, Hanlo PW, Wurzer HA, Avezaat CJ, de Jong DA, Gooskens RH, Hermans J. J Neurosurg. 1998 Mar;88(3):490-5. Links

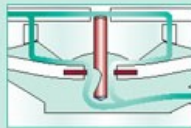
OBJECT: The goal of this prospective study was to compare outcome after placement of a low- or medium-pressure shunt in patients with normal-pressure hydrocephalus (NPH). METHODS: Ninety-six patients with NPH were randomized to receive a low-pressure ventriculoperitoneal shunt (LPV; 40 +/- 10 mm H<sub>2</sub>O) or medium high-pressure ventriculoperitoneal shunt (MPV; 100 +/- 10 mm H<sub>2</sub>O). The patients' gait disturbance and dementia were quantified by applying an NPH scale, and their level of disability was evaluated by using the modified Rankin scale (mRS). Patients were examined prior to and 1, 3, 6, 9, and 12 months after surgery. Primary outcome measures were determined by differences between preoperative and last NPH scale scores and mRS grades. The LPV and MPV shunt groups were compared by calculating both the differences between mean improvements and the proportions of patients showing improvement. Intention-to-treat analysis of mRS grades yielded a mean improvement of 1.27 +/- 1.41 for patients with LPV shunts and 0.68 +/- 1.58 for patients with MPV shunts (**p = 0.06**). Improvement was found in 74% of patients with LPV shunts and in 53% of patients with MPV shunts (**p = 0.06**) and a marked-to-excellent improvement in 45% of patients with LPV shunts and 28% of patients with MPV shunts (**p = 0.12**). All outcome measures indicated trends in favor of the LPV shunt group, with only the dementia scale reaching significance. After exclusion of serious events and deaths unrelated to NPH, **efficacy analysis showed the advantage of LPV shunts to be diminished.** Reduction in ventricular size was also significantly greater for patients in the LPV shunt group (p = 0.009). Subdural effusions occurred in 71% of patients with an LPV shunt and in 34% with an MPV shunt; however, their influence on patient outcome was limited. CONCLUSIONS: Outcome was better for patients who had an LPV shunt than for those with an MPV shunt, although most differences were not statistically significant. **The authors advise that patients with NPH be treated with an LPV shunt.**

# SURGICAL MANAGEMENT OF IDIOPATHIC NORMAL-PRESSURE HYDROCEPHALUS

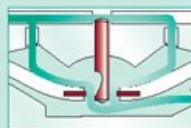
NEUROSURGERY

... The choice of valve type and setting should be based on empirical reasoning and a basic understanding of shunt hydrodynamics. The most conservative choice is a valve incorporating an antisiphon device, with the understanding that underdrainage (despite a low opening pressure) may occur in a small percentage of patients because of the antisiphon device. On the basis of retrospective studies, the use of an adjustable valve seems to be beneficial in the management of INPH.

# The Integra NPH Low Flow Valve



**Stage 1: 30-120 mm H<sub>2</sub>O**  
Differential Pressure (DP) valve.  
*Functions efficiently at low pressure to minimize under-drainage complications.*

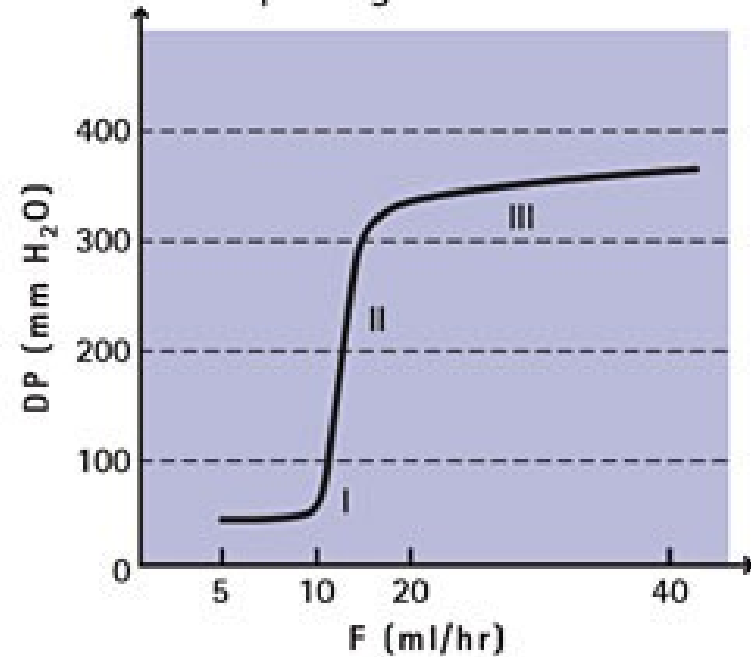


**Stage 2: 120-300 mm H<sub>2</sub>O**  
Flow Regulating valve.  
*Maintains a close balance between CSF flow and production rate.*



**Stage 3: Above 300 mm H<sub>2</sub>O**  
Safety valve.  
*Immediately restores normal ICP during unexpected pressure elevation. Rarely needed.*

## Operating Characteristics



## **Assessment of low-flow CSF drainage as a treatment for AD: results of a randomized pilot study.**

**Silverberg GD, Levinthal E, Sullivan EV, Bloch DA, Chang SD, Leverenz J, Flitman S, Winn R, Marciano F, Saul T, Huhn S, Mayo M, McGuire D.**

**OBJECTIVE:** This prospective, randomized, controlled study was designed to investigate the safety, feasibility, and preliminary efficacy of long-term CSF drainage via a low-flow ventriculoperitoneal shunt in subjects suffering from AD. **METHODS:** Twenty-nine subjects selected for probable AD (National Institute of Neurological and Communicative Diseases and Stroke-Alzheimer's Disease and Related Dementias Association criteria) were screened to exclude normal pressure hydrocephalus or other etiologies of dementia and randomized to treatment (shunt) or no treatment groups. The study endpoint was the comparison of group performance on psychometric testing at quarterly intervals for 1 year. Shunted subjects had CSF withdrawn for MAP-tau and Abeta((1-42)) assays at the same time intervals. **RESULTS:** There was no mortality from the surgical procedure, and no patient sustained a subdural hematoma. Five notable postoperative adverse events, which resolved without permanent neurologic deficit, were reported in the shunt group. Group mean Mattis Dementia Rating Scale total scores showed little change over the year in the shunt-treatment group, in contrast to a decline in the control group ( $p = 0.06$ ). Mini-Mental State Examination mean scores supported a trend in favor of shunt treatment ( $p = 0.1$ ). There was a concomitant decrease in ventricular CSF concentrations of AD biomarkers MAP-tau and Abeta((1-42)). **CONCLUSIONS:** The surgical procedure and the device are reasonably safe. Adverse events were consistent with shunt procedures for hydrocephalus in this older population. The endpoint data show a trend in favor of the treated group. A larger, randomized, double-blinded, controlled, clinical trial is underway.

Neurology. 2002 Oct 22;59(8):1139-45

## COGNIShunt® System for Alzheimer's Disease

**This study has been completed.**

**Sponsored by:**

**Eunoe**

**Information provided by:**

National Institute on Aging (NIA)

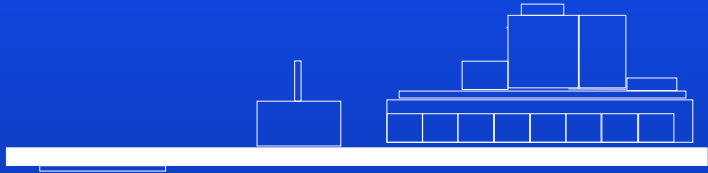
**ClinicalTrials.gov Identifier:**

NCT00056628

Based on the encouraging preliminary data, Eunoe entered into a pivotal study that eventually recruited 215 patients at 22 sites. On December 8, 2003, enrollment to the **study was halted** by the company based on the results of a planned interim analysis.

On June 14, 2004, the **study was closed** based on the results of the second interim analysis which showed that the difference between treatment groups for the MDRS, while still favoring the COGNIShunt group, was less than that of the first interim analysis.





Medos Valve

Nulsen and Spitz -  
Original Ball Valve



Diaphragm valve



Delta Valve

Anti-siphon  
device

Orbis Sigma



Horizontal Vertical  
Valve



# Valve Design Cycle

- Innovation often based on concept of improved “physiological function”
- Exciting early results
- Failure of Efficacy on prospective evaluation
- Unanticipated Consequences

# Shunt Technology

- Balls
- springs
- diaphragms
- slit valves



- Implanted sensors
- communications interface
- microprocessor control
- MEMS technology

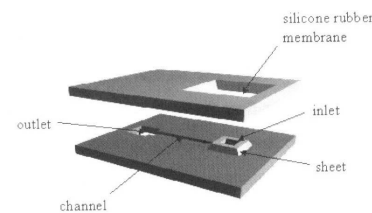
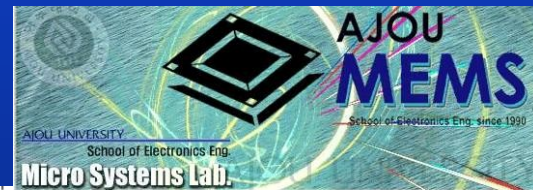
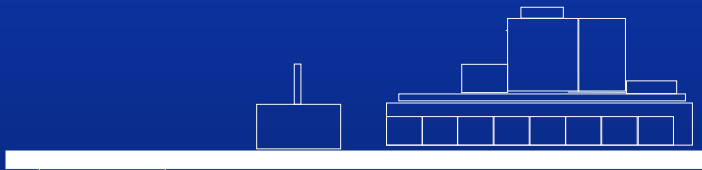


Fig. 11. The structure of the micro valve.

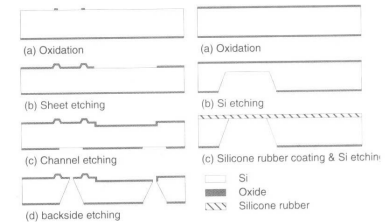


Fig. 12. The fabrication process of the micro valve.

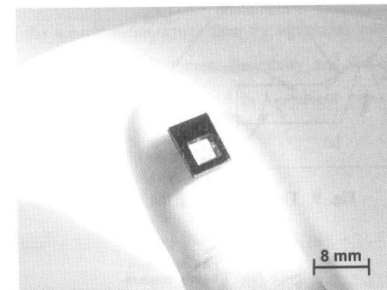
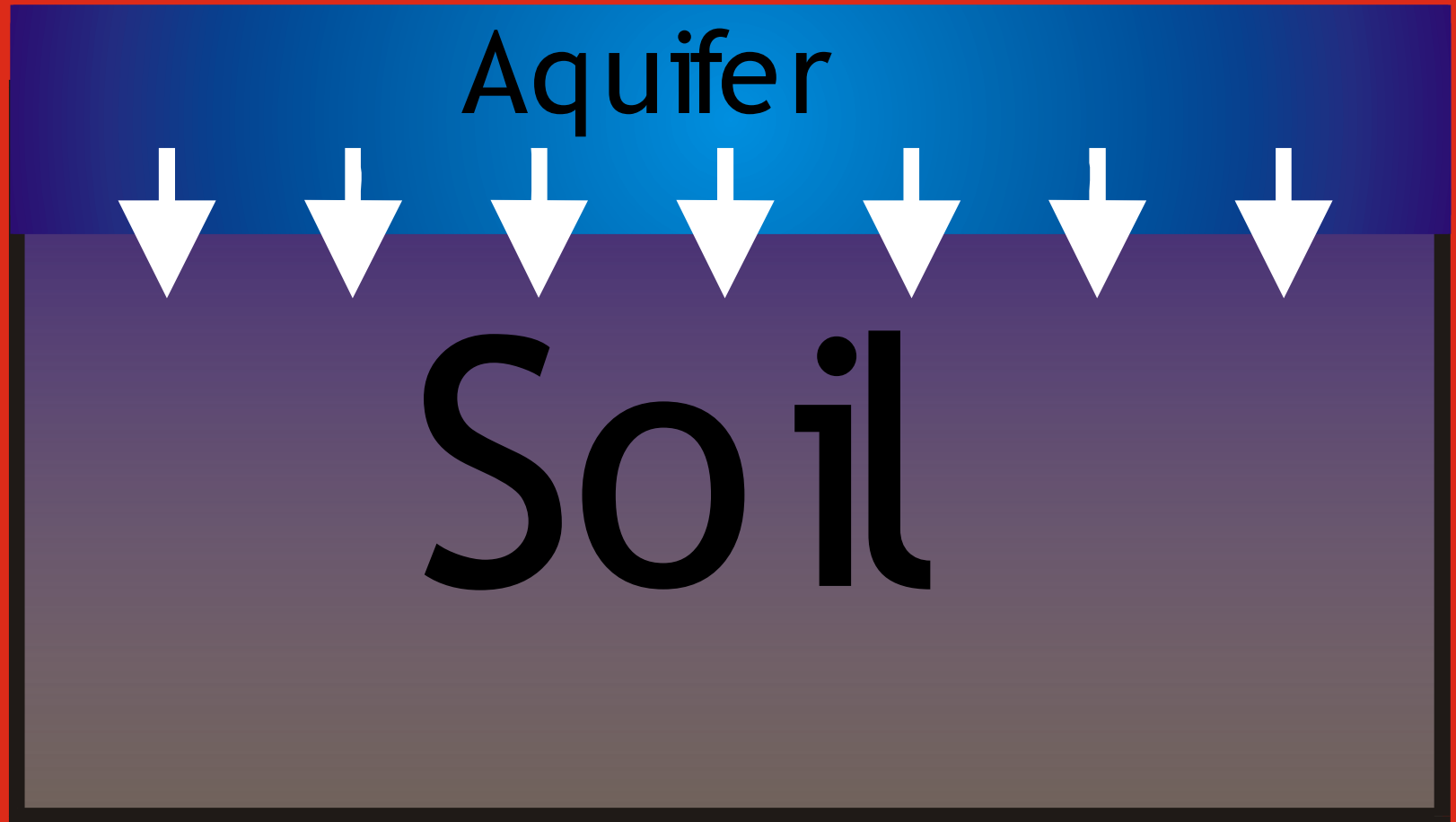


Fig. 13. The photograph of the fabricated micro valve.

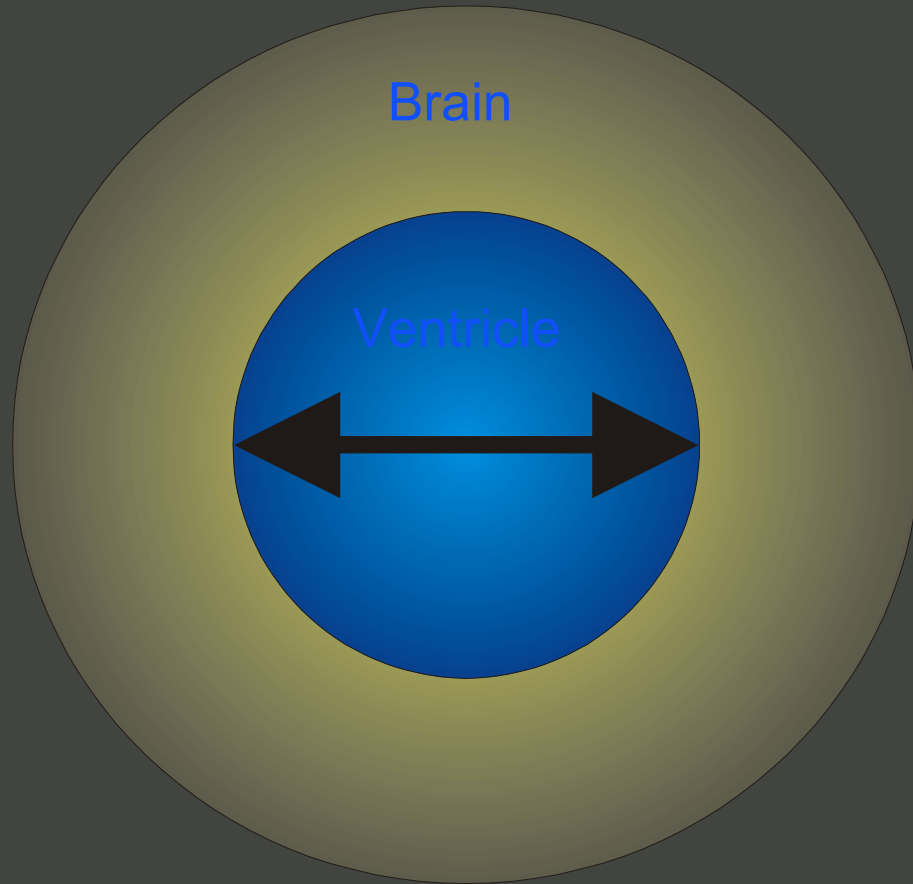
# Consolidation Models

- Brain as a saturated sponge
- Flow through porous media
- Brain has visco-elastic properties
  - Will continue to deform at same pressure
  - Will not relax to baseline when pressure dropped

# SOIL MECHANICS



# CYLINDRICAL MODEL



# Development of Model

Crucial step: Appropriate constitutive equation (stress v. strain), for instance:

(Hooke's Law)

$$\sigma_{ij} = \sum_{k=1}^3 \sum_{l=1}^3 C_{ijkl} e_{kl}$$

(General, linear elastic solid)

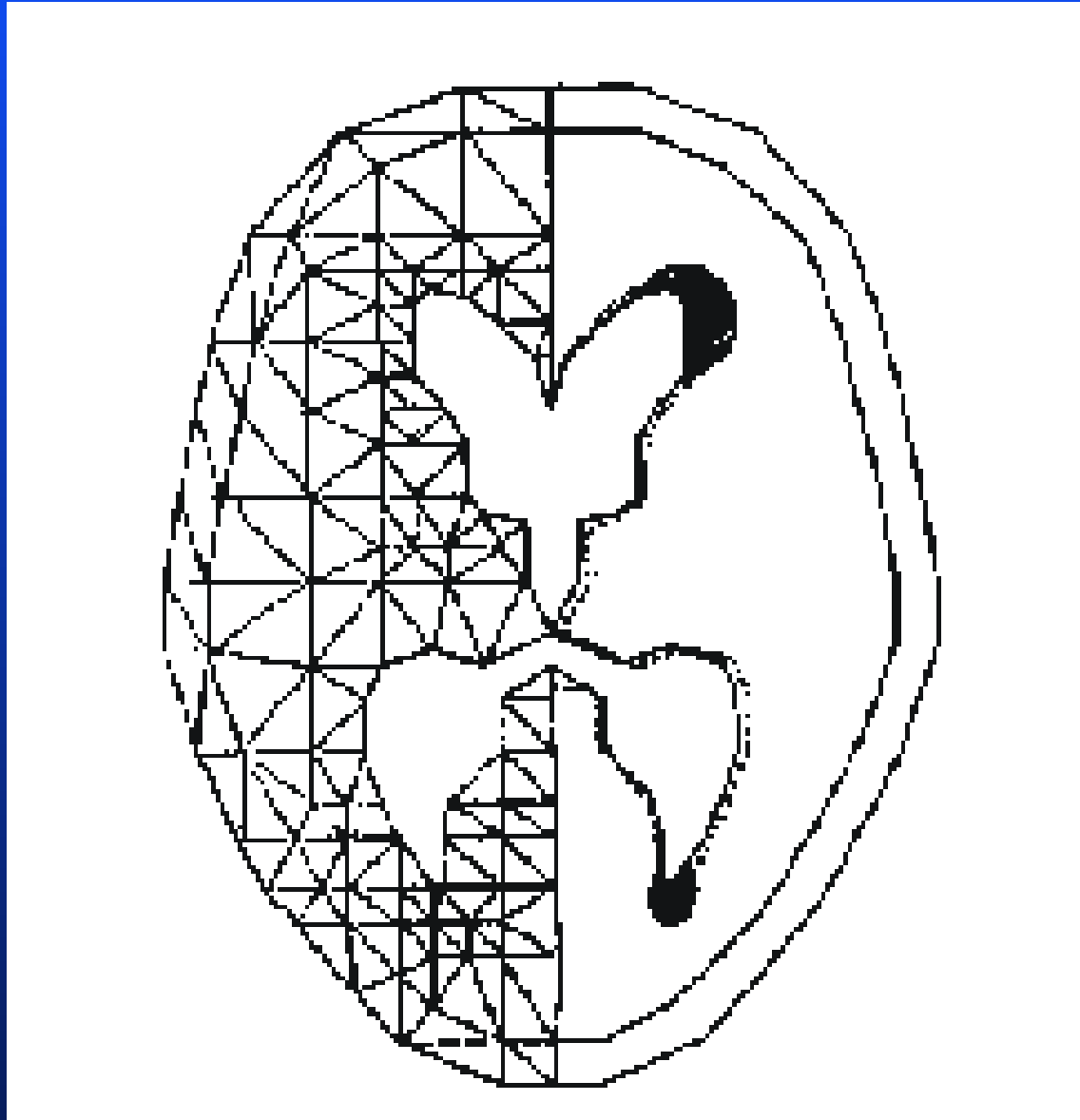
$$\sigma_{ij} = \lambda e \delta_{ij} + 2\mu e_{ij}$$

(Linear, isotropic solid)

$$\sigma_{ij}(r, t) = \int_{-\infty}^t \sum_{k,l=1}^3 G_{ijkl}(t - \tau) \frac{\partial e_{kl}}{\partial \tau}(r, \tau) d\tau$$

(Linear viscoelastic)

# Finite Element Analysis



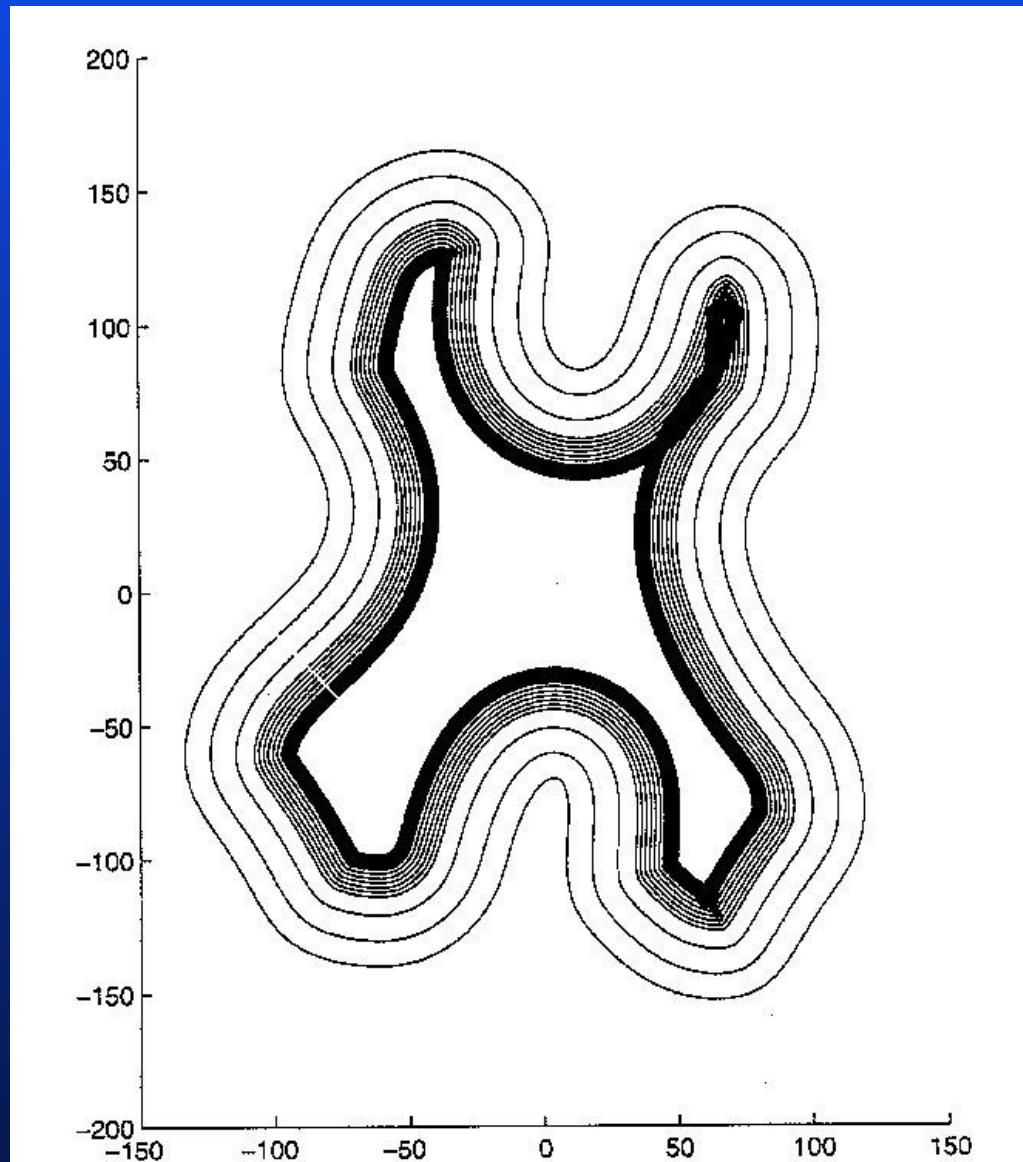
Nagashima 1990



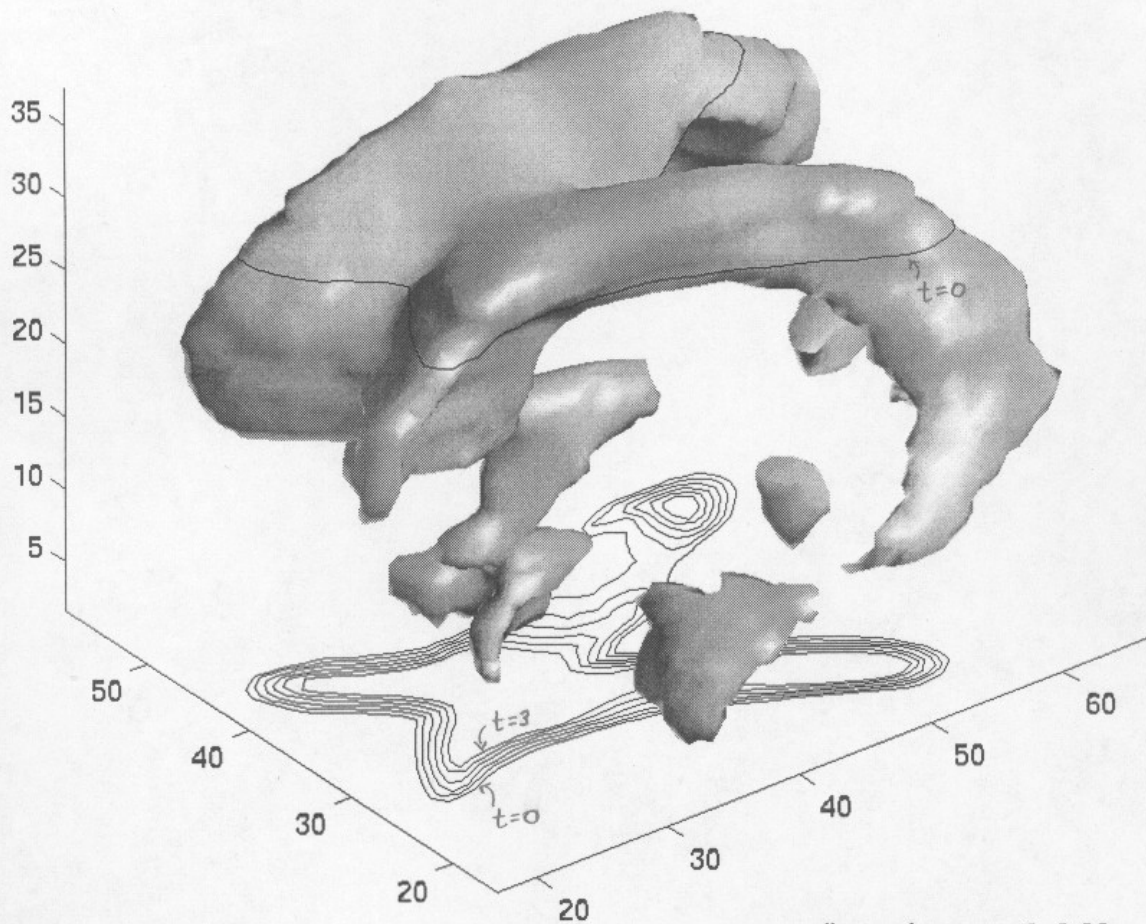
# Consolidation Models

- Progress
  - Reasonable “early” predictions
    - Pressure distribution
    - Deformation
    - Fluid flow
  - Helpful estimate of Poisson ratio  $\sim .38$  – stability of numerical simulations
- Limitations
  - Long time periods
  - Large deformations
  - Unknown brain parameters

# Ventricular Wall Motion Simulation (Elliptical Fourier Series)

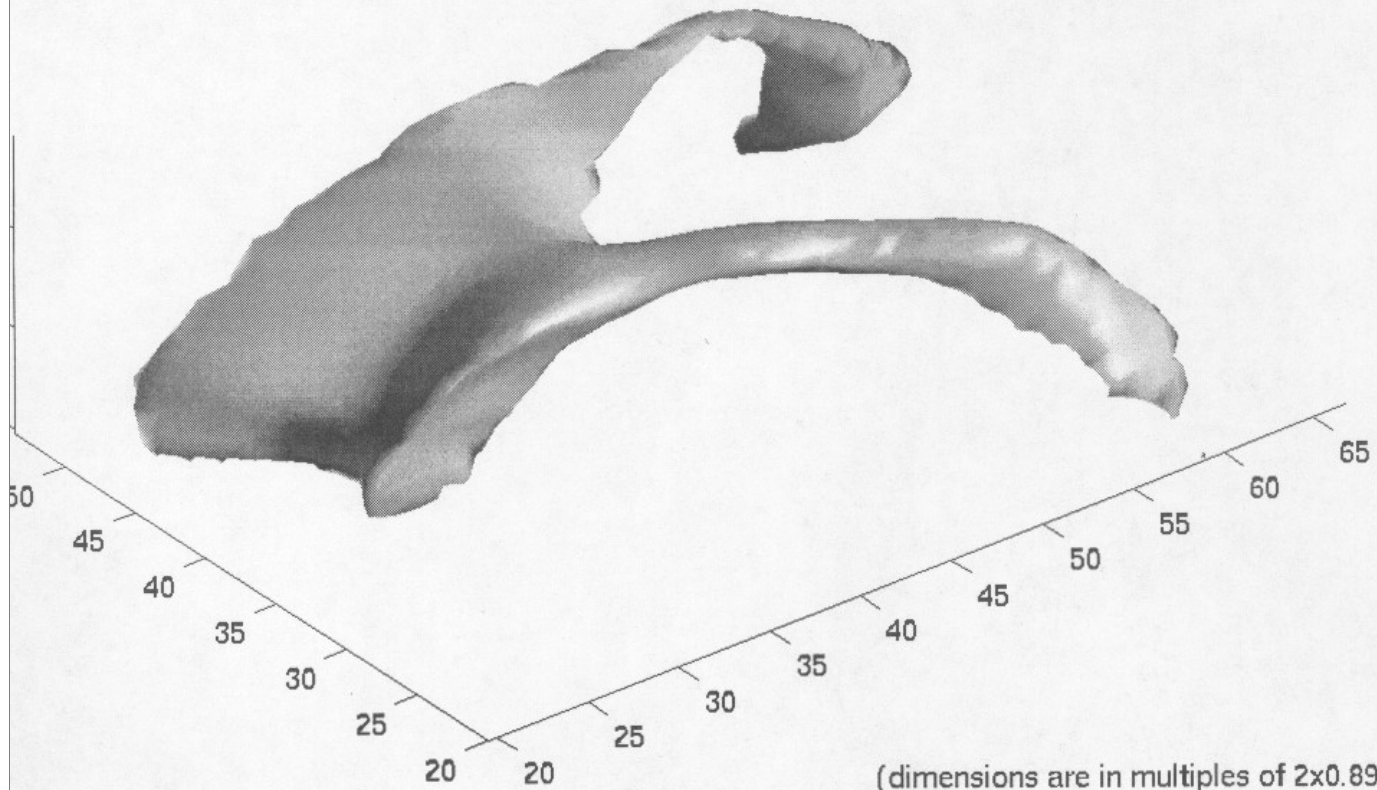


Ventricular walls at  $t=0$ , with <sup>a</sup>cross sections for  $t=0..3$  months, speed =  $-1\text{mm/month}$



dimensions are  $2 \times 0.89\text{mm}$  per "tick"

Ventricular walls at t=3



(dimensions are in multiples of  $2 \times 0.89\text{mm}$ )

- Accurate placement of the ventricular catheter reduces the shunt failure rate ?



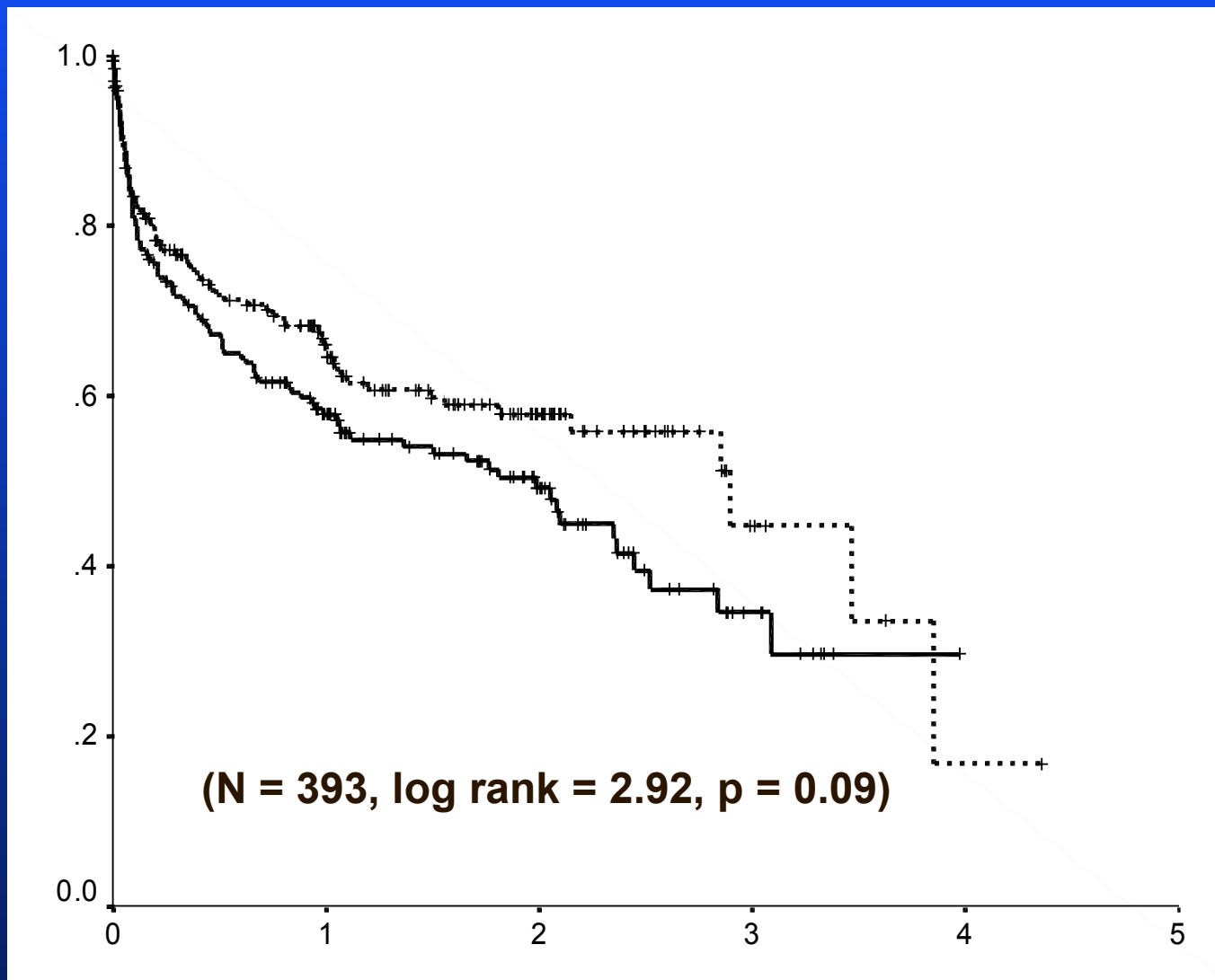
# Lack of benefit of endoscopic ventriculoperitoneal shunt insertion: a multicenter randomized trial

**JOHN R. W. KESTLE, M.D., JAMES M. DRAKE, M.D., D. DOUGLAS COCHRANE, M.D.,  
RUTH MILNER, M.Sc., MARION L. WALKER, M.D., RICK ABBOTT III, M.D.,  
AND FREDERICK A. BOOP, M.D. FOR THE ENDOSCOPIC SHUNT INSERTION TRIAL PARTICIPANTS**

*University of Utah, Primary Children's Medical Center, Salt Lake City, Utah; University of Toronto, The Hospital for Sick Children, Toronto, Ontario; University of British Columbia, British Columbia's Children's Hospital, Vancouver, British Columbia, Canada; Beth Israel Medical Center, New York, New York; and University of Tennessee, Memphis, Tennessee*

# Shunt survival in endoscope (—) and non endoscope (.....) groups

Proportion of shunts functioning

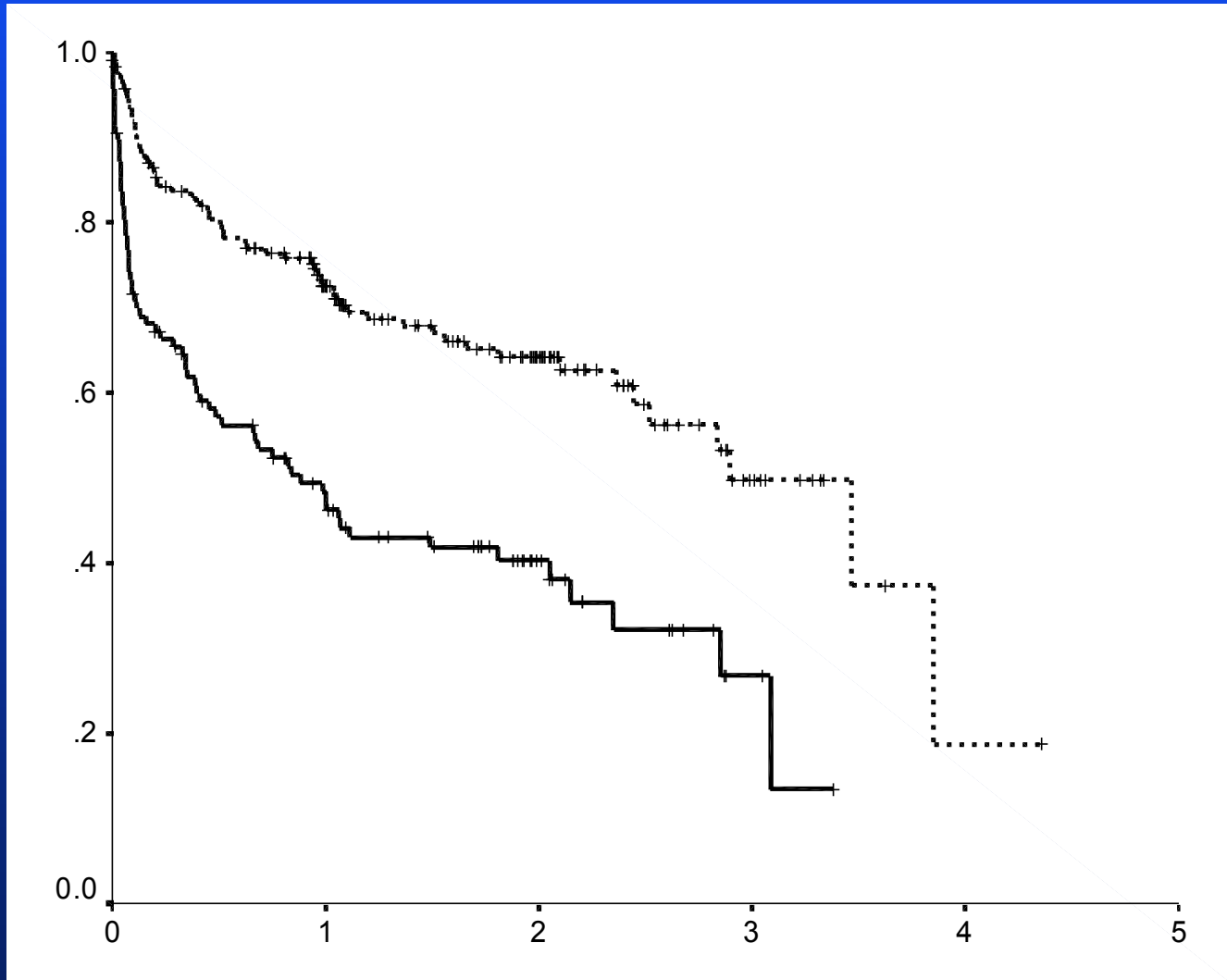


Time (years)

Kestle, Drake, Cochrane et al, J Neurosurgery, 2003

# Ventricular catheter tip away (.....) from choroid or not (—) at follow-up

Proportion of shunts functioning

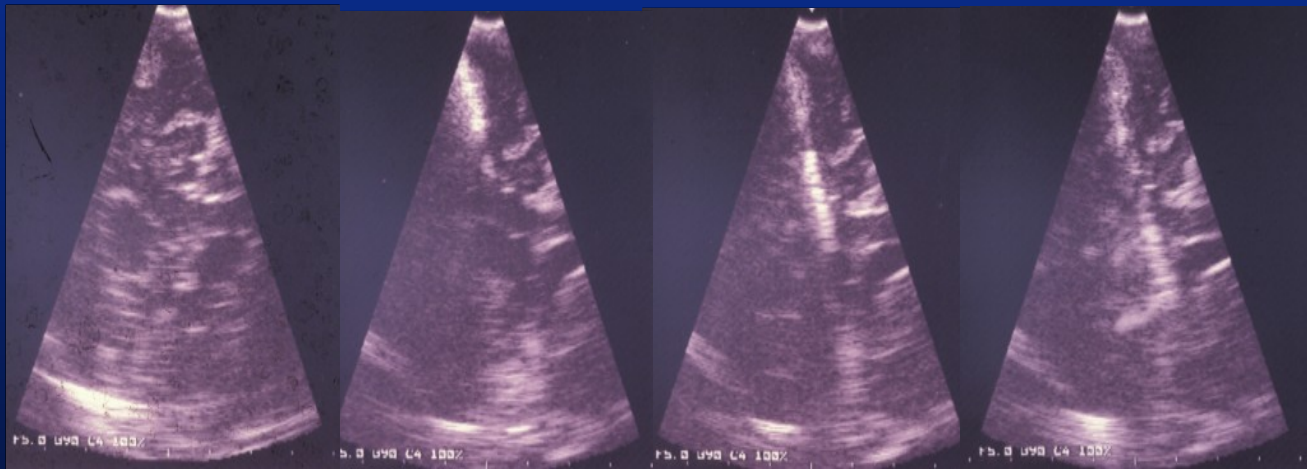
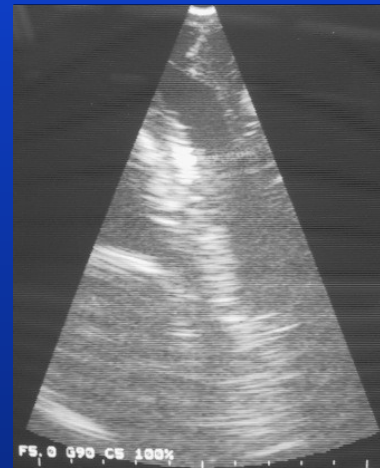
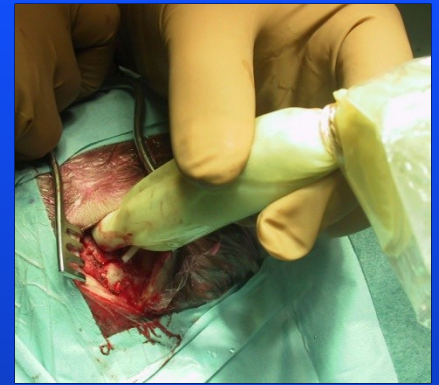


Time (years)



# Operative Ultrasound

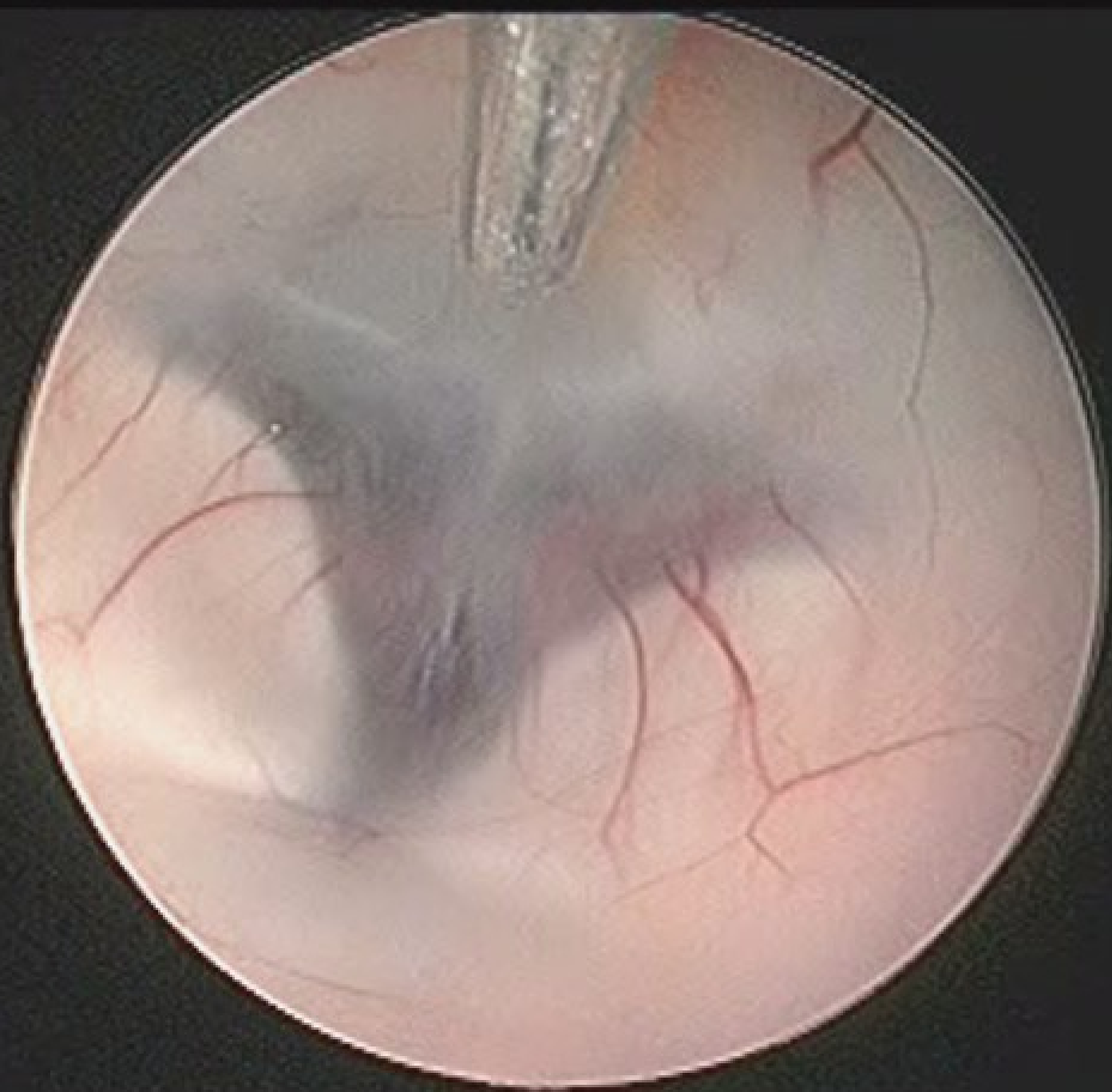
- Very user dependent
- dynamic view of ventricles
- catheter trajectory, path, tip position, hemorrhage, shunt function
- small ventricles, loculated ventricles
- ? every case

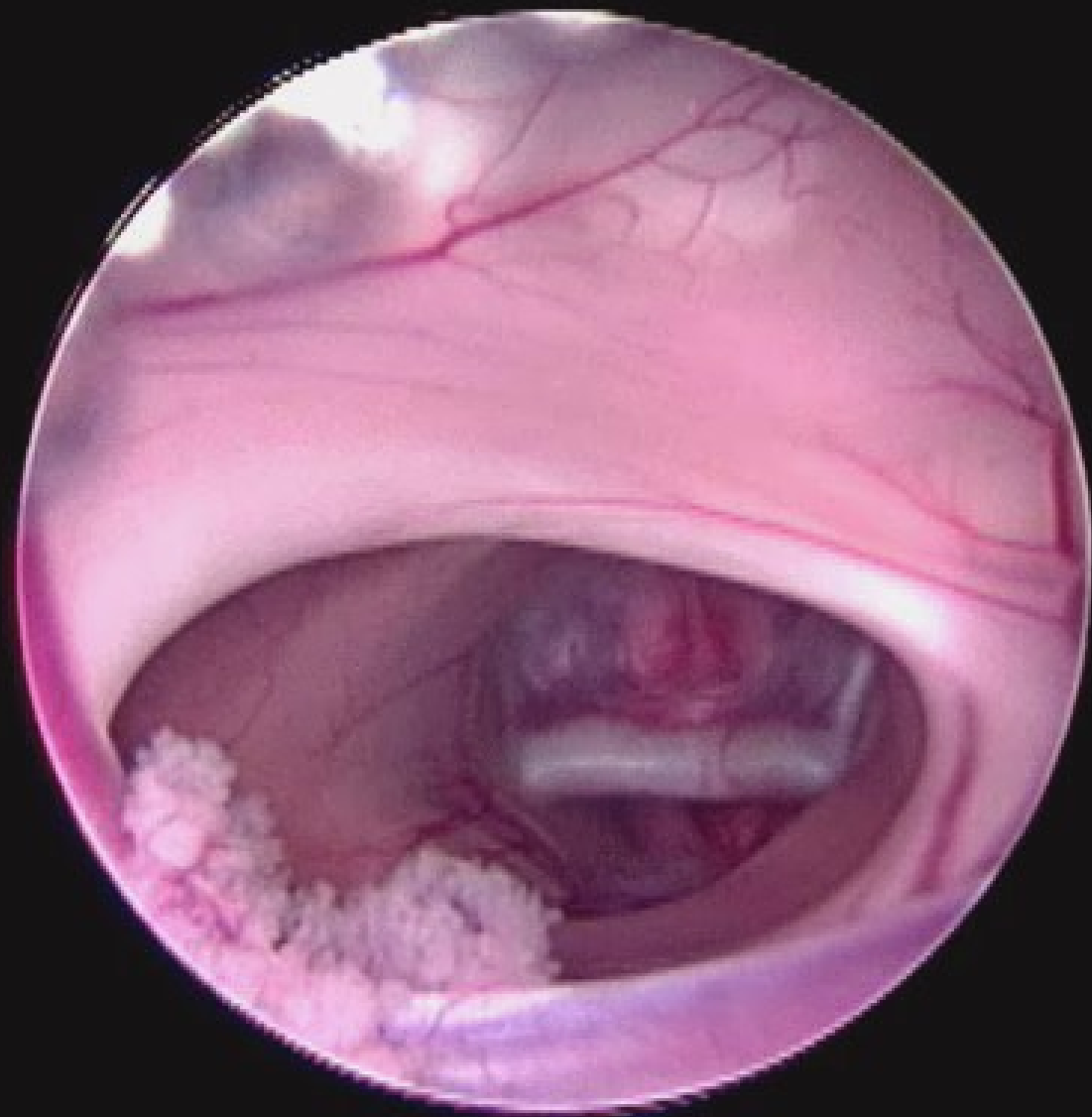


511/512  
74Hz

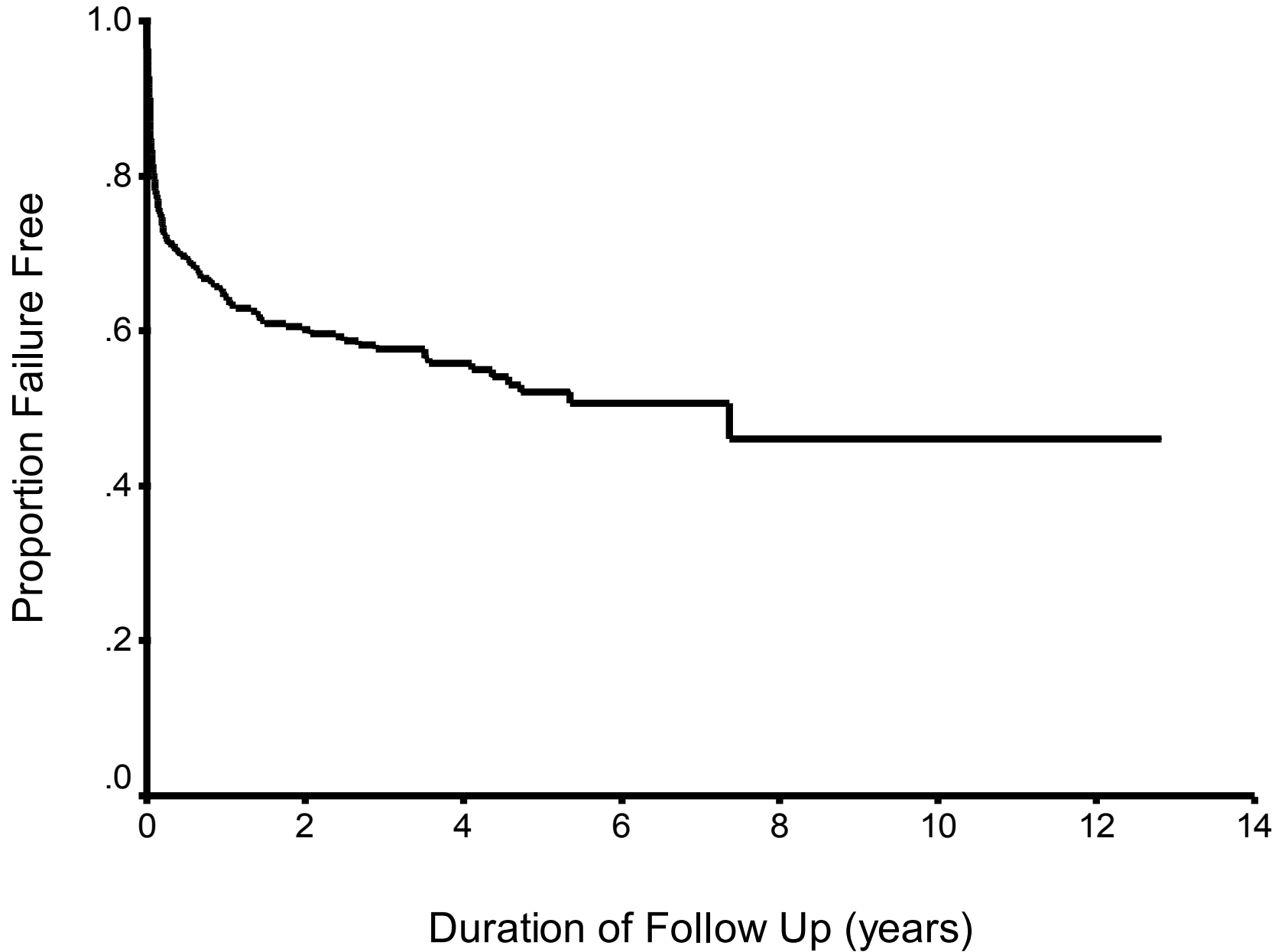
08:34:46  
5.0  
DVA: 90%



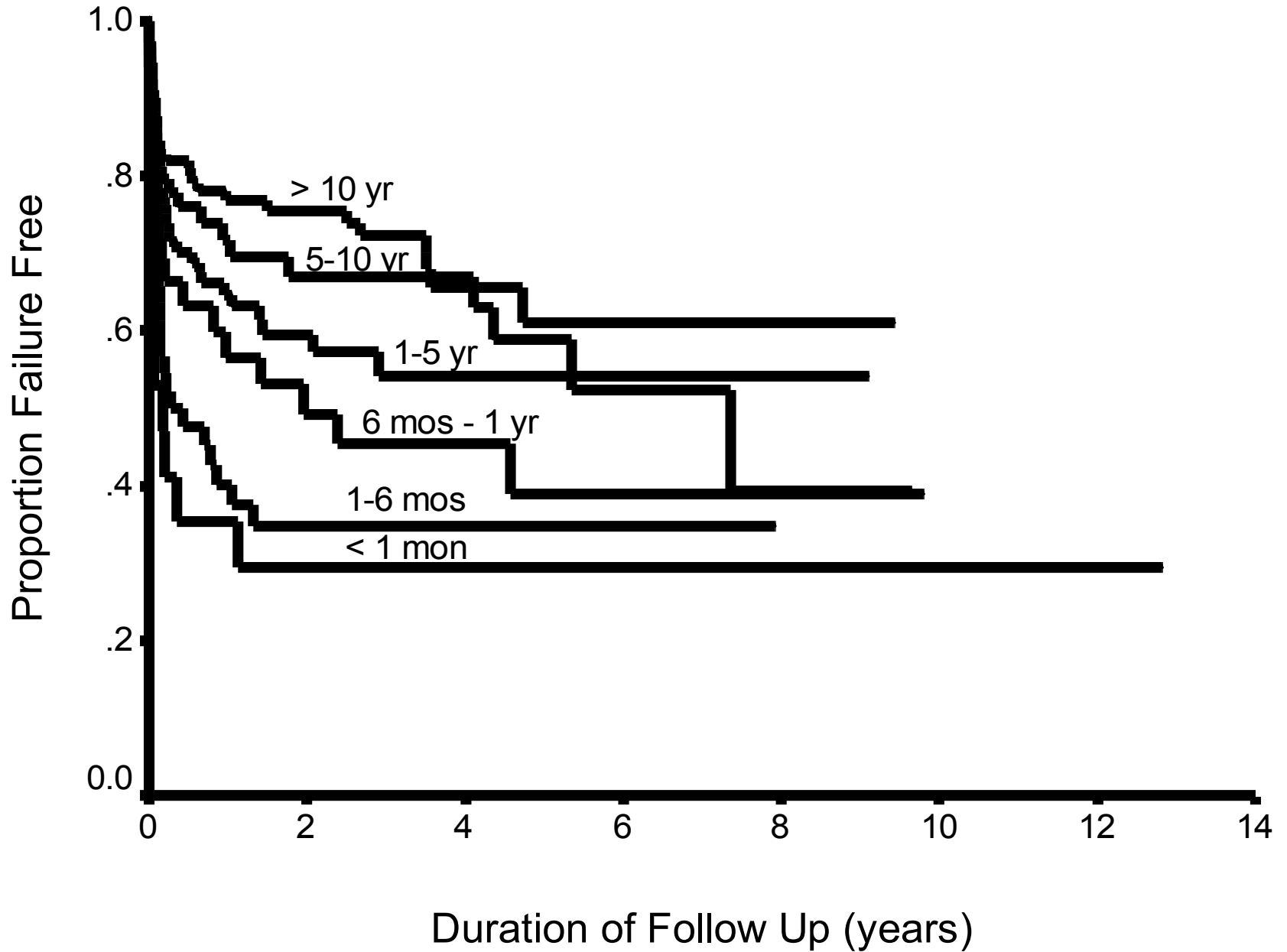




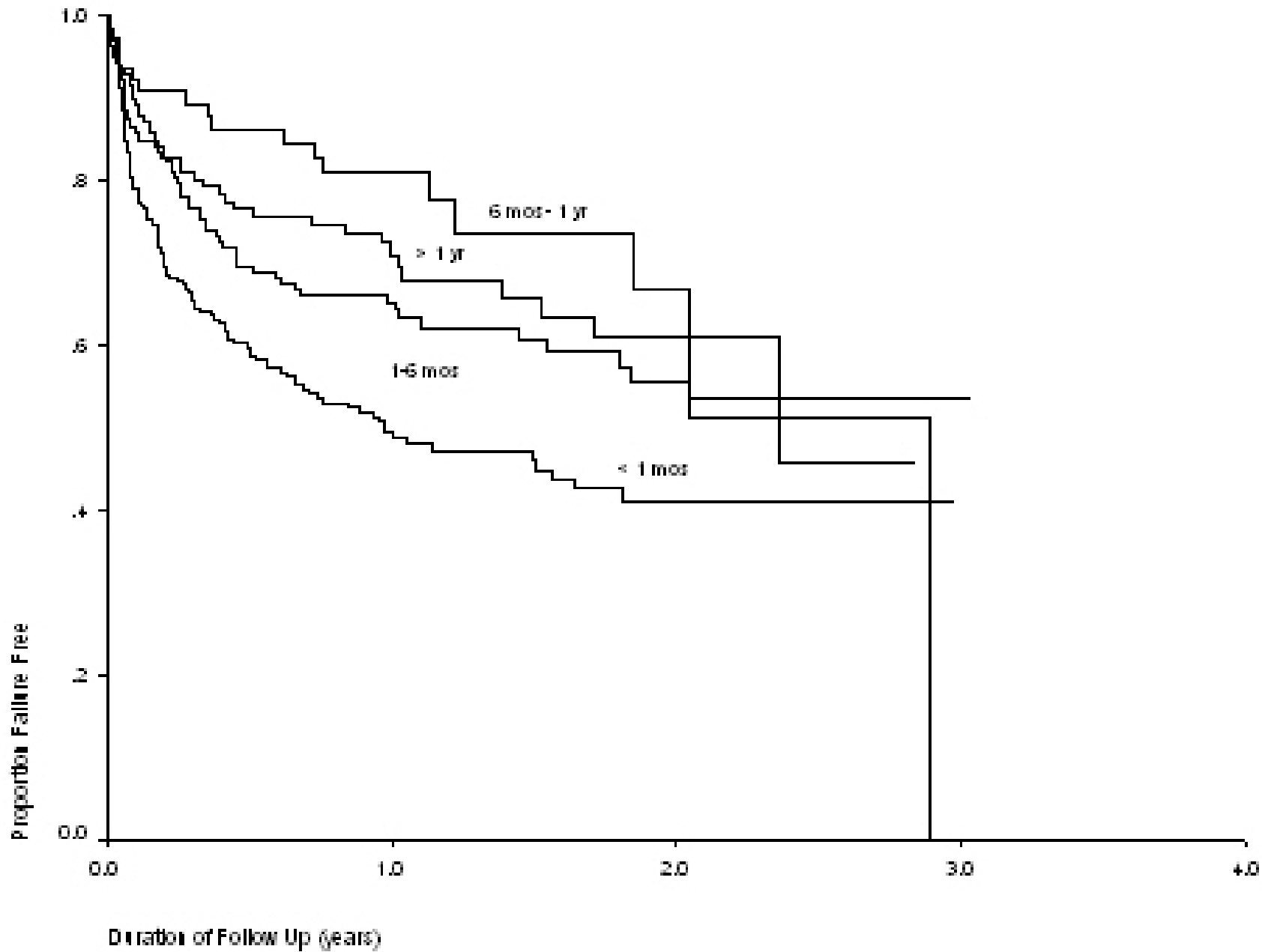
# Failure Rate Overall (368 pts)



# Failure Rate by Age Group

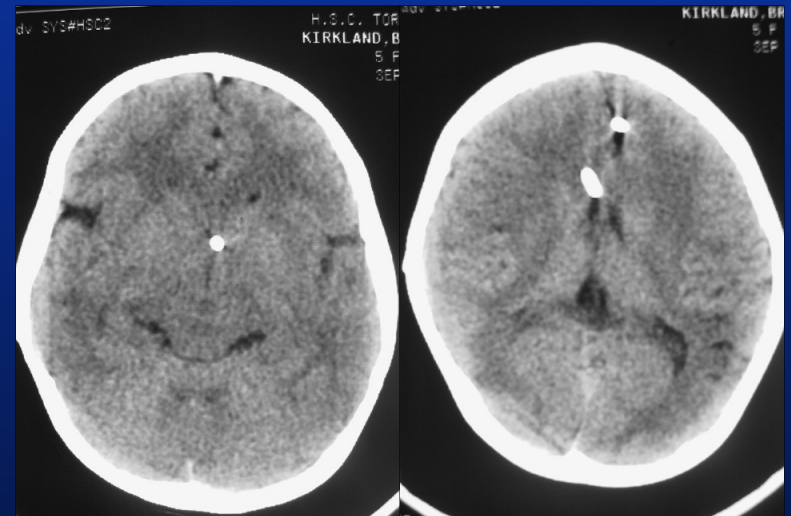
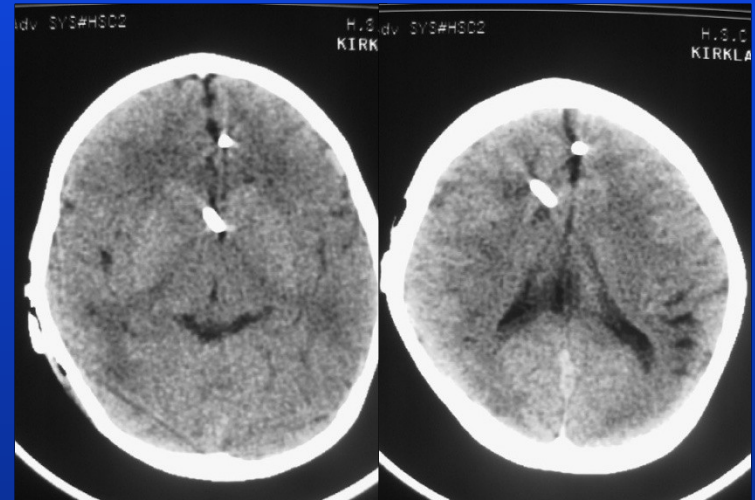
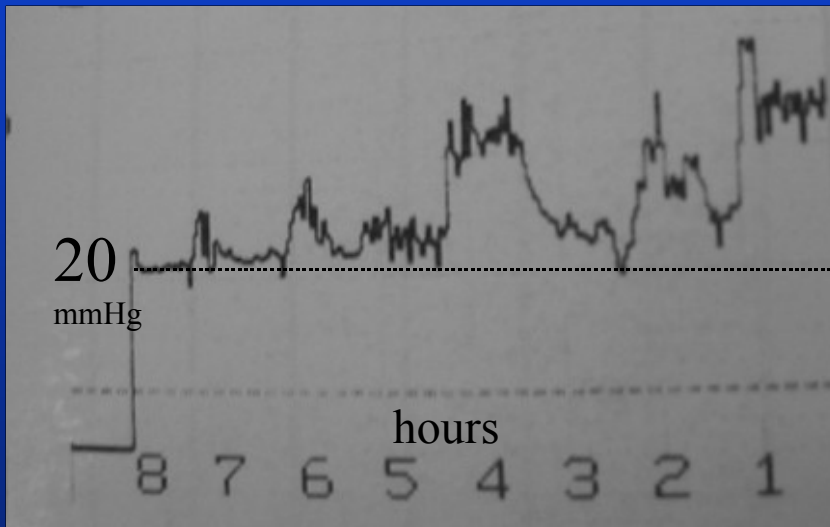


# Shunt Failure Rate by Age Group



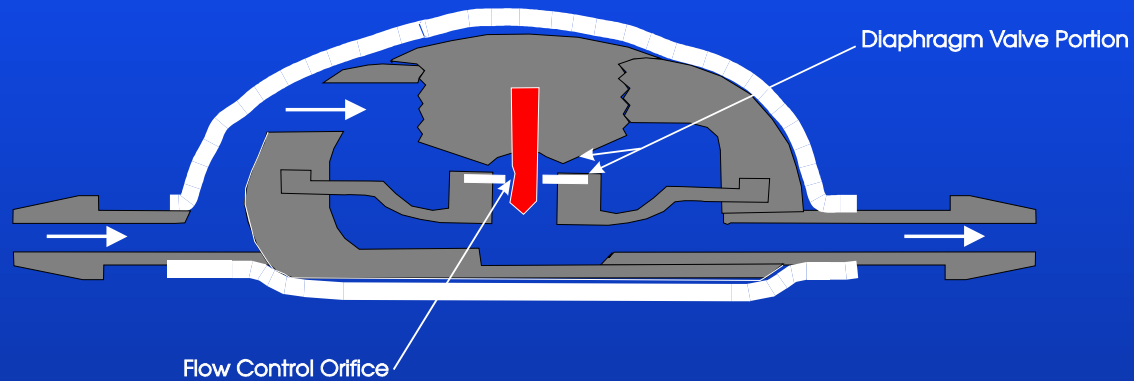
# Slit Ventricle Syndrome

4 yr old, shaken baby  
chronic headache, patent low pressure  
shunt, several revisions





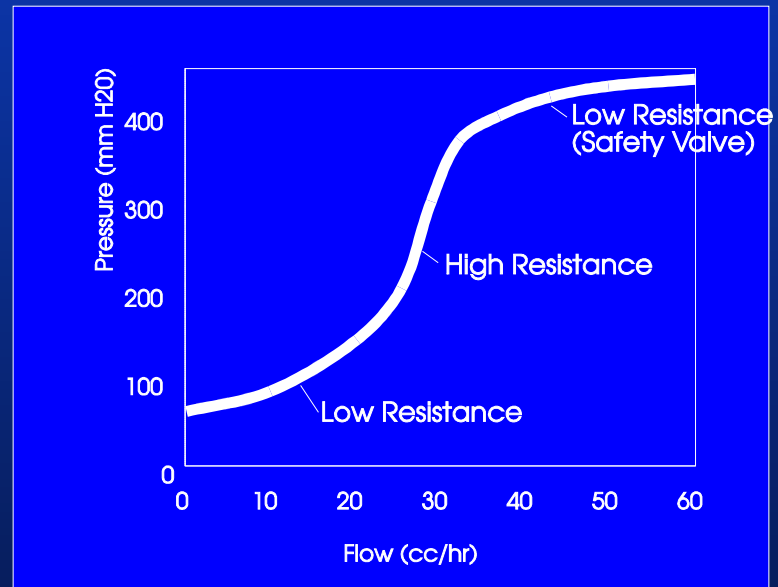
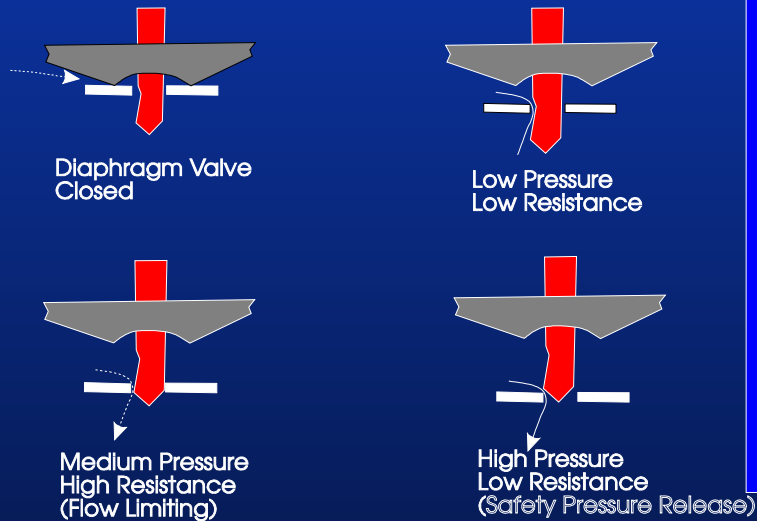
# Cordis Orbis Sigma



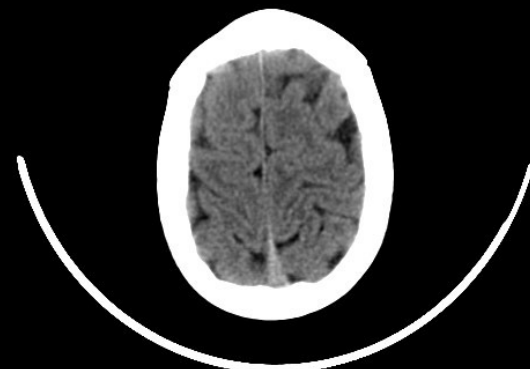
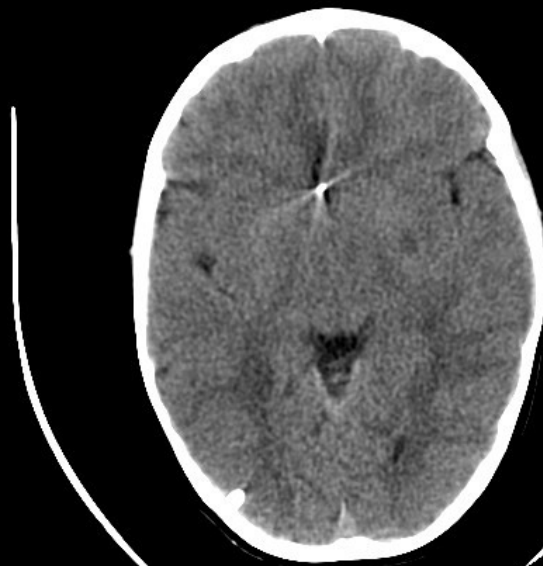
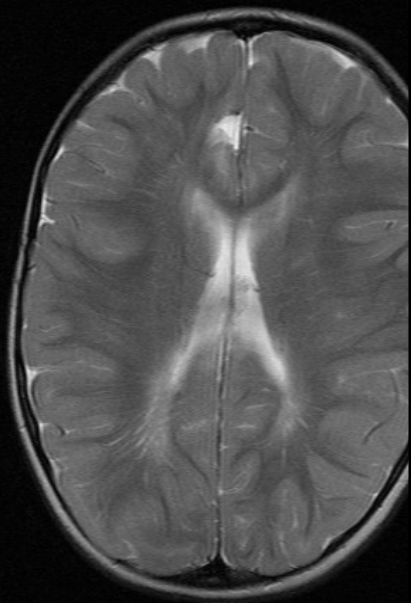
## Mechanism

## Pressure Flow Characteristics

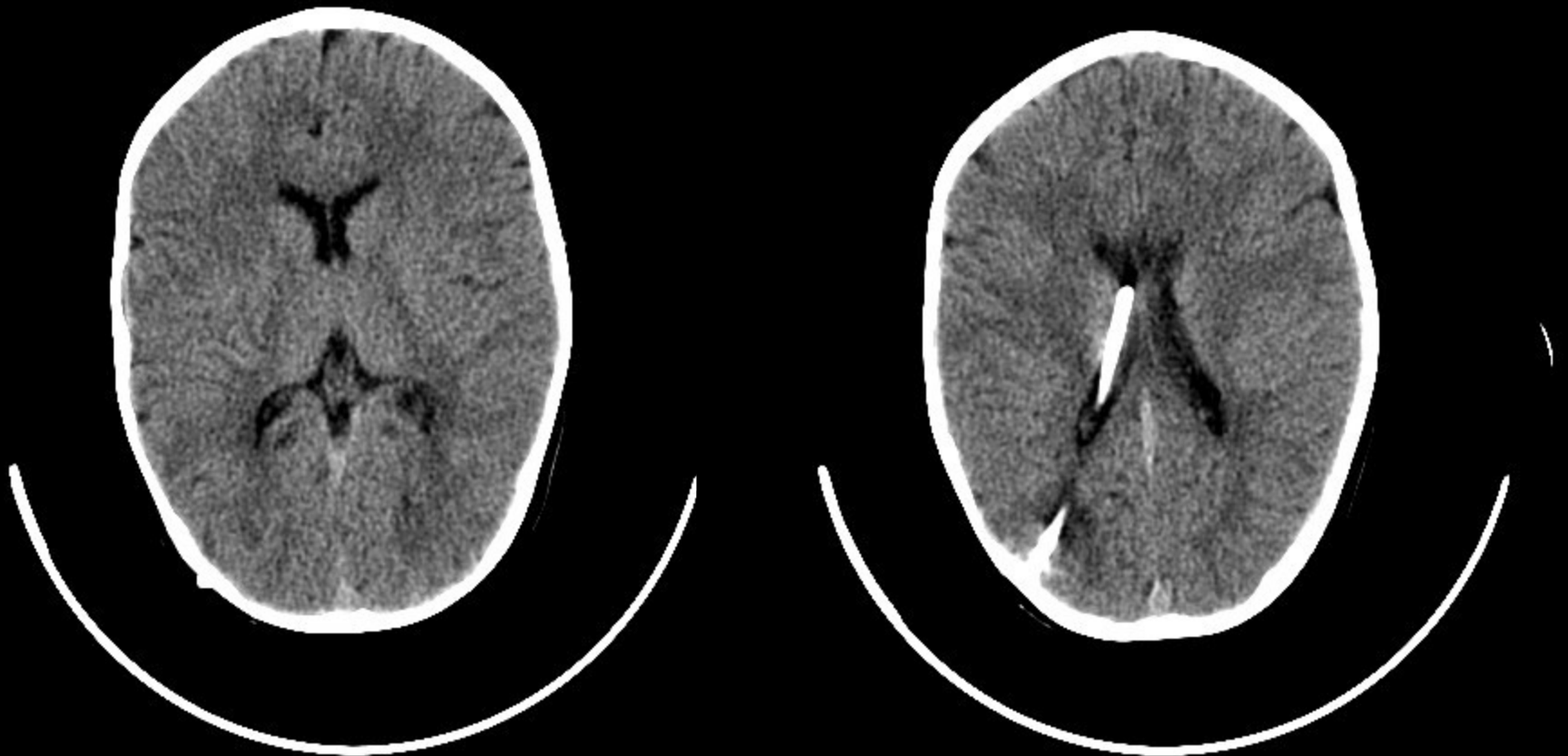
### Variable Resistance Valve



3.5 yr old boy, SAH, aneurysm age 7 mos, anterior cerebral artery, coiled, post SAH shunt. 6 mos Hx of irritability and vomiting, repeated hospital admissions other centre  
? Cyclical vomiting

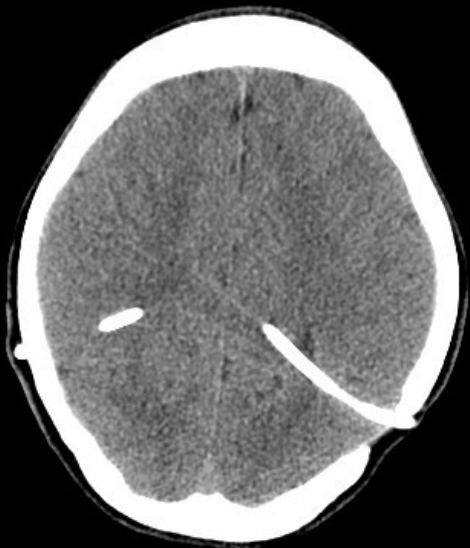


ICP monitor, ICP 40 mm Hg, leaking CSF from insertion site. Taken back to OR, shunt patent both ends, Orbis Sigma II valve change, gradual decline in pressure. 1 Revision 6 mos later, remains well, no vomiting or headache, more than 2 years



# Case Example

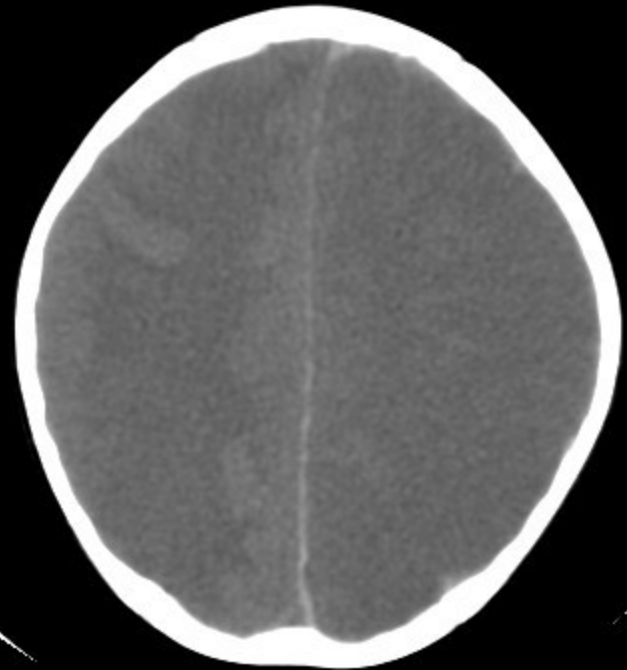
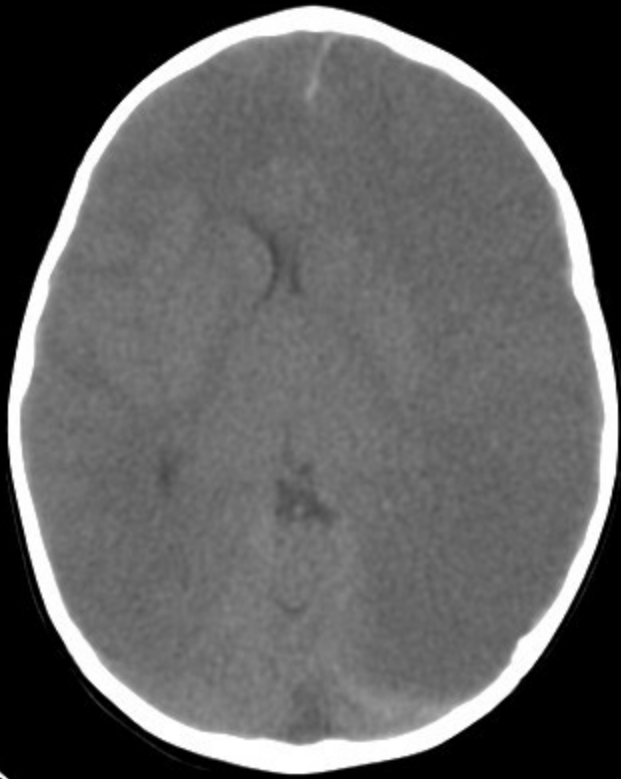
- 10 year old girl
- Severe headache “screaming”
- Bilateral shunts, multiple revisions last 3 months, small ventricles, had LP for “? meningitis”, very high ICP, culture negative.
- Father crown attorney, president of local hydrocephalus association
- Patient transferred from other centre



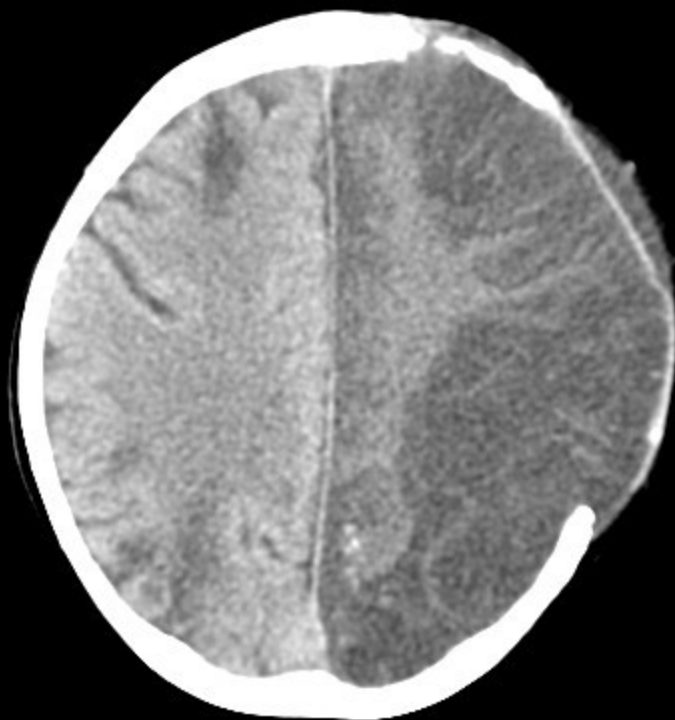
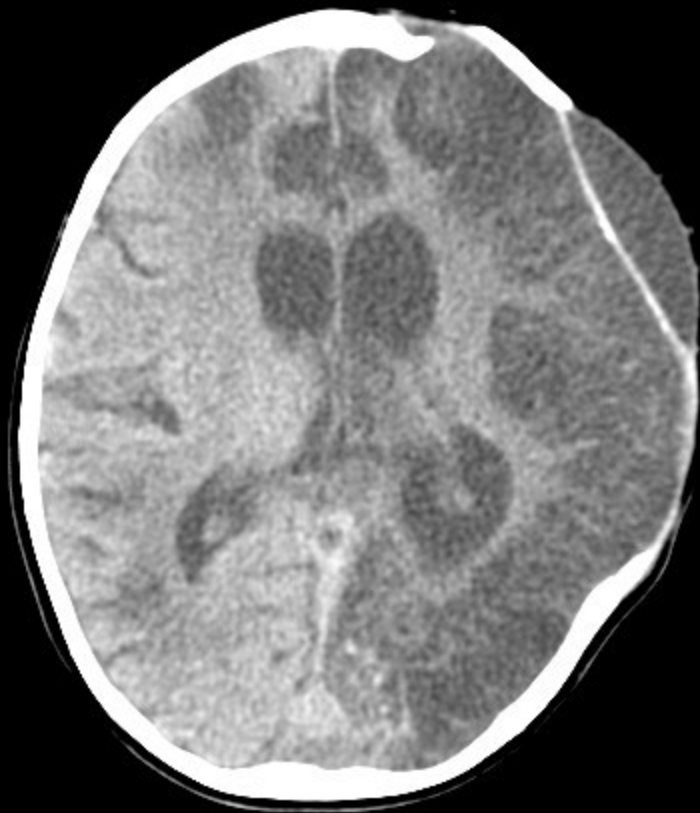
Patent shunt system, very high ICP by ventricular catheter manometry, ventricular catheter repositioned under ultrasound, Orbis Sigma II valve, headache much improved – only 6 mos of FU!



17 month girl, probable non-accidental injury



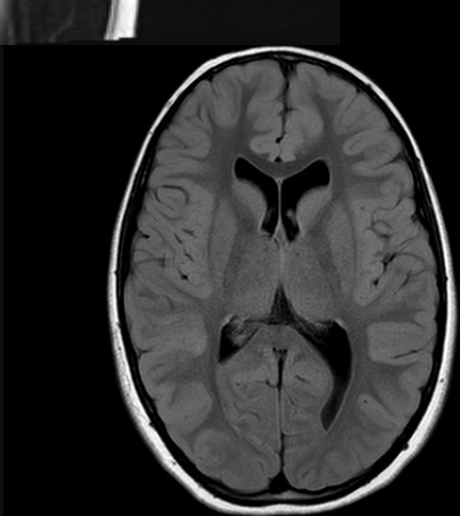
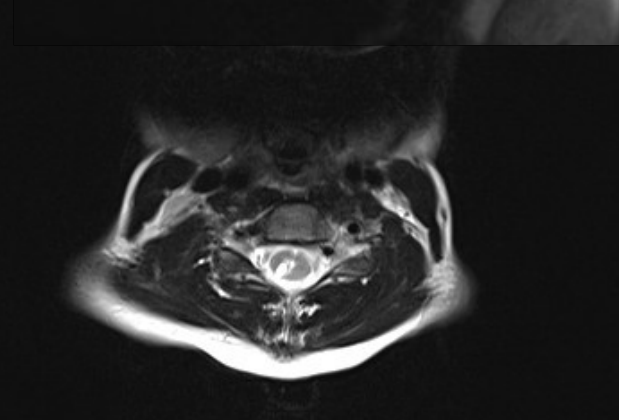
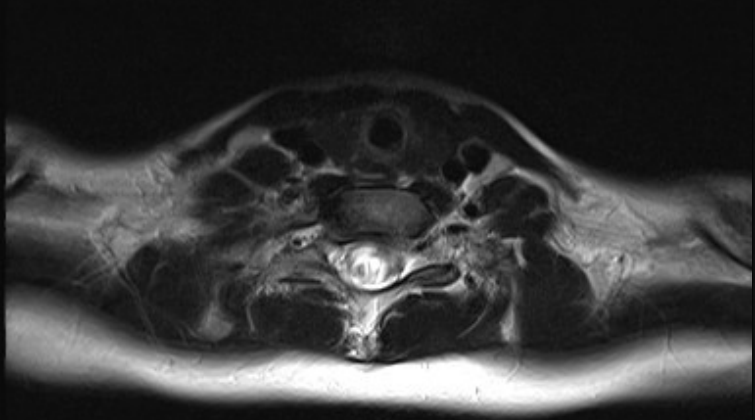
18 months later





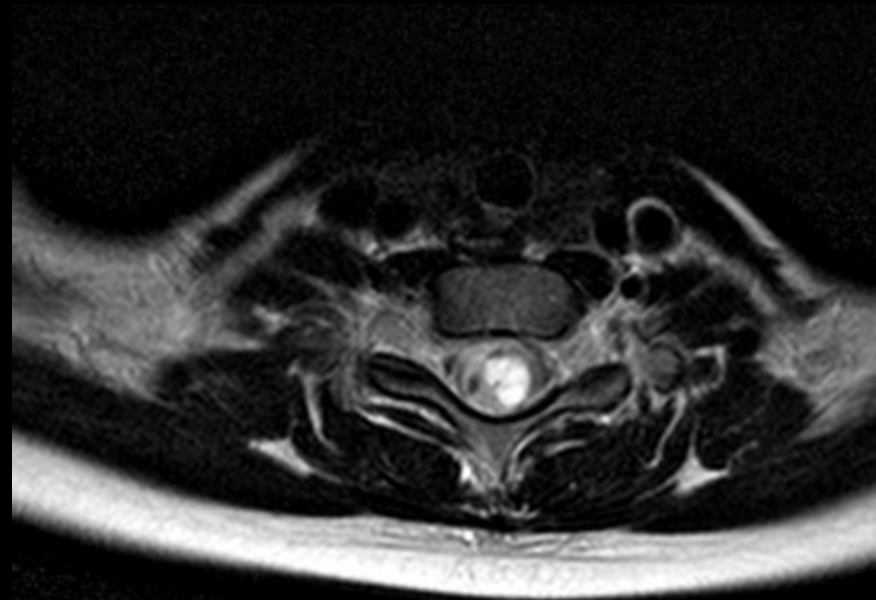
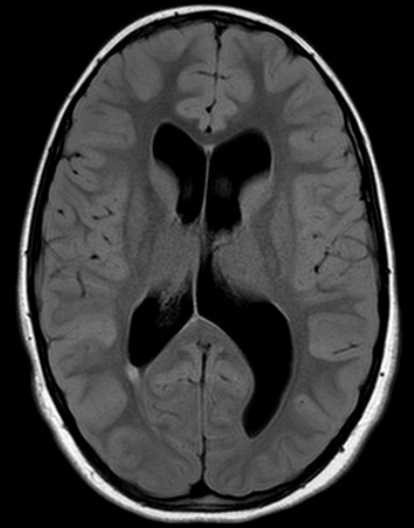
13 yr old female,  
arthrogryposis, scoliosis.  
Previous history of palatal  
insufficiency, mechanical.





# Operation

- Bony decompression including C1
- Dural opening, cerebellar tonsils dissected under microscope, 4TH ventricle opened. Tonsils moved up, more rounded. Pericranial duraplasty.
- No immediate problems. 6 weeks post op, C/O headache. Exam normal, no papilledema.



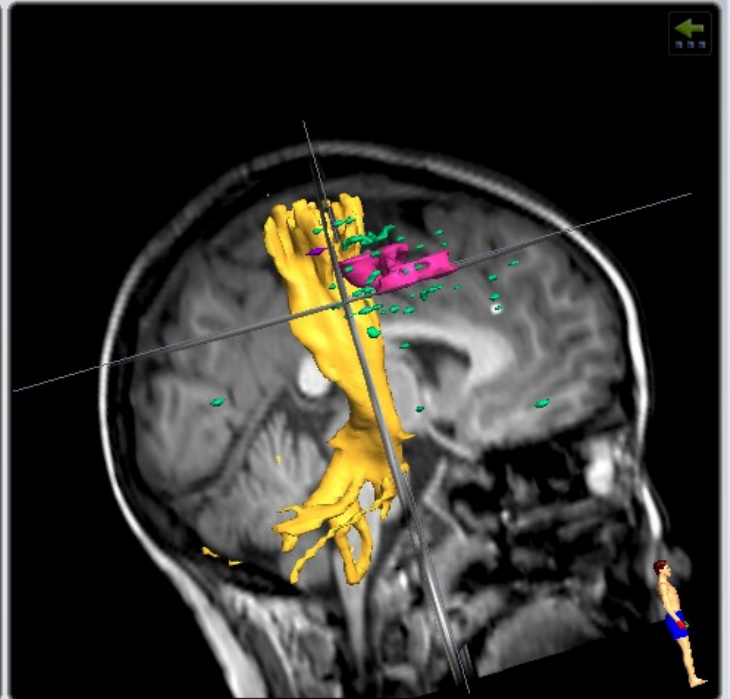
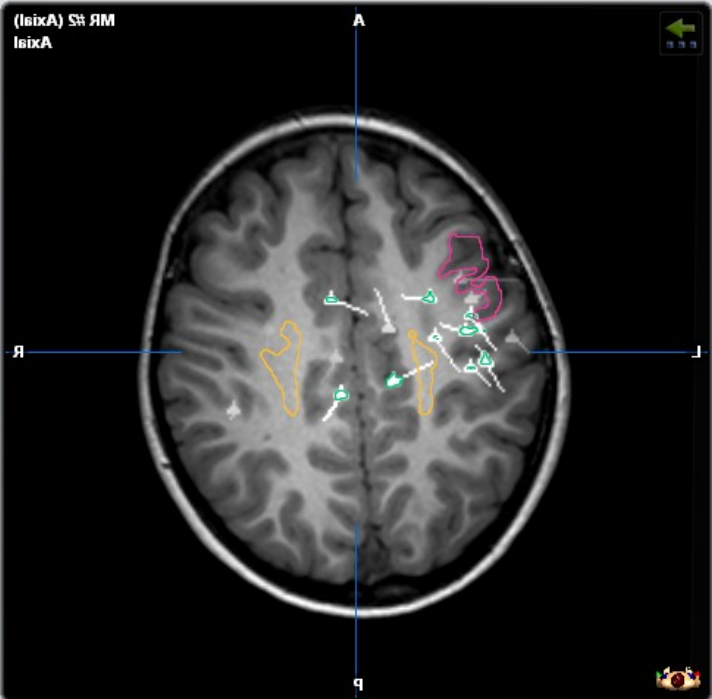
2 months post op



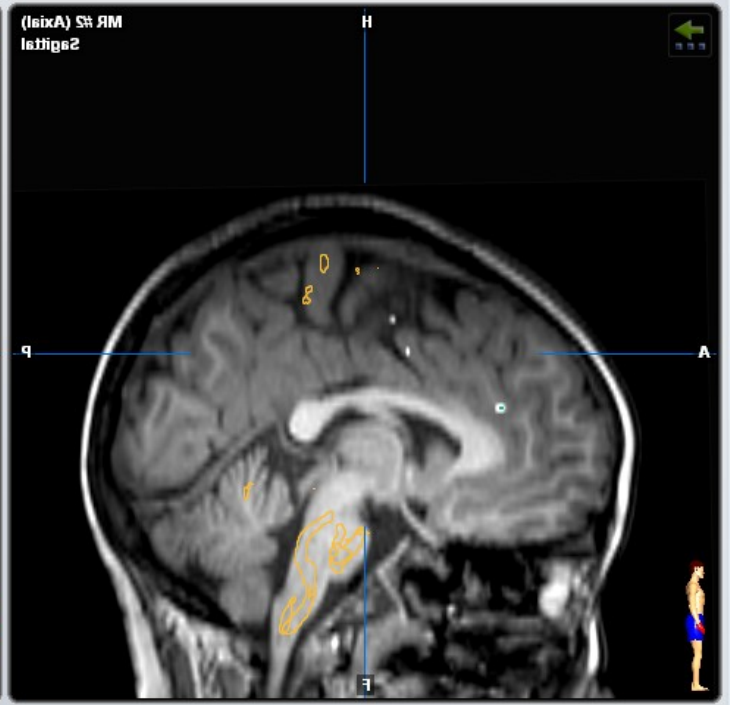
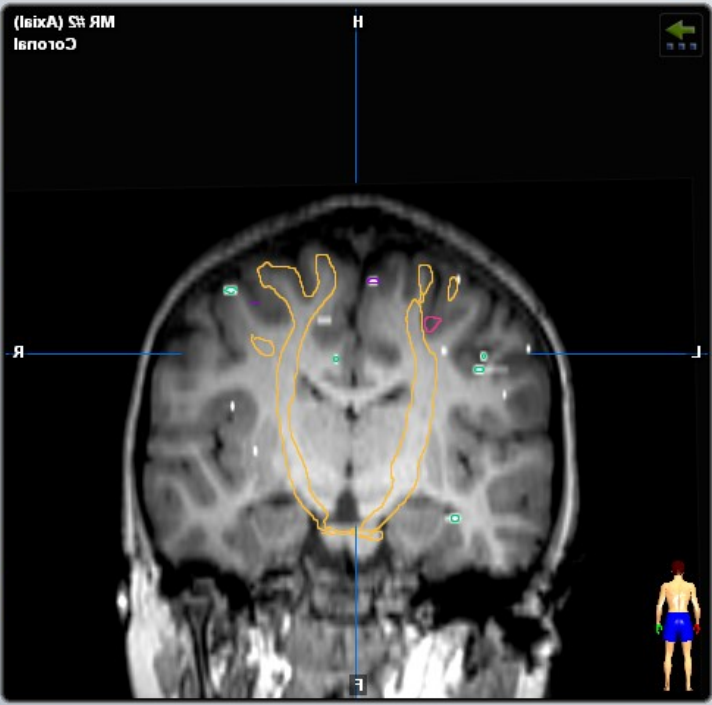
5 months post op

- Not symptomatic
- Scoliosis bit worse
- Now what ?
  - ETV
  - Shunt
  - Explore spinal “cyst”
  - Re-explore CV junction

(IsixA) St RM  
IsixA



(IsixA) MR St RM  
Coronal

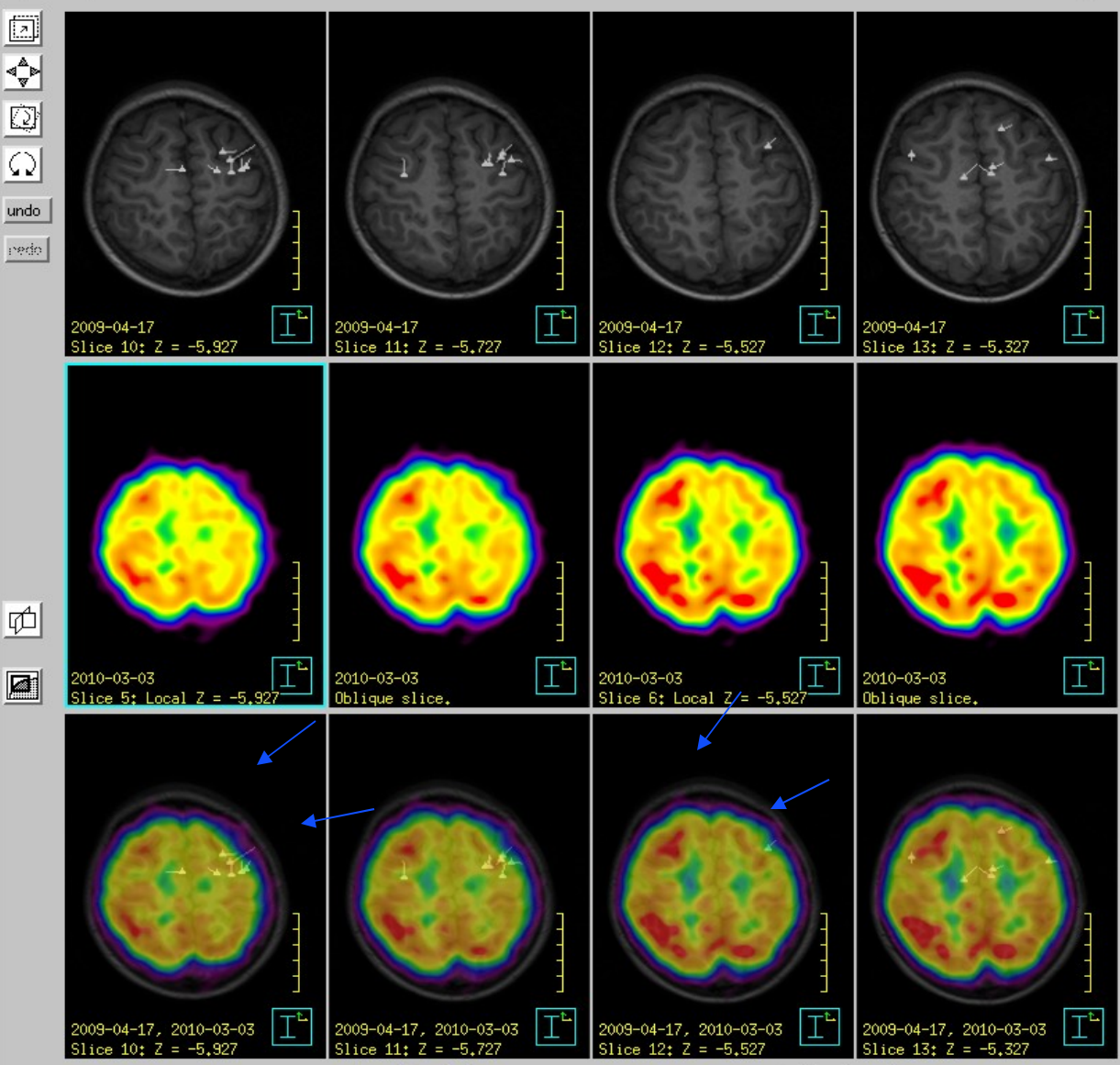


Primary Image Set: **MRI AXIAL**  
 2D Color: **greyscale**  
 Secondary Image Set: **Resample:**  
 2D Color: **rainbow1**  
**Registration Setup**

Available Fusion Image Sets:

Move Secondary Center to Primary Center  
 Reset Secondary to Initial Position

2D Fusion View Parameters  
 Image thickness:  cm  
 Tile size: (of currently selected Fusion window)  pixels



Transverse Orientation

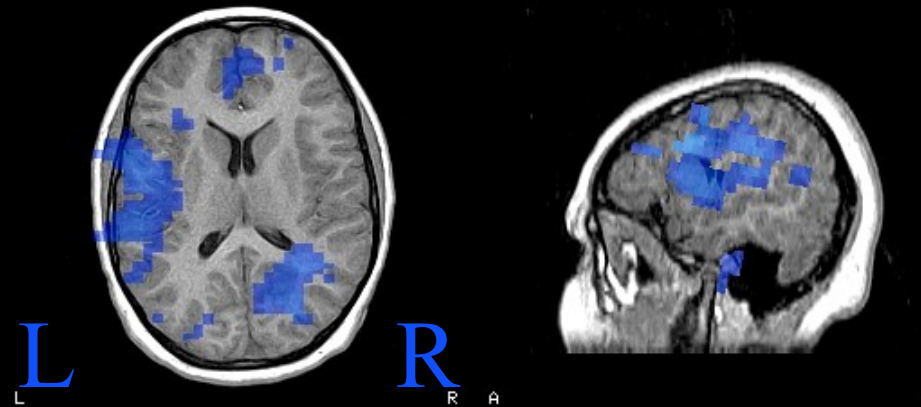
Primary Secondary  
 Window / Level  
   
 Units: **SUV**  
 Ramp: **Linear**  
 Edit Presets...  
 Select Preset...  
 Alpha Blending:   
 Independent Window / Level  
 Yes  No



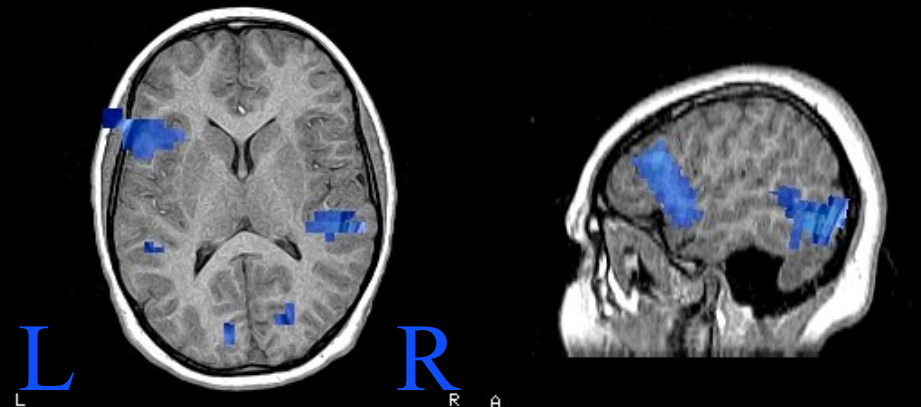


## TASK: MEG expressive language task to picture naming and picture verb generation

·picture naming task  
·left hemisphere frontal  
and temporal activation



·picture verb generation  
·left hemisphere frontal  
activation



# Flight Simulator



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### Surgeons practice on virtual brain

**A high-tech simulator lets brain surgeons "practice" on virtual versions of their patients before the real surgery.**



Dr. Ryan D'Arcy (left) and Dr. David Clarke pose in front of the neurosurgical simulator developed by NRC.

Brain surgeons around the world are abuzz over a unique virtual-reality neurological simulator, called NeuroTouch.

NeuroTouch was officially introduced at the XIV World Conference of Neurological Surgery held in Boston in late summer 2009. Developed by NRC, the groundbreaking technology enables brain surgeons to rehearse a delicate

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NRC Corporate website:

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