Risks and misdirection: critical areas to focus shunt technology development

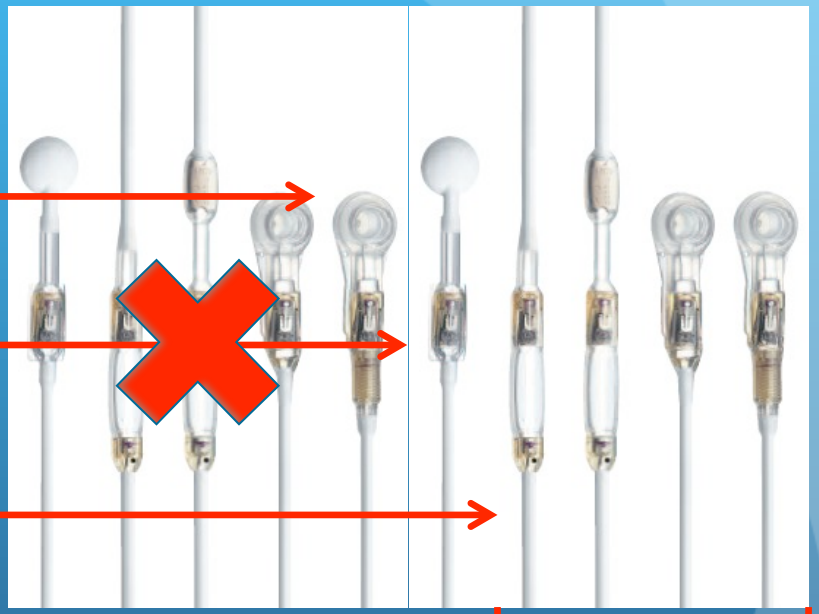
David Watson

Disclaimers

- Consultant to Acandis GmbH – Developing devices for Interventional Neuroradiology for stroke and aneurysms
  - *This makes me an outcast in some Neurosurgical wards!!*
- Past head of R&D for PS Medical (1989-1995) and Inventor of the Delta and Strata Valves
  - No current Industry Affiliations in the field of Hydrocephalus.*
- *Personally own several patents (and more pending) for devices for the treatment of hydrocephalus.
- *In negotiations with funders to create a new start-up for developing better shunt products based on my IP.
- Some work presented herein was accomplished with gracious support from the Gross Family and the Batterman Foundation.

So what is the ‘state of the art’?

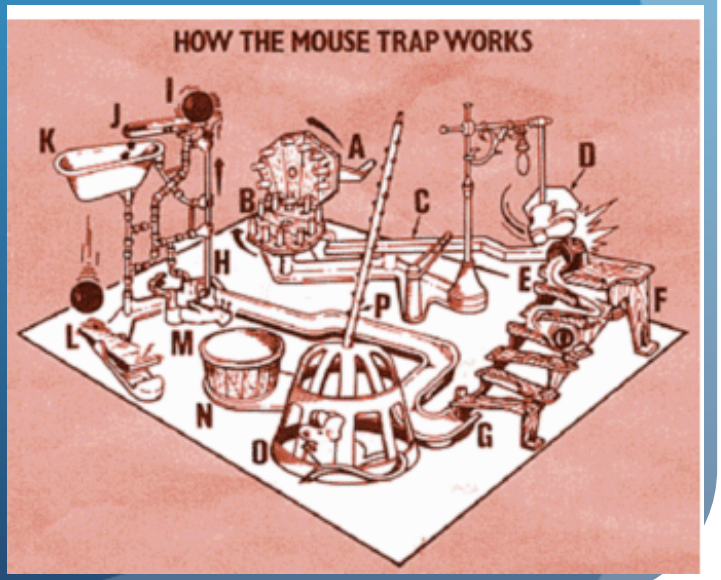
- Shunt failure rates as high as:
  - 40% in first year
  - 50% by year two
  - 59% at 4 years



4 year Shunt Survival = 41%

So the status quo is dismal, but what can industry do?

- Shunt systems are fairly standardized
  - Develop a new ventricular catheter?
  - Develop new valve technologies?
  - Develop new distal catheters?
  - Reinvent the whole procedure?



What are the primary failure modes?
1- Obstruction

- A clinical or device issue?
  - Obstruction is the highest failure mode – ironically high in the early months but persists for years
    - Ventricular catheter – Misplaced or occluded?
    - Valve – Occluded with debris, or mechanical failure?
    - Distal Catheter – Kinked, broken, or occluded?

What are the primary failure modes?
2) Overdrainage

- A clinical or device issue?
  - Wrong valve choice?
  - Wrong Pressure choice?
  - Changing patient needs?
  - Valve failure?

So how do we do it better?

- *The bar is pretty low and has been for years - So one would think!*

We need data to drive product designs and clinical decisions

- Clinical Data for “normal” ICP, CSF flow, etc. is scant due to the invasive nature of getting the data. Problem #1 – we need more data.
- Does “Normal Data” directly apply to patients with compromised CSF anatomy?
- Even if we are ‘Low’,

‘Medium’ or ‘High’

is that true all day long?

Can Results of past studies help drive clinical decisions?

- The Valve Trial – Failed to pick a valve with better shunt survival
- Endoscopic Vent catheter placement – failed to show a better shunt survival

Where is the industrial incentive?

But a better system could gain significant market share!

So where is the innovation?

- Valve Technology
  - Flow Control vs Pressure Control?
  - Siphon Control?
  - Sinushunt?
  - Smart Shunts?

  - What Inspires Innovation? – DATA, OBSERVATION, COMPETITION

From the Way-Back Machine, What inspired the Delta Valve?

- Late 1980's – PS Medical (SCD) and HS (Anti-Siphon Device) were accessory valves that Shut off flow in response to hydrostatic pressure. The Orbis-Sigma and Adjustable Medos-Hakeim were recently released.
- 1990 – Placement of SCD low on the neck yielded better clinical symptoms. ZIPS shunt – Eldon Foltz
- PS wanted me to integrate the SCD to the Flow Control Valve to save surgical attachment time
  - Placing the valve on the neck not clinically acceptable to most MD's

What inspired the Delta Valve?
Continued

- I theorized a re-engineering of the SCD to compensate for HP rather than close in response to it.
- My boss rejected my suggestion at re-engineering SCD -> he wanted a quick 510(k)!
- I obeyed – Perhaps the last time I ever did!
- The mold was damaged in early prototyping
- I snuck two versions through during repair of the mold(s)
- The Delta and Strata Valve were somewhat successful thereafter!

What new valves have been approved since the early 1990s?

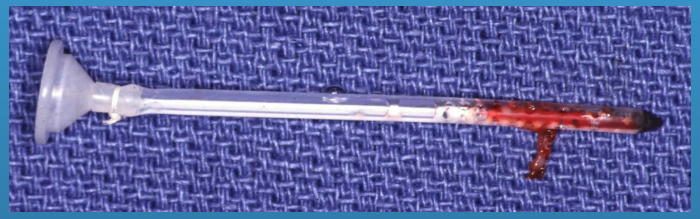
- ?

What new catheters have been approved since the early 1990s?

- ?

So now 20 years later - What?

Combining experience from my PS and CytoTherapeutics years, I postulated a microporous membrane solution to Ventricular Catheter Obstructions.



(12) **United States Patent**
Watson

(10) **Patent No.: US 7,763,142 B2**
(45) **Date of Patent: Jul. 27, 2010**

(54) **PROCESS FOR CREATING AN INGROWTH PREVENTING INDWELLING CATHETER ASSEMBLY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 996 days.

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(22) Filed: **Dec. 15, 2004**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(60) Provisional application No. 60/272,722, filed on Mar. 1, 2001.

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B29C 65/00 (2006.01)
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A61M 25/14 (2006.01)
A61M 25/16 (2006.01)

(52) **U.S. Cl.** **156/293**; 156/294; 156/304.5; 604/8; 604/524; 604/528

(58) **Field of Classification Search** 156/144, 156/293, 294, 304.5; 604/8, 523, 524, 526, 604/528

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,020,913	A		2/1962	Heyer
3,690,323	A		9/1972	Wortman et al.
3,710,781	A	*	1/1973	Huthcins et al. 600/488
4,445,891	A	*	5/1984	Patel 604/103
4,601,724	A		7/1986	Hooven et al.
4,767,400	A		8/1988	Miller et al.
4,950,224	A		8/1990	Gorsuch et al.
4,950,232	A		8/1990	Ruzicka et al.
4,985,022	A	*	1/1991	Fearnot et al. 604/288
5,074,849	A	*	12/1991	Sachse 604/540
5,152,743	A		10/1992	Gorsuch et al.
5,152,753	A		10/1992	Laguette et al.
5,154,693	A		10/1992	East et al.
5,178,158	A		1/1993	de Toledo
5,201,754	A	*	4/1993	Crittenden et al. 606/194
5,284,761	A		2/1994	Aebischer et al.
5,334,169	A		8/1994	Brown et al.
5,372,587	A	*	12/1994	Hammerslag et al. 604/95.04
5,405,316	A		4/1995	Magram
5,431,817	A	*	7/1995	Braatz et al. 210/490
5,462,523	A		10/1995	Samson et al.

(Continued)

OTHER PUBLICATIONS

David J. Gower, M.D., David Watson, Derek Harper, e-PTFE Ventricular Shunt Catheters, Neurosurgery, Dec. 1992, pp. 1132-1135, vol. 31, No. 6, University of Oklahoma Health Sciences Center, Oklahoma City, OK.

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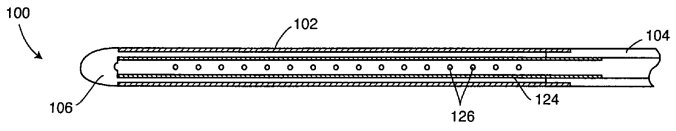
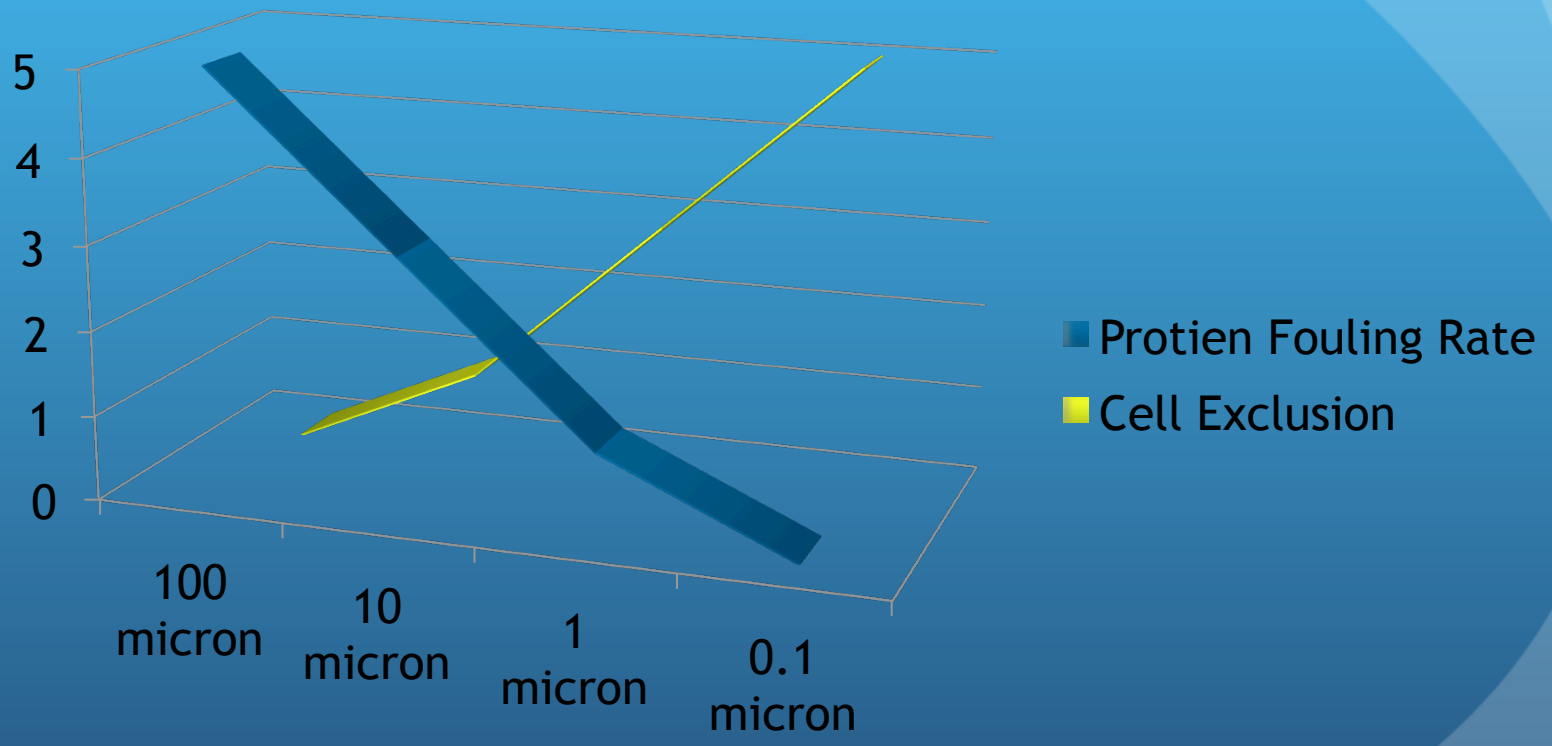
(57) **ABSTRACT**

A surgically implantable delivery or drainage catheter assembly includes a porous fiber membrane that is permeable to the intended drainage or delivery fluid, yet has an outer surface morphology and porosity that prevents the ingrowth of tissue. The porous fiber membrane is created using a phase-inversion process which is controlled to select a desired porosity. A reinforcement member is also disposed within the porous fiber membrane.

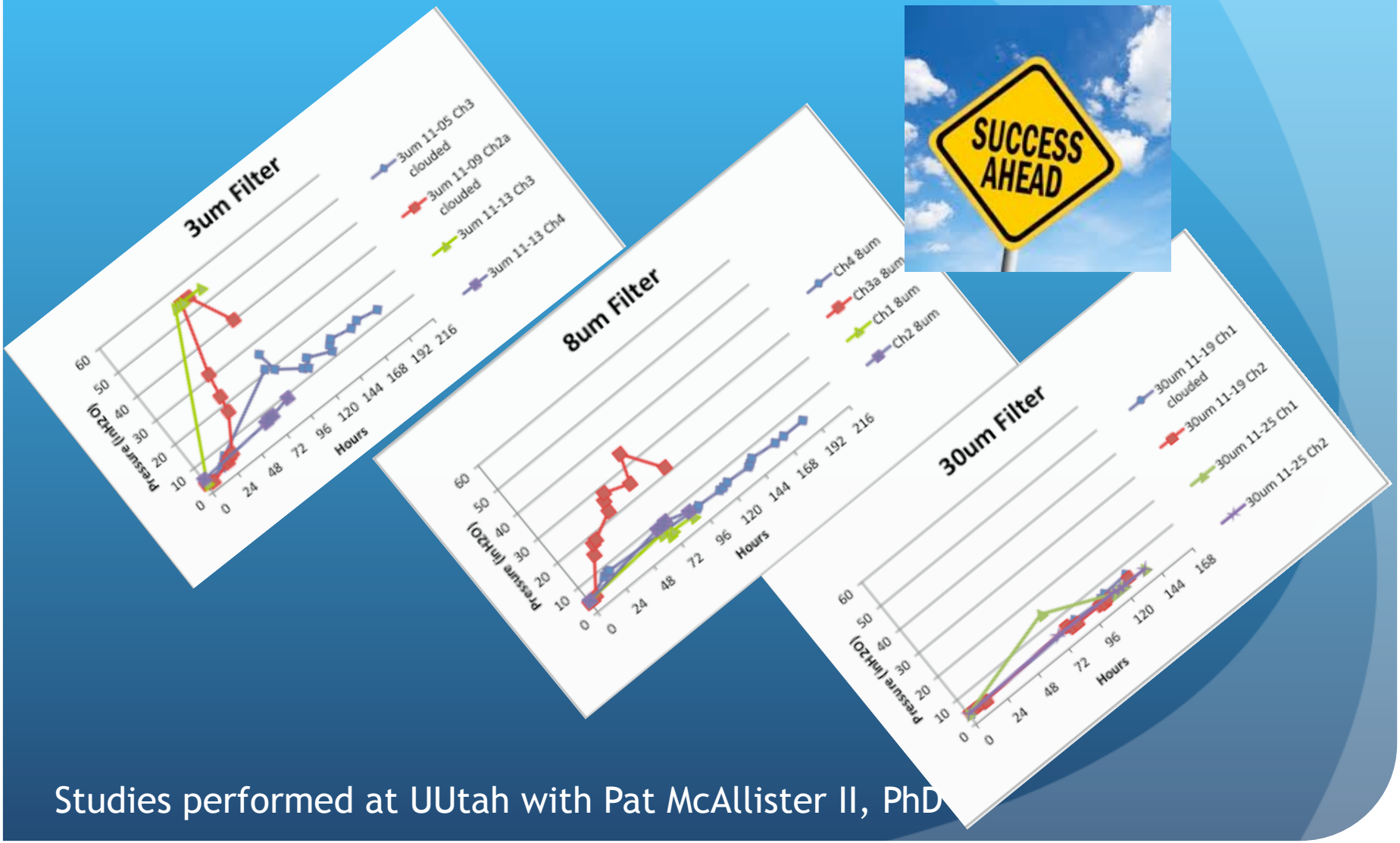
35 Claims, 2 Drawing Sheets



The Theory - use size exclusion to prohibit tissue ingrowth

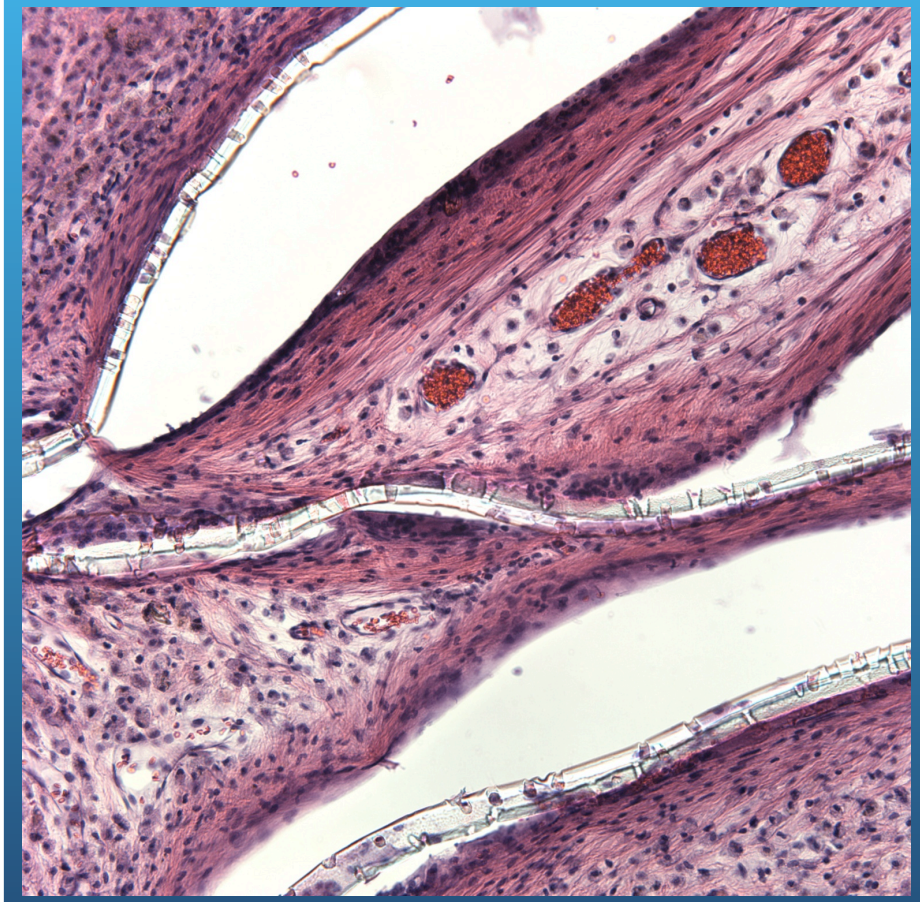


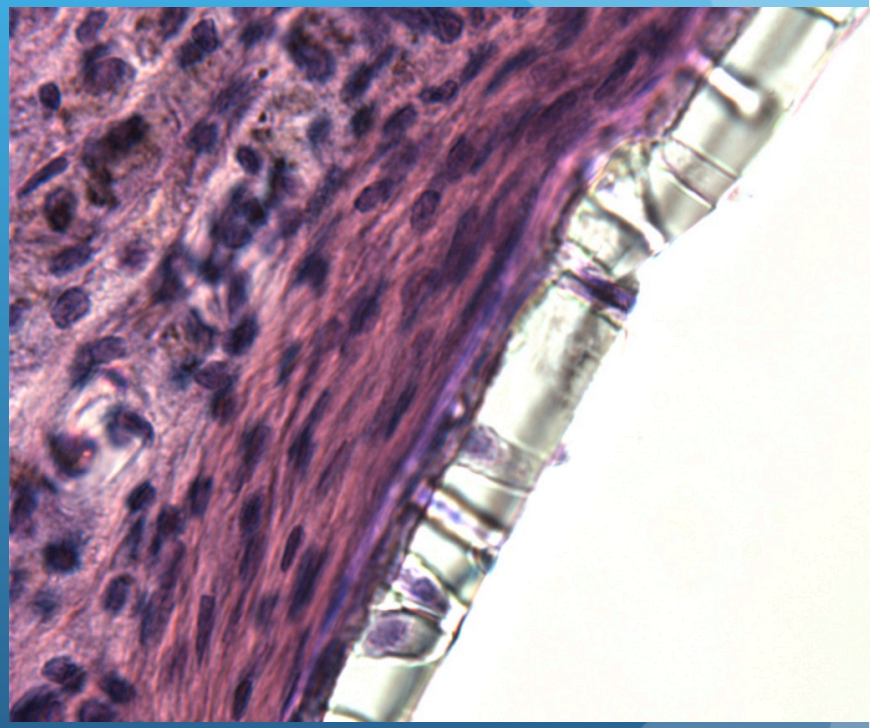
Using human CSF we obtained protein fouling curves



Studies performed at UUtah with Pat McAllister II, PhD

Intra Ventricular Microporous membranes in NZWR





So where's our new Catheter?

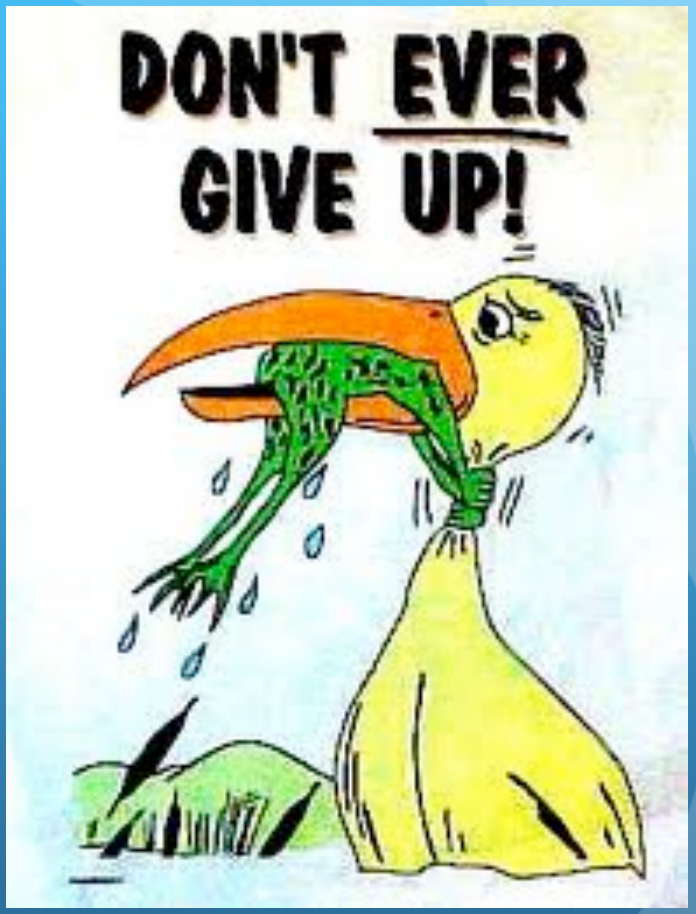
- Lessons learned
  - Handling hCSF for long periods is not as easy as it sounds
  - Implanting microporous membranes into the small ventricles w/o lots of damage is not as easy as it sounds
  - Getting enough data is not as easy as it sounds
  - Using size exclusion alone is not as easy as it sounds

So what is next?

We still have:

- Ventricular Catheters with high occlusion rates
- Valves that occlude, over drain or encapsulate with tissue
- Catheters that break

- The sign posts are clear..



- Thank you for your attention