Analysis of Clinical Records as a Means to Validate Non-Invasive Assessment of Intracranial Pressure Using the Cerebral and Cochlear Fluid Pressure (CCFP) Analyzer

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Background

- Visual impairment / intracranial pressure (VIIP) is a top risk for human spaceflight
- Currently no reliable means to monitor intracranial pressure (ICP) noninvasively
- The Cerebral and Cochlear Fluid Pressure (CCFP) Analyzer may be a viable option
- Additional validation required

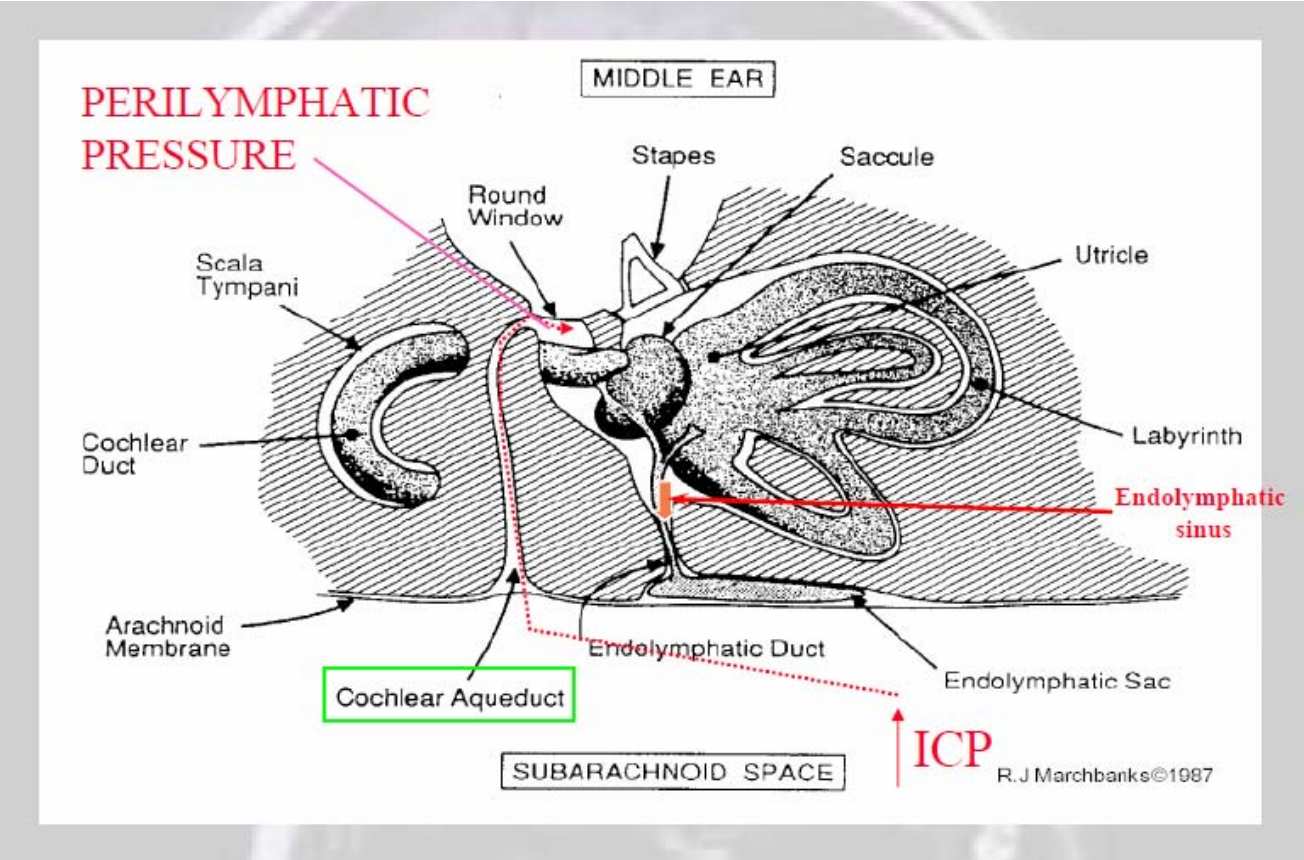
Background

- The Ear and Balance Institute (Covington, LA) has used the CCFP as a screening tool for over 10 years
- Extensive clinical record database that includes lumbar puncture (LP) data
- vh3
- retrospective clinical study was designed

Slide 3

vh3 Capitalize the "R"
vhurst, 2/4/2014

CCFP Physiology



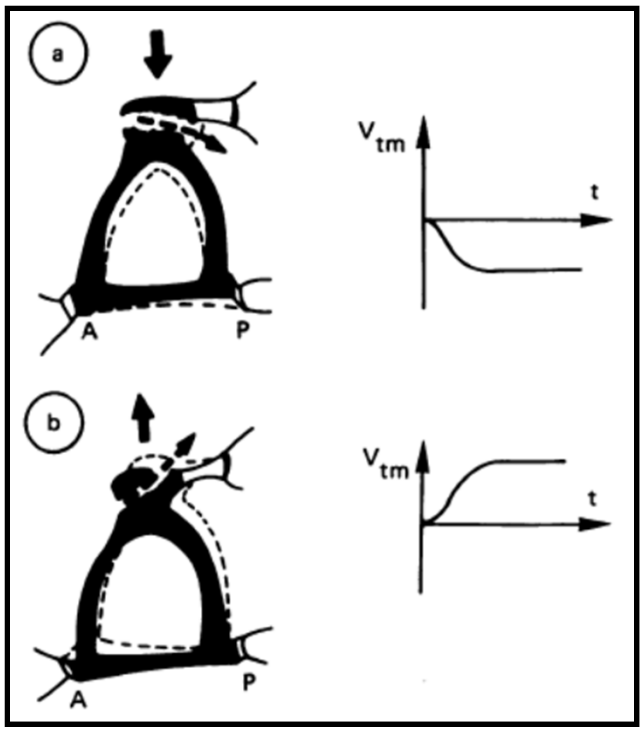
Tympanic membrane displacement (TMD) concept: vh4. cochlear aqueduct connects the subarachnoid space to the perilymph and causes changes in ICP to be manifest as changes in the resting position of the stapes in the oval window.

Figure from: Marchbanks, R.J. and Reid, A. Cochlear and cerebrospinal fluid pressure: their interrelationships and control mechanisms. British Journal of Audiology, 1990; 24: 179-187.

Slide 4

vh4 Should this be in bold like the words before it?
vhurst, 2/4/2014

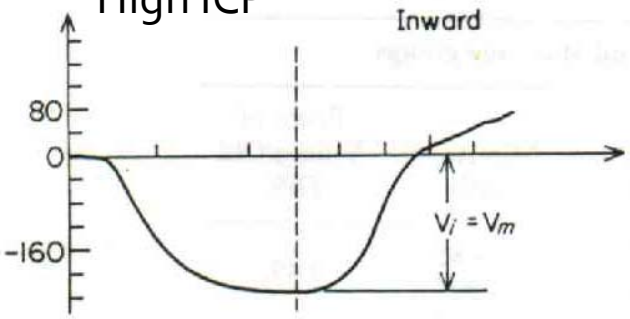
CCFP Evoked Mode

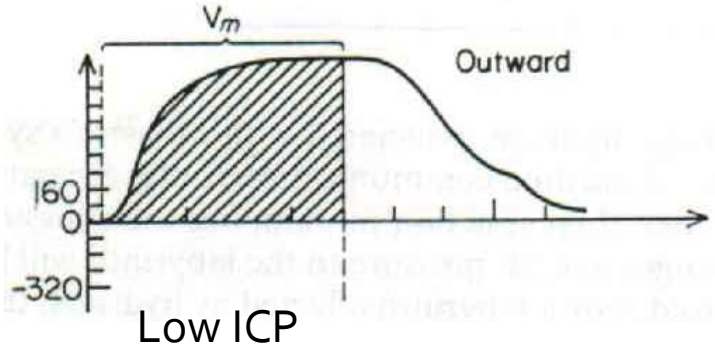


- Stapes resting position is affected by ICP
- **In response to a 1KHz tone**, the acoustic reflex changes stapes position and moves the tympanic membrane
- Volume change (tympanic membrane displacement) is measured in external ear canal (T_{tm}, measured in nL)
- Inward motion → - V_{tm} (panel a)
- Outward motion → + V_{tm} (panel b)
- Direction and magnitude indicate ICP changes

CCFP Evoked Mode

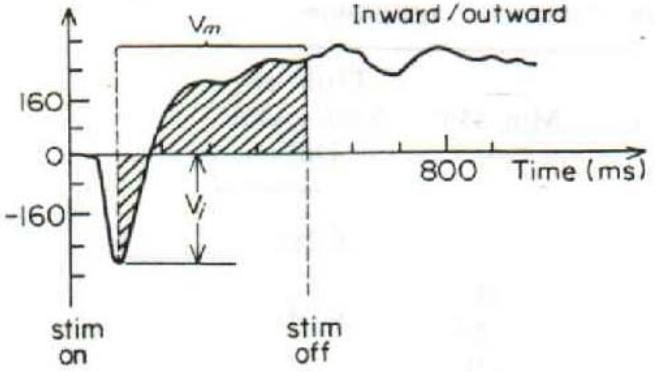
High ICP





Low ICP

Normal/Low ICP



From: Philips, A.J. and Marchbanks RJ. Effects of posture and age on tympanic membrane displacement measurements. British Journal of Audiology, 1989, 23: 279-284.

CCFP Evoked Mode

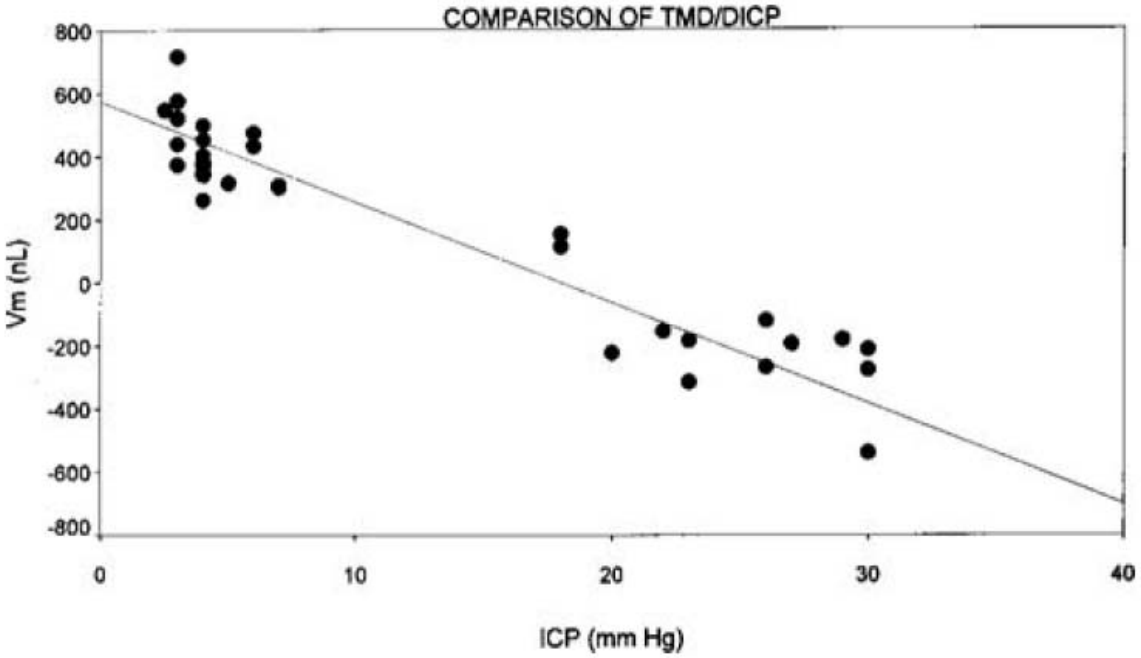
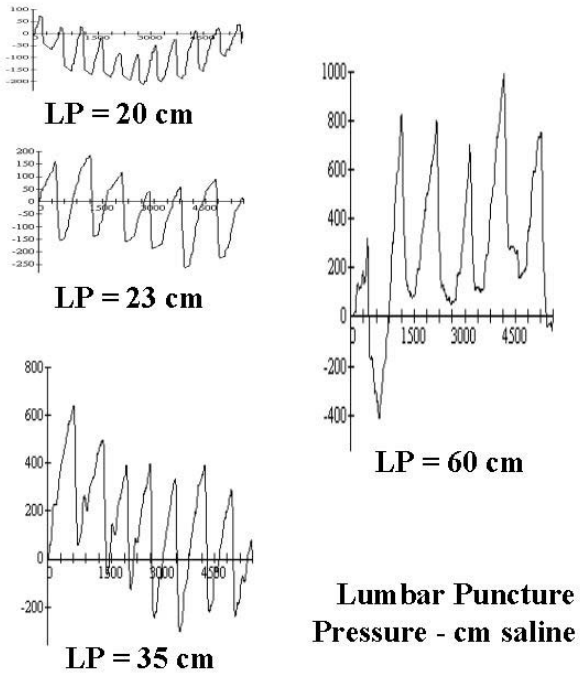


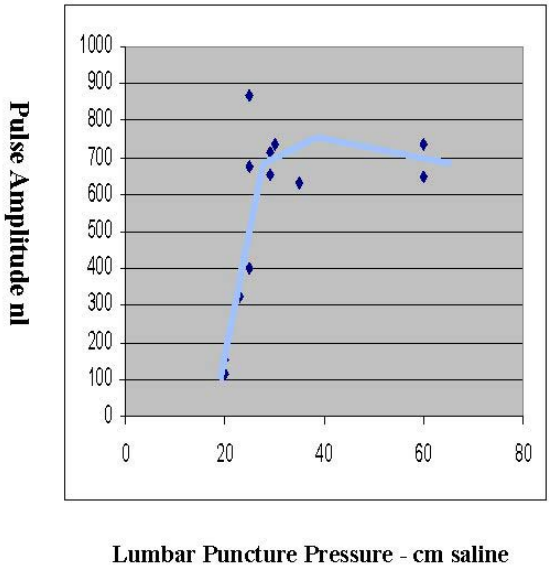
FIG. 8. Scattergram demonstrating Vm values and direct ICP measurements. Correlation coefficient is 0.94, r = 9242, r_s = 0.96627, $\kappa = 0.72$, and $p < 0.001$ (CI 0.9–0.94).

*Figure 8 from: Samuel M, Burge DM, Marchbanks RJ. Tympanic membrane displacement testing in regular assessment of intracranial pressure in eight children with shunted hydrocephalus. J Neurosurg 1998;88:983-95.

CCFP Passive Mode

- Passive recording of tympanic membrane movement





Data from a 15 year old idiopathic intracranial hypertension (IIH) patient; From: Measurement of inner ear fluid pressure and clinical applications. Marchbanks RJ (2003) Chapter 17, pp 289-307. In 'Textbook of Audiological Medicine: Clinical aspects of hearing and balance'. Ed L. Luxon. Martin Dunitz Ltd. 2003, ISBN 1-90186-534-7.

Inclusion/Exclusion Criteria

- CCFP and LP measures within several days, with CCFP occurring first
- No medical interventions between measures
  - Medication changes, surgery
  - Existing stable medication was not an exclusion
- LP-CCFP data pairs included:
  - 29 without superior semicircular canal dehiscence (SSCD)
  - 35 with SSCD

Caveats

- LP and CCFP data not collected at the same time
  - ICP variability
  - Patient medication compliance
- All subjects have some pathology, most are ear related
  - SSCD (~50%)
  - and perilymph fistula (~65%)

Superior Semicircular Canal Dehiscence (SSCD)

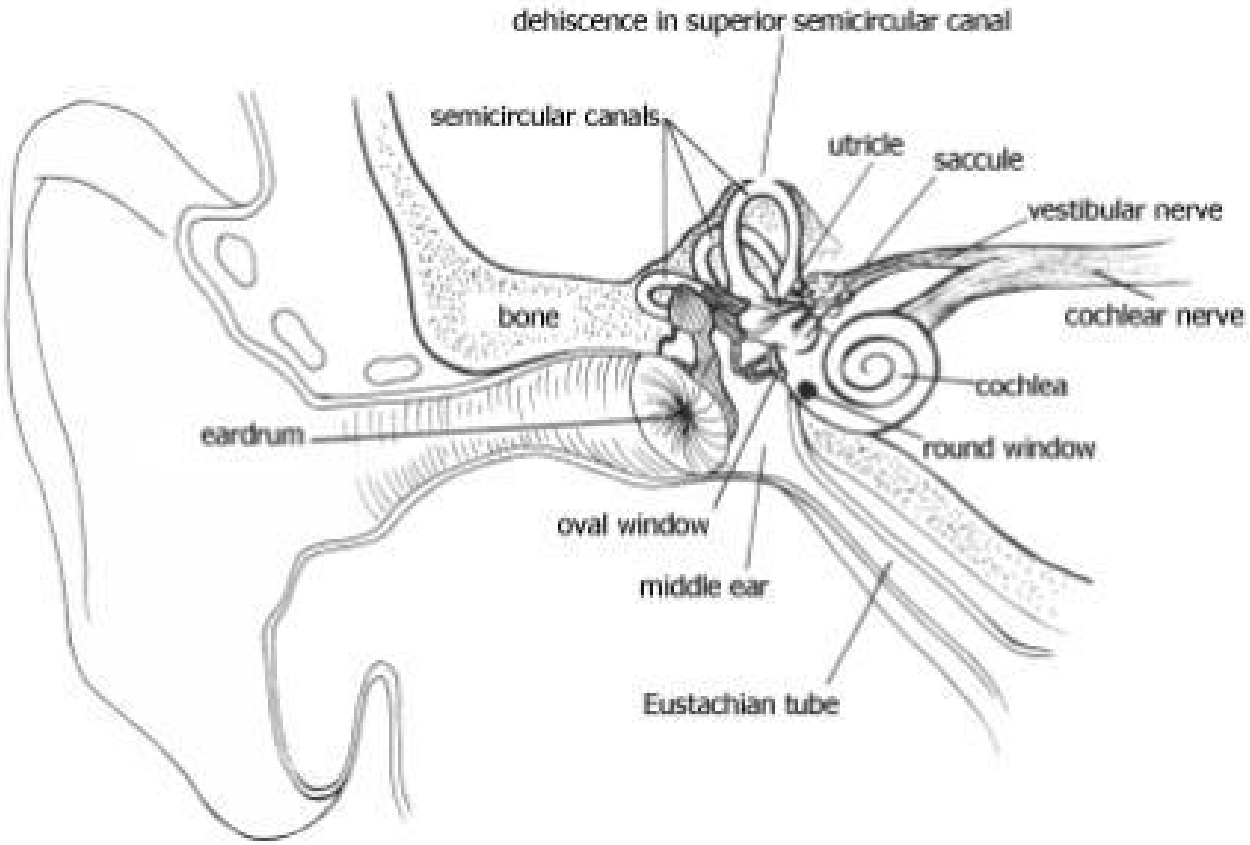
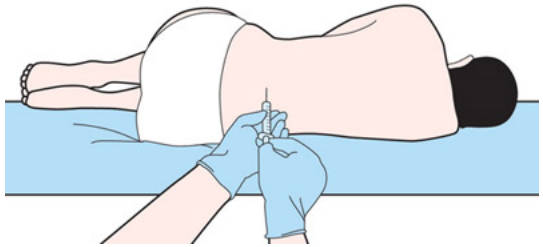


Image from http://vestibular.org/superior-canal-dehiscence-scd

Methods

- LP opening pressures taken in lateral decubitus



- CCFP taken from ear with better hearing and and middle ear measures
- When multiple dB levels of test data were available, higher results were used
  - maximizes saturation of the acoustic reflex

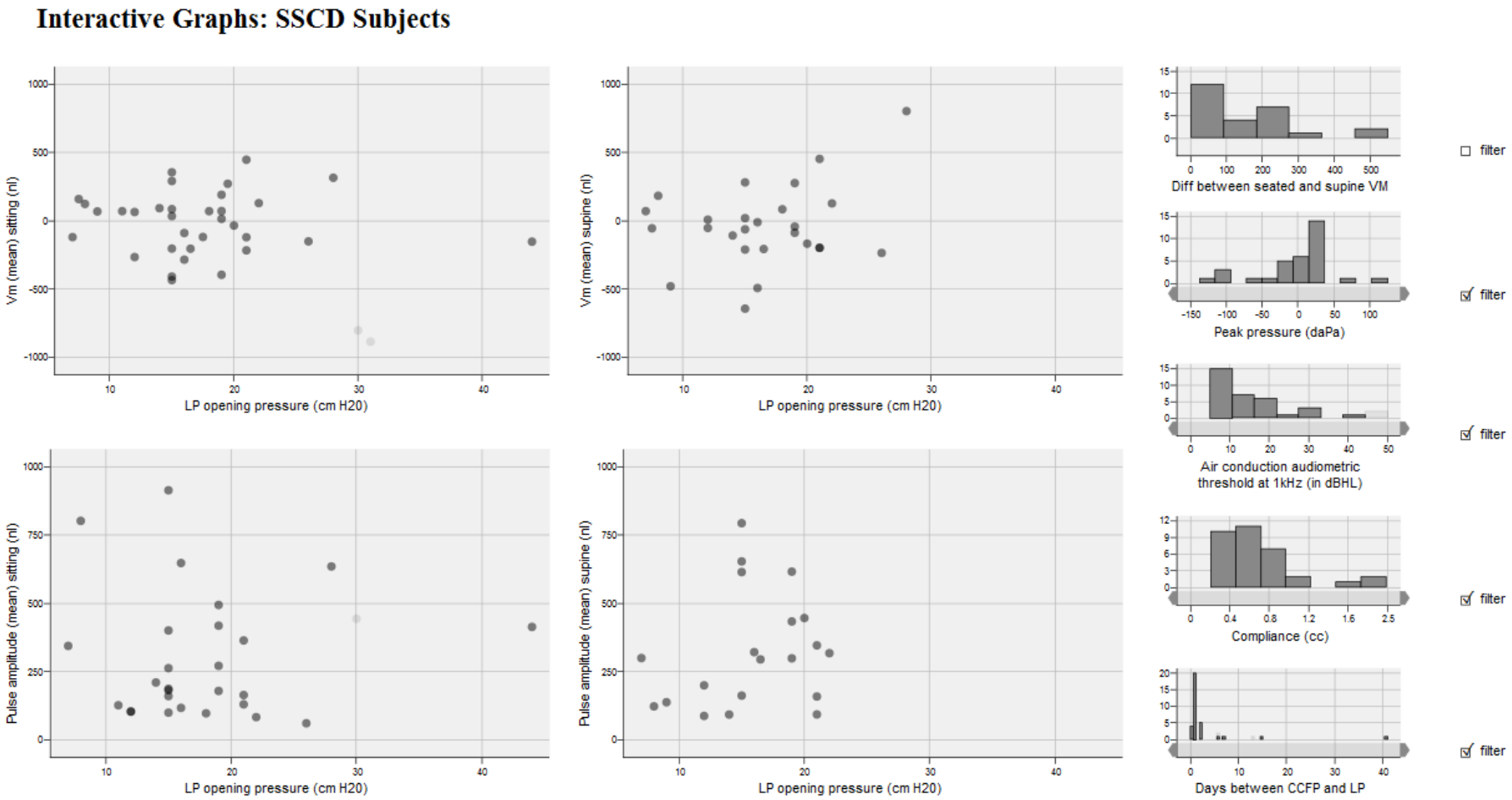
Data

- 47 parameter fields
  - clinical data- not all fields had available data
  - many fields used for subject sorting and verification of valid LP-CCFP paired data
- Primary analysis focused on: LP, Vm (seated and supine), pulse amplitude (seated and supine), air conduction audiometric threshold at 1kHz, middle ear peak pressure and compliance, and age at time of test

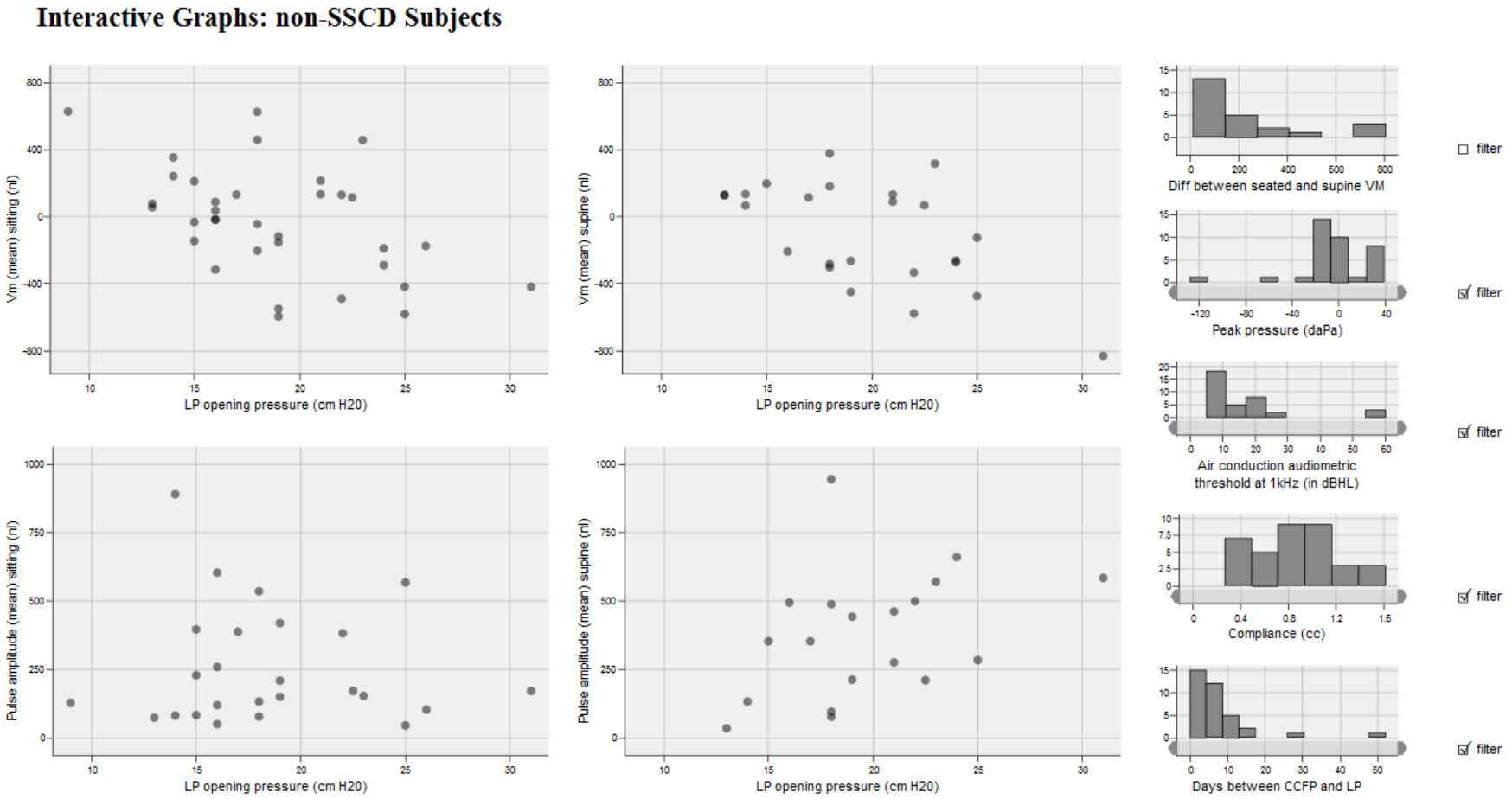
Data

- Interactive graphs
  - courtesy of James Fiedler of the JSC Biostatistics Laboratory
  - *Note to reviewers: the following 2 slides are screenshots of the interactive graphs that will be demonstrated during this portion of the presentation*

Data: SSCD


Interactive Graphs: SSCD Subjects
Vm (mean) sitting (nl)
LP opening pressure (cm H20)
Vm (mean) supine (nl)
LP opening pressure (cm H20)
Pulse amplitude (mean) sitting (nl)
LP opening pressure (cm H20)
Pulse amplitude (mean) supine (nl)
LP opening pressure (cm H20)
Diff between seated and supine VM
filter
Peak pressure (daPa)
filter
Air conduction audiometric threshold at 1kHz (in dBHL)
filter
Compliance (cc)
filter
Days between CCFP and LP
filter

Data: non-SSCD



Statistics

- Somers' D: LP vs Vm
  - Assumption-free
  - Allows for data clustering (multiple measures per person)
- SSCD Subjects
  - Seated: Coefficient= -.109, std err =.147, p=.460
  - Supine: Coefficient= -.037, std err =.162, p=.819
- Non-SSCD Subjects
  - Seated: Coefficient= -.323, std err =.114, **p=.004**
  - Supine: Coefficient= -.339, std err =.118, **p=.004**

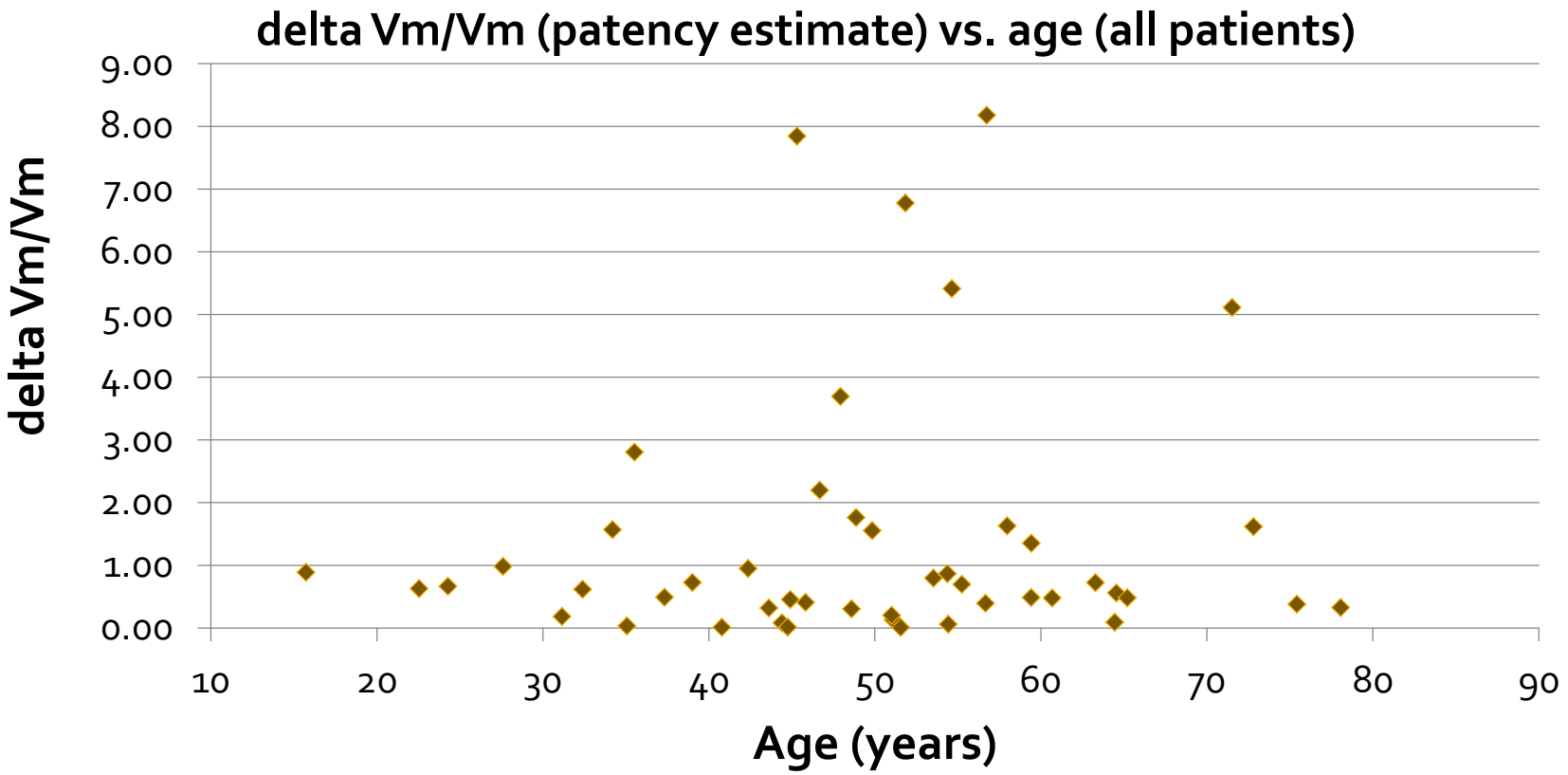
Statistics

- Mixed-effects regression- LP compared to:
  - Vm
  - Days between LP and CCFP
  - Pulse amplitude
- Untransformed data
  - ln(LP) similar results

Statistics

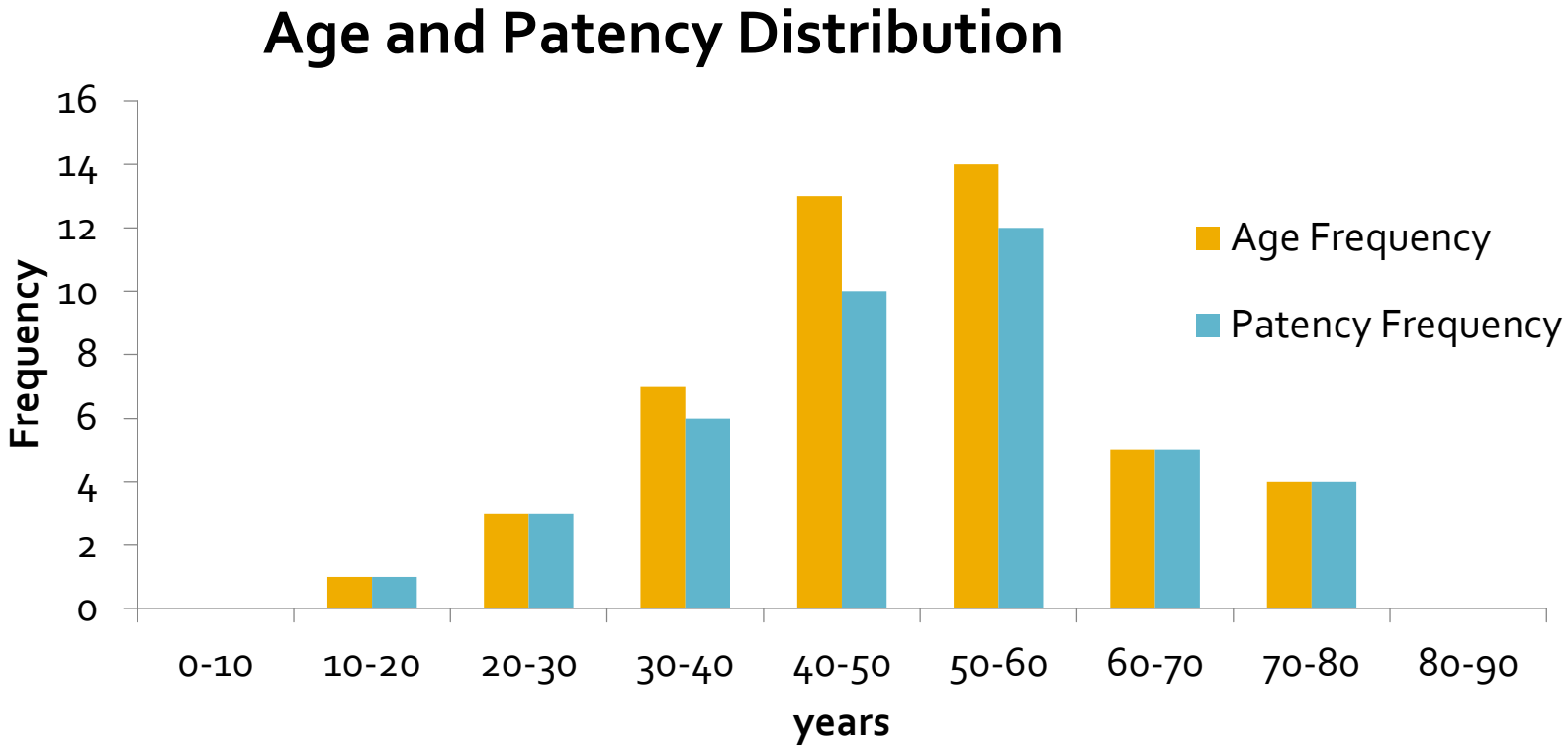
- Non-SSCD Subjects
  - Vm Seated: Coefficient= -.0084, std err =.0026, **p=.001**
    - No significant effect of days between tests and pulse amplitude
  - Supine model did not fully converge
    - Vm Coefficient= -.0053, std err =.0029, p=.068
    - Pulse Amplitude Coefficient= -.0074, std err =.0046, p=.104
    - No significant effect of days between tests

Cochlear Aqueduct Patency



delta Vm/Vm > 0.1 indicates patent cochlear aqueduct

Cochlear Aqueduct Patency



Age group	0-10	10-20	20-30	30-40	40-50	50-60	60-70	70-80	80-90
Patency rate (%)	-	100	100	86	77	86	100	100	-

Sleep – Wake LP measures

	LP (cm H_2O) vh5		
	wake	sleep	delta
	25	43	18
	18	27	9
	23	28	5
	16	19	3
	17	25	8
	15	32	17
Average	**19**	**29**	**10**

Patients are in lateral decubitus position for both measures

Patients are being closely monitored by anesthesiologist; not likely a hypoventilation effect

Slide 22

vh5 Captilize

vhurst, 2/4/2014

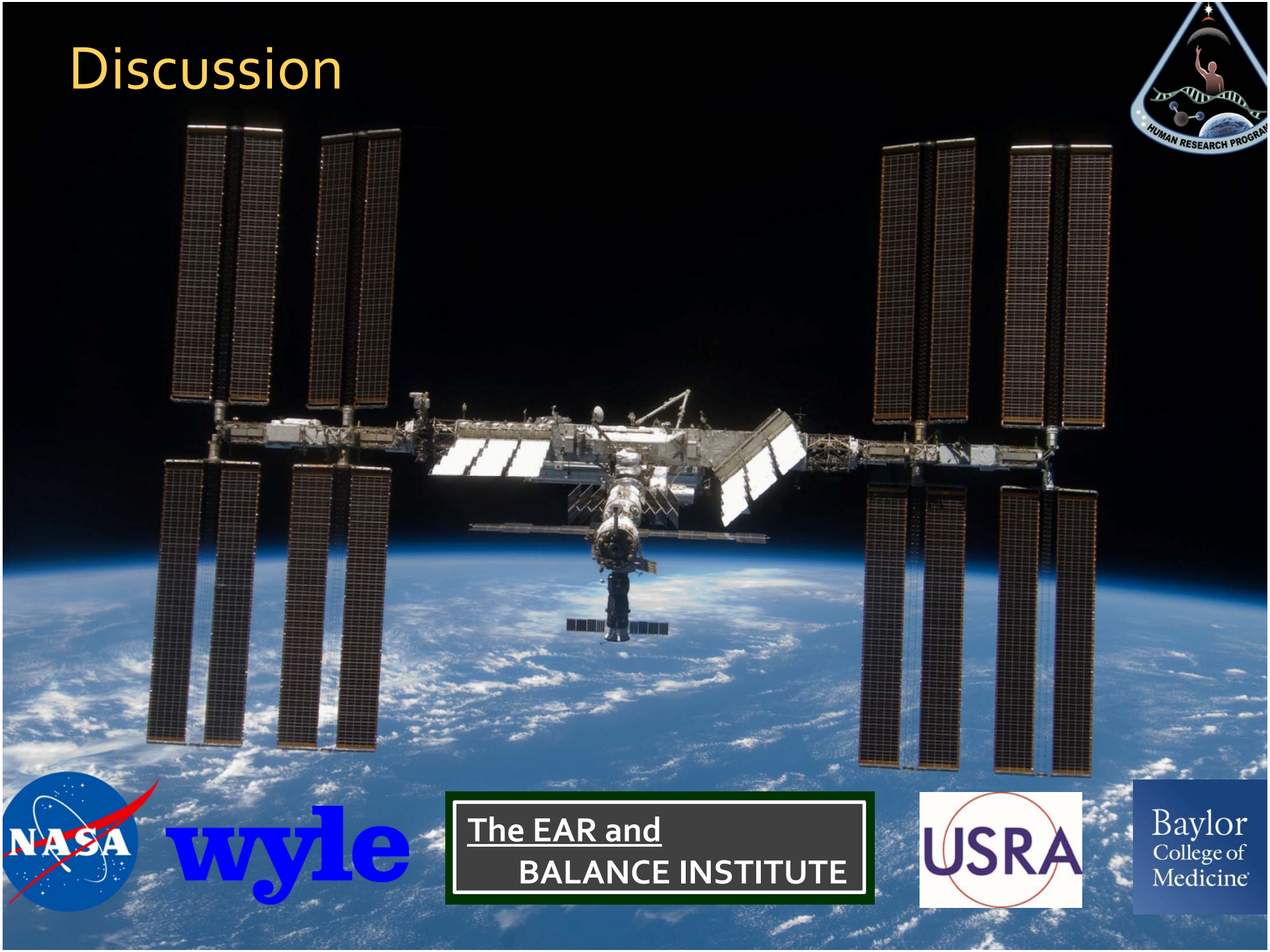
Conclusions

- There is a significant correlation of LP and seated Vm in the non-SSCD subjects in this population
- There is trending of LP with seated Vm and seated pulse amplitude in the non-SSCD subjects in this population
- Clinical factors such as hearing loss likely affect repeatability and reliability, although specific contribution levels could not be identified within this data set
- In this population, cochlear aqueduct patency rates are high and do not appear to decline with age
- Considering the limitations associated with this clinical data set, results are highly encouraging as to the utility of the CCFP as an ICP screening tool

Acknowledgements

- Rachel Brady – spreadsheet work
- James Fiedler- interactive graphing software

Discussion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