

Cochlear Hybrid System: Factors Involved in Outcomes

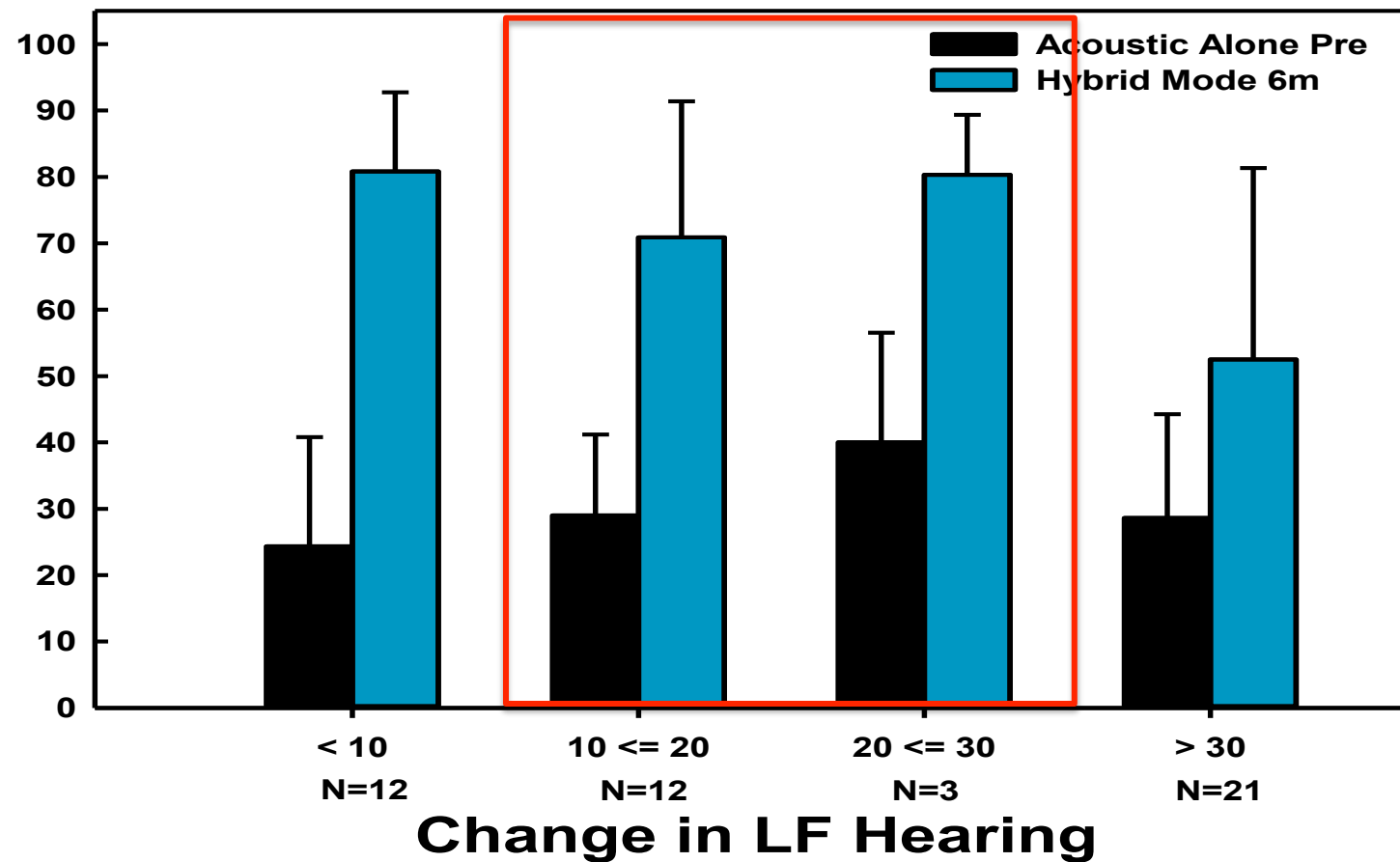
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Professor and Chairman
ACIA Nashville 12/19/14

FDA Presentation

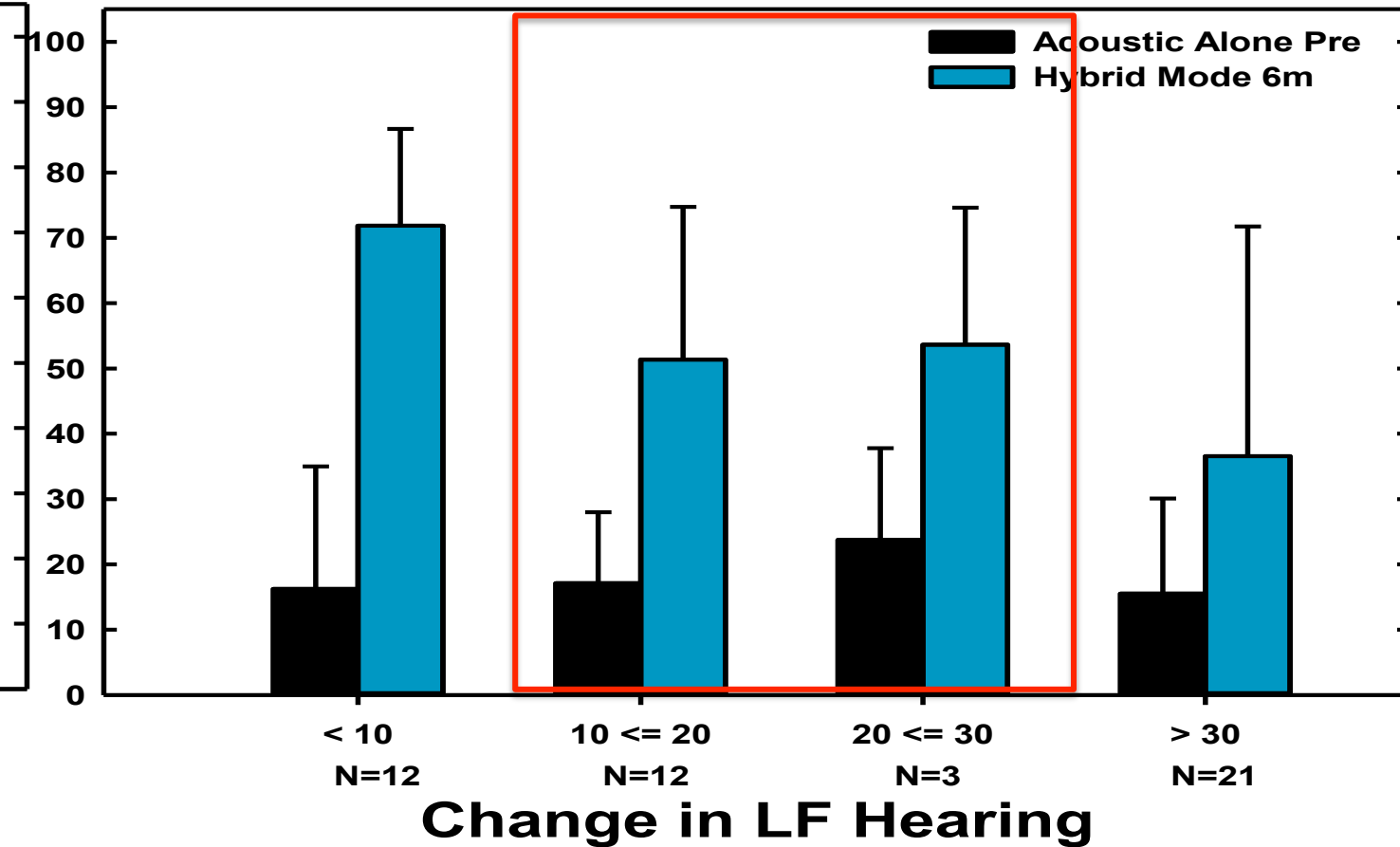
- Panel in November- led to approval
- Multicenter Data on 50 patients
- Discuss Outcomes of Study
- Discuss factors that might influence outcomes

Outcomes by Hearing Loss

CNC Word Recognition N=48

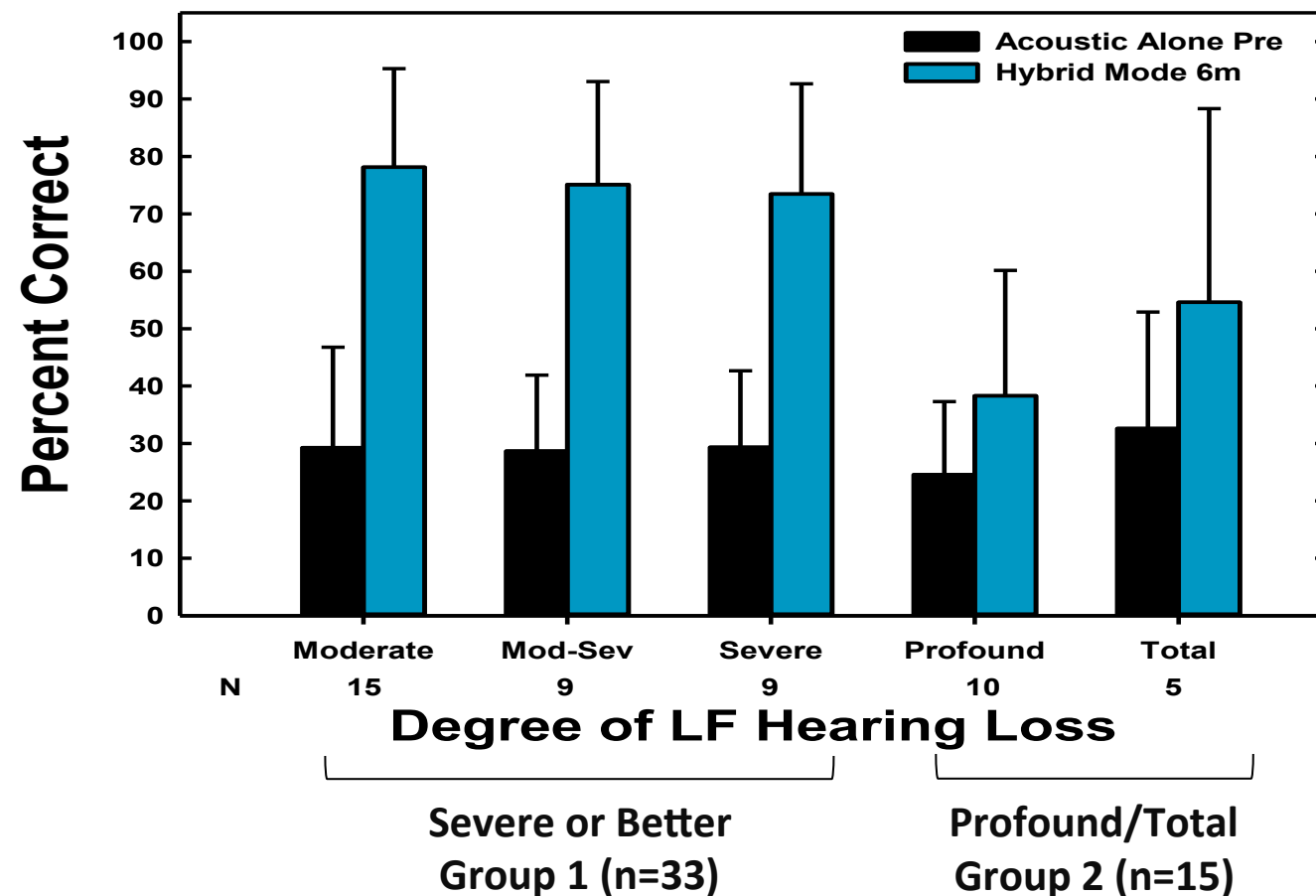


AzBio +5dB SNR N=48

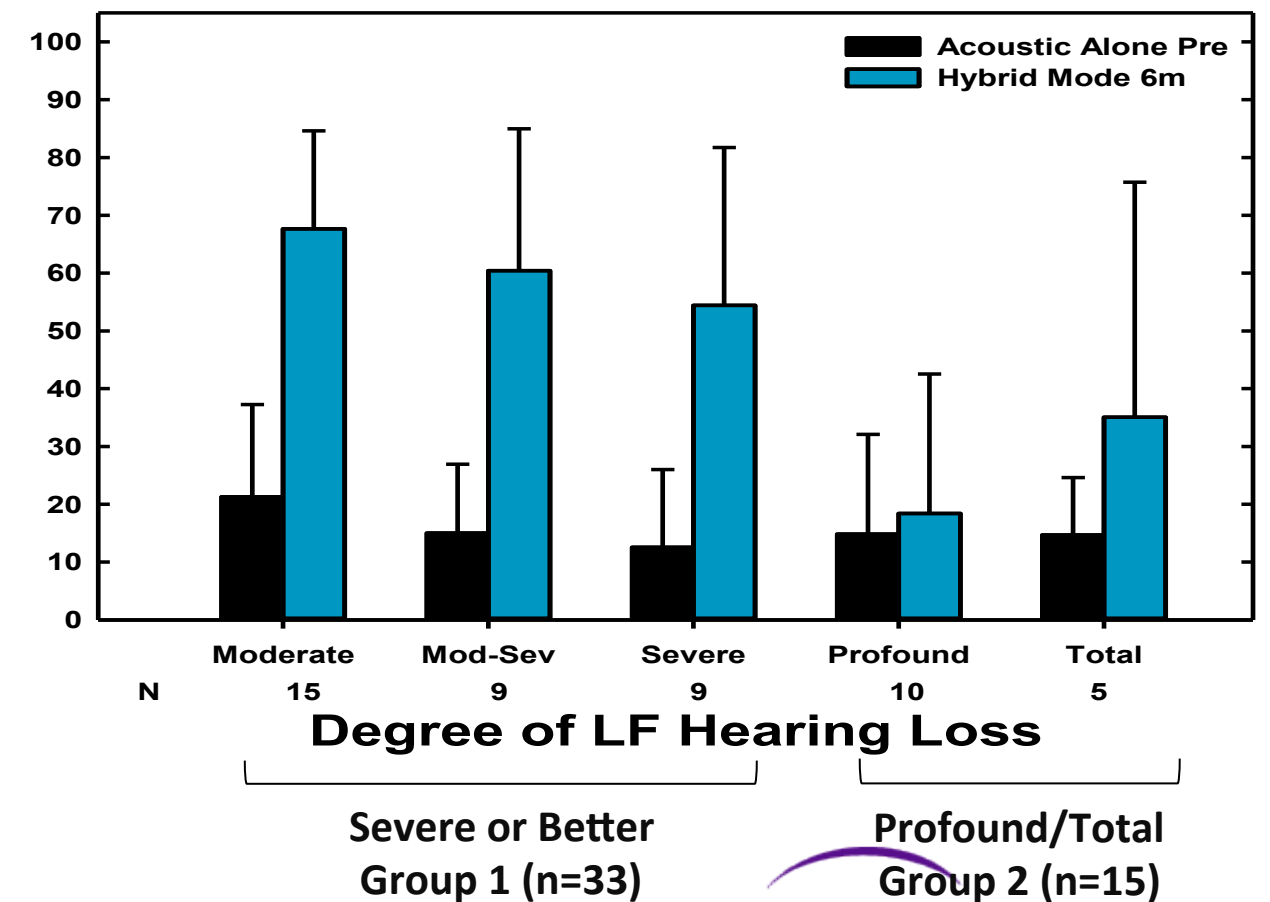


Clinical Significance of Groups 1 and 2

**CNC Word Recognition
6 Months Postactivation N=48**

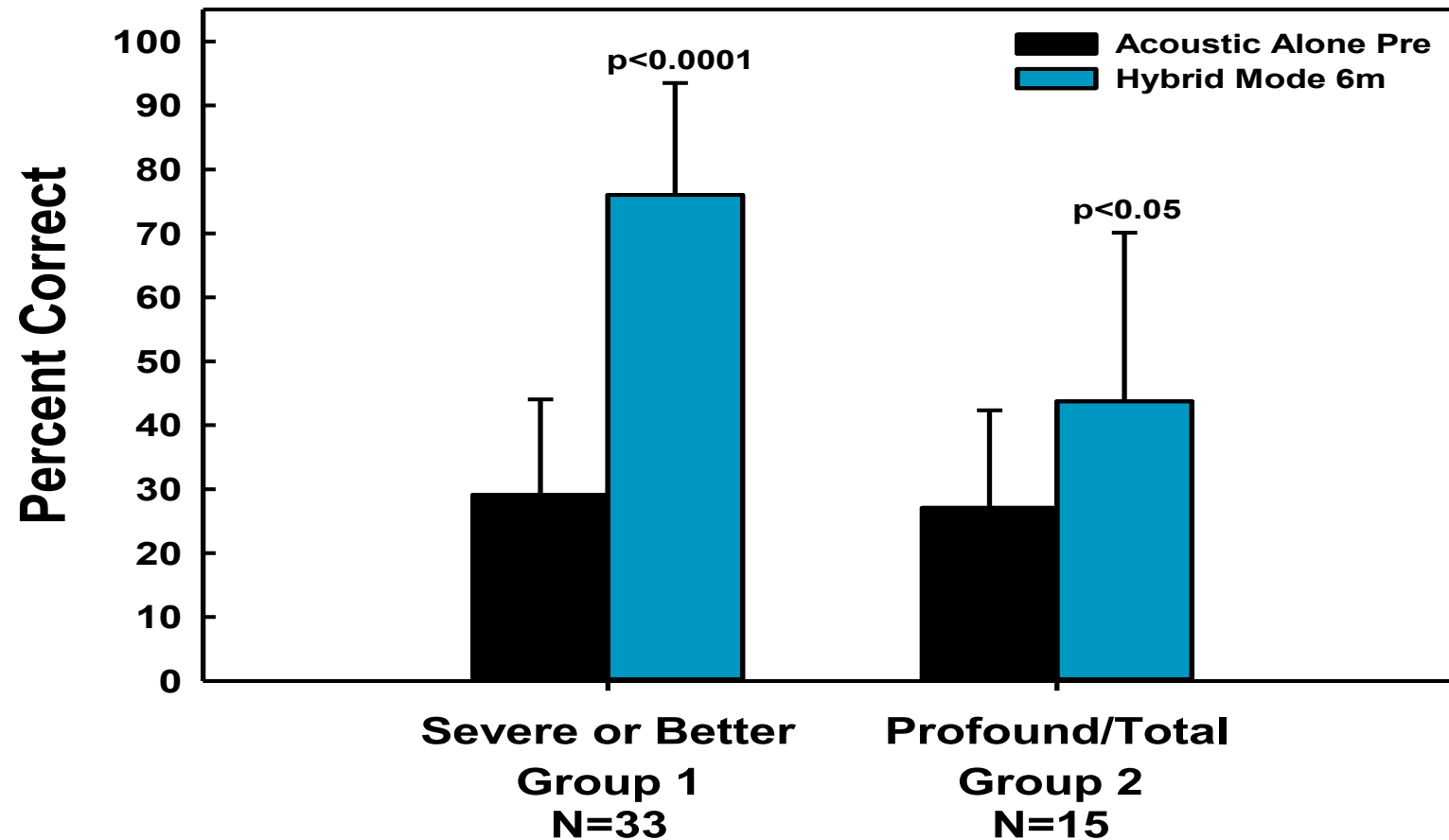


**AzBio +5dB SNR
6 Months Postactivation N=48**

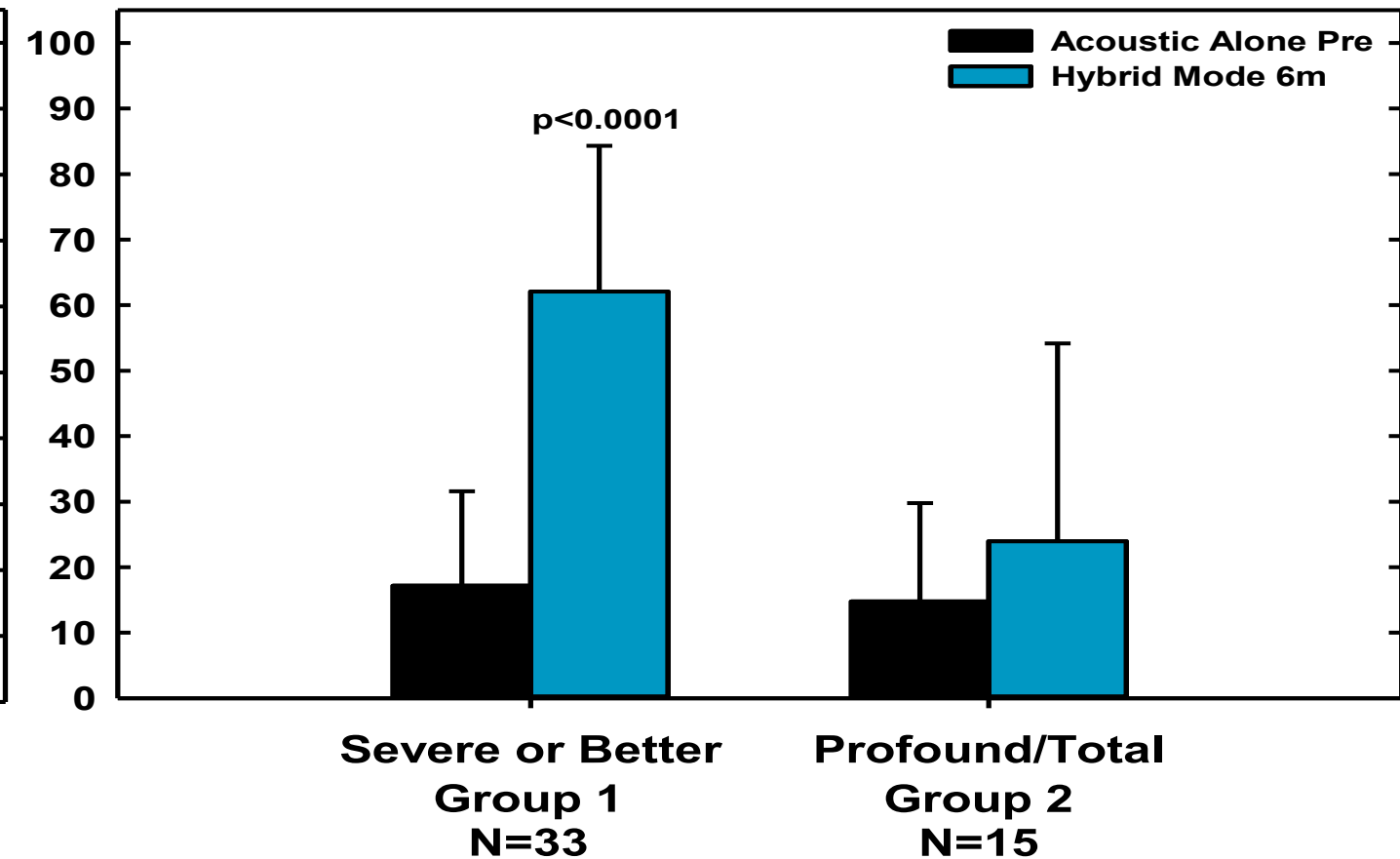


Clinical Significance of Groups 1 and 2

**CNC Word Recognition
6 Months Postactivation N=48**



**AzBio +5dB SNR
6 Months Postactivation N=48**



Potential Predictive Factors – Hearing Sensitivity

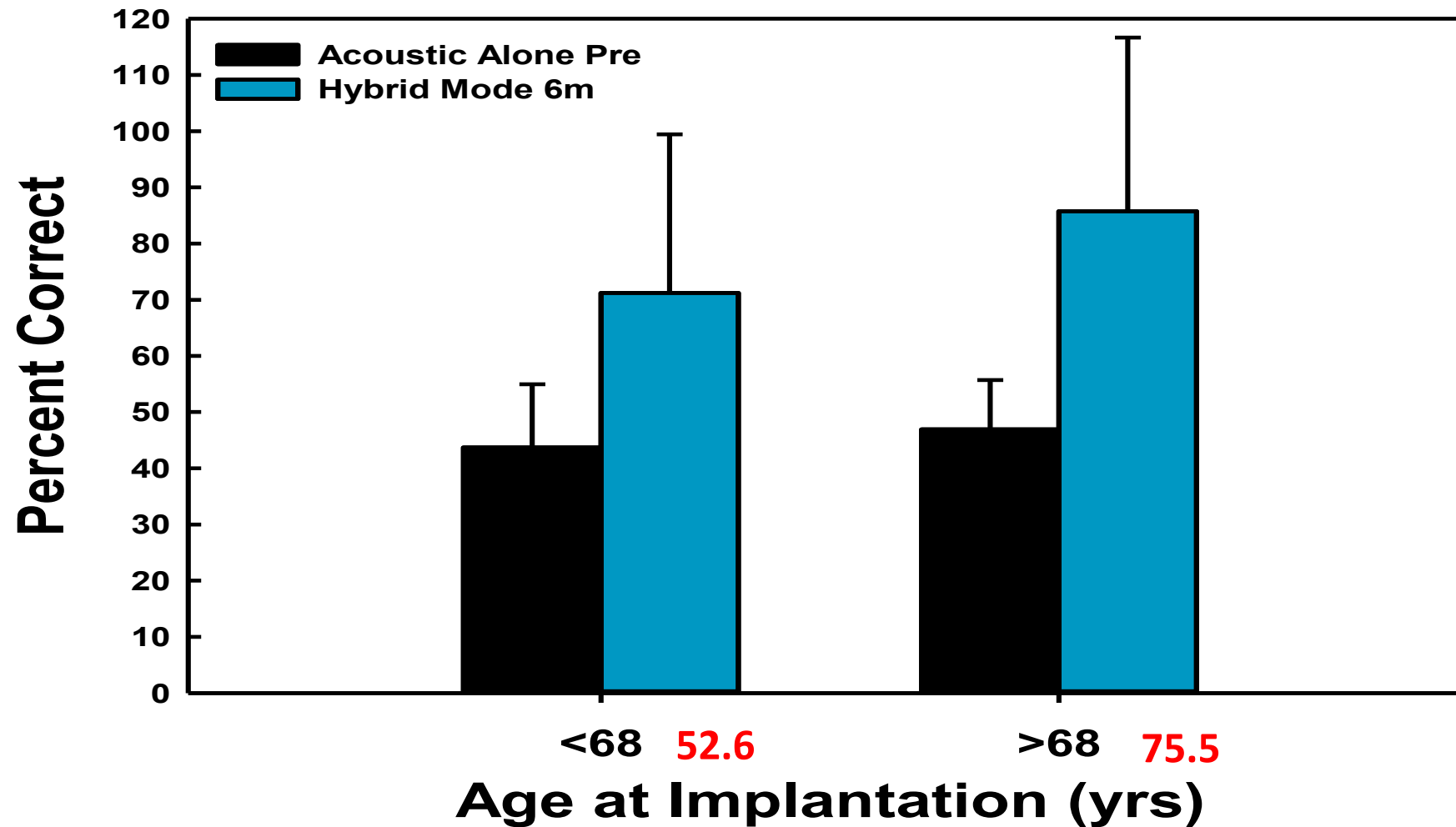
Outcome Measure	Gender P-value*	Age P-value*	Duration of Loss P-value*	Duration of Severe to Profound Loss P-value*	Etiology P-value*	Baseline CNC Score P-value*	Baseline AzBio Score P-value*
Change LFHL	0.010	0.160	0.722	0.275	0.970	0.450	0.900
Degree LFHL	0.016	0.088	0.536	0.581	0.949	0.910	0.264

*ANOVA p-value.

Age >70, long duration of HF PSNHL, Male Gender

Hearing Status Dichotomized by Median Age

Degree LFHL 6m by Median Age N=50



US07-1523 and US14-1050 LVCF

Pre- to postoperative change
and degree of LFHL NS between groups.

Pre- to postoperative
change:

27.5 dB for < 68 years

38.9 dB for > 68 years

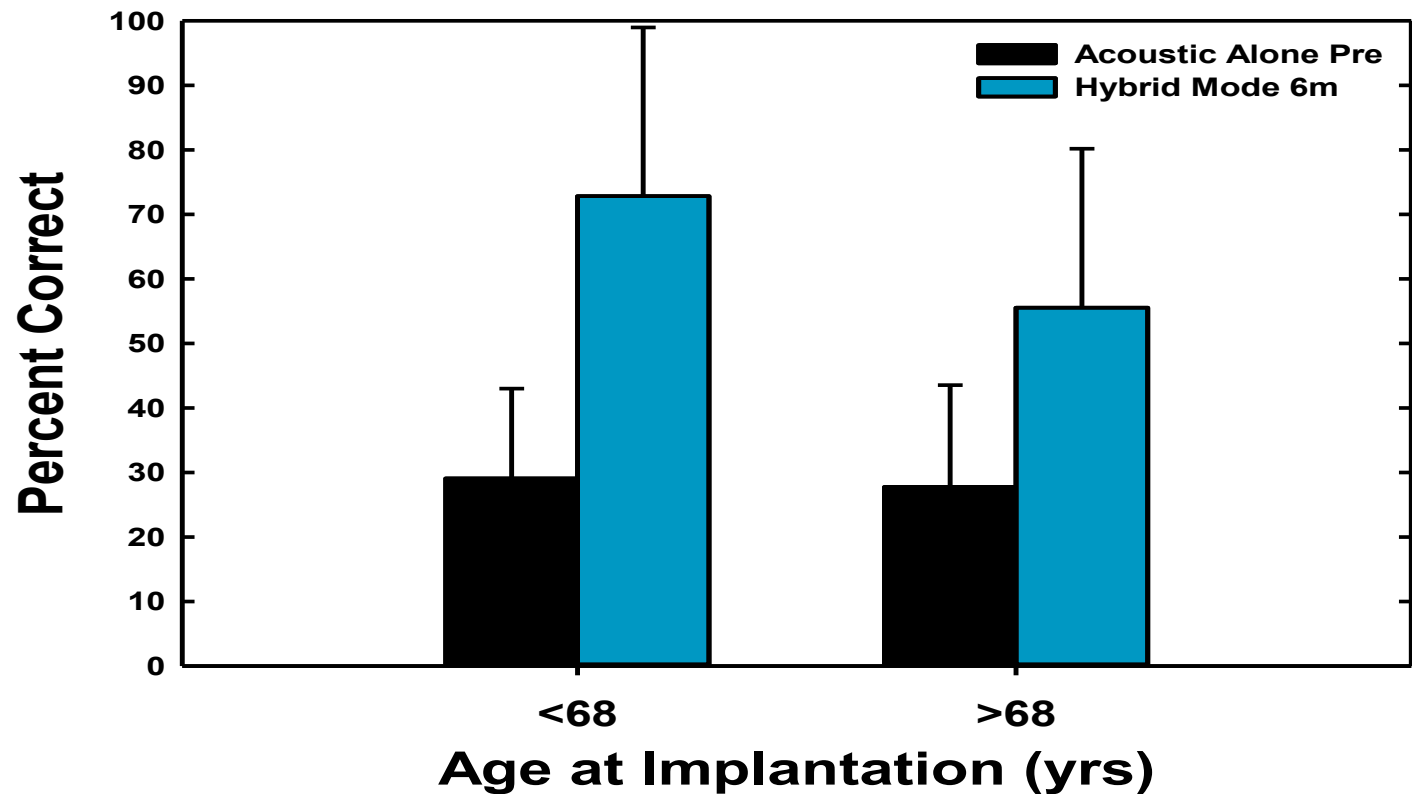
10/17 profound losses were
> 68 years

4/5 complete losses were >
68 years

(5th subjects was 67.9
years)

Outcomes Dichotomized by Median Age

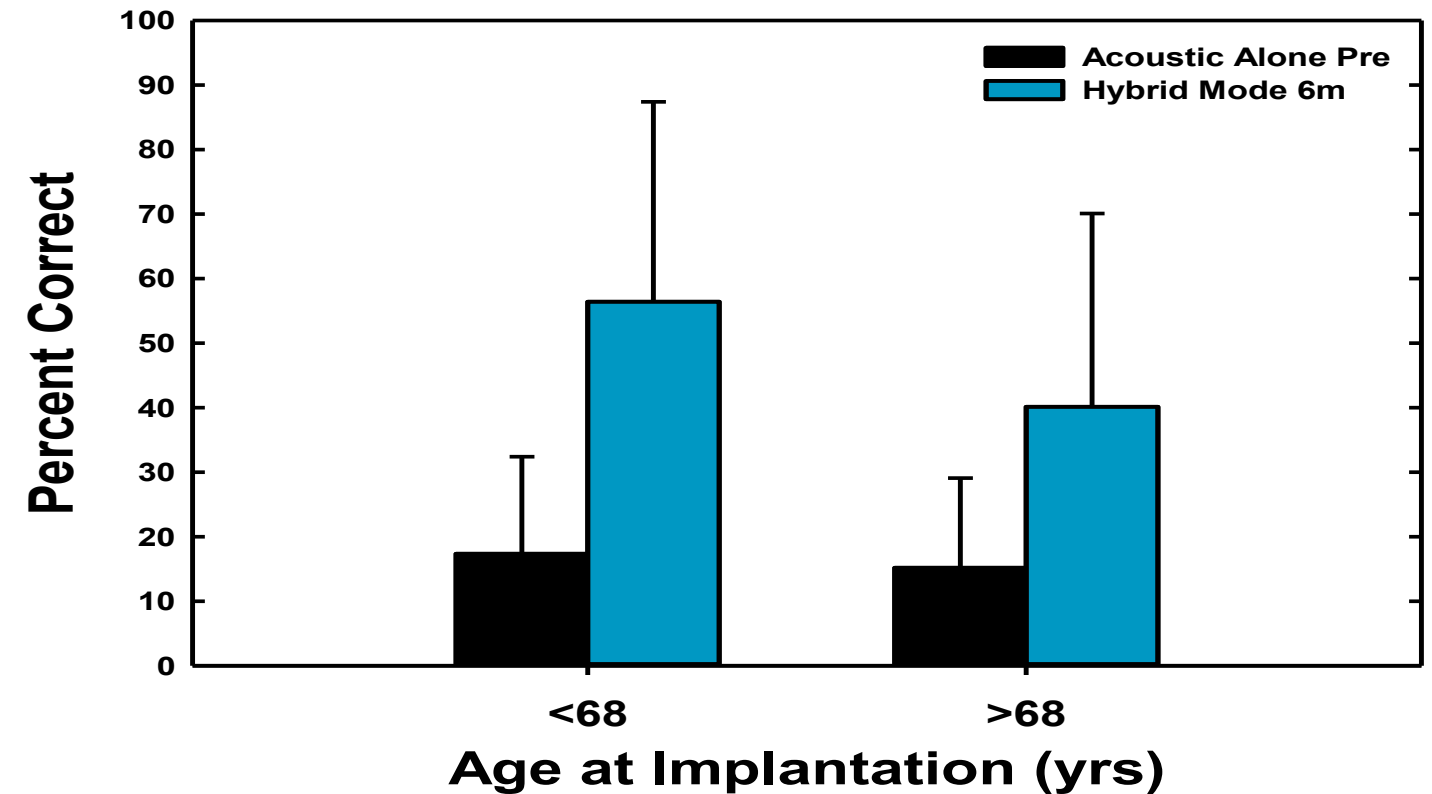
**CNC Words Dichotomized
by Median Age N=50**



US07-1523 and US14-1050 LVCF

Improvement significantly greater for < 68 years ($p = 0.027$) but pre- to postoperative improvement significant for both groups.

**AzBio +5 dB SNR Dichotomized
by Median Age N=50**



US07-1523 and US14-1050 LVCF

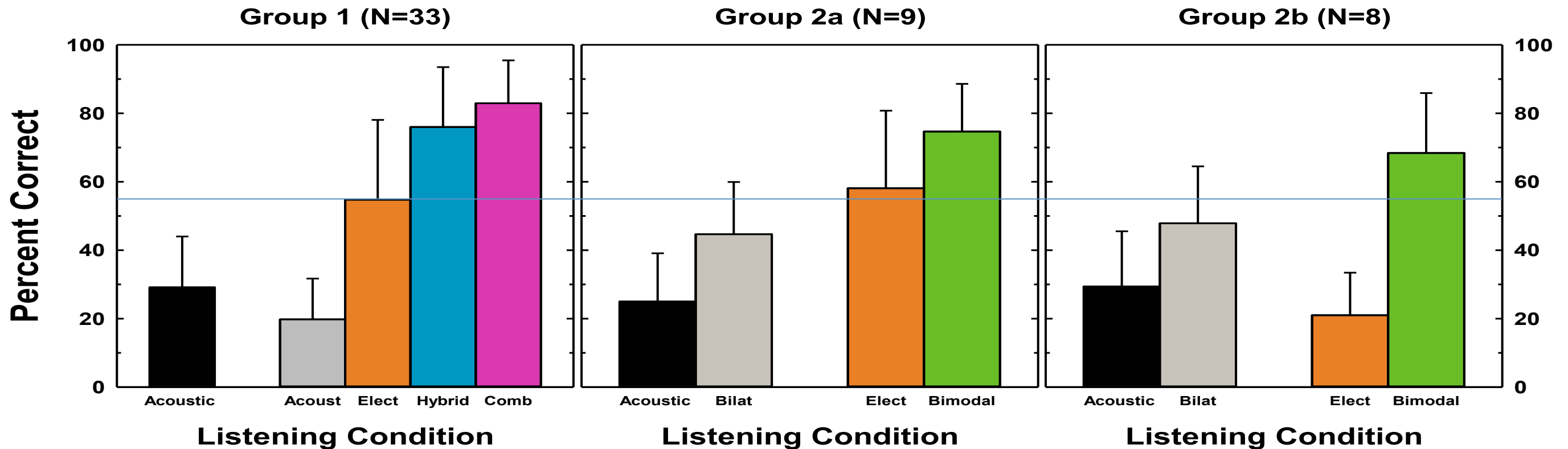
Improvement significantly greater for < 68 years ($p = 0.038$) but pre- to postoperative improvement significant for both groups.

Age Conclusions

- Younger subjects (< 68 years) as a group experienced greater pre- to postoperative improvement and higher absolute levels of performance for CNCs and AzBio in noise
 - BUT older subjects still showed significant improvement over their preoperative status
- May have been related to shorter duration of overall hearing loss based on multivariate analyses

Group 2a/2b Analyses

CNC Word Recognition



Moderate to Severe hearing loss by 6 months and benefit on one or both CNC/AzBio

Profound Loss by 6 months and NOT benefit on either CNC/AzBio

Group 1 & 2 Baseline Characteristics

	Baseline Characteristics								
	Degree LFHL	CNC Score	AzBio Score	Age	Duration	Duration SP	Gender		
	Mean dB HL (SD)	Mean % (SD)	Mean % (SD)	Mean yrs. (SD)	Mean yrs. (SD)	Mean yrs. (SD)	Males	Females	
	Range	Range	Range	Range	Range	Range			
Group 1 N=33	42.0 (9.5) 19-59	29.1 (14.9) 10-64	17.2 (14.4) 0-64.1	61.8 (15.2) 37.5-86.2	25.5 (13.1) 3.4-52.4	12.5 (SD) 1.6-30.1	13	20	
Group 2a N=9	53.4 (9.7) 33-63	25.0 (14.1) 9-49	19.7 (17.9) 4.9-26.7	64.1 (15.7) 23-75.1	22.3 (5.2) 13.1-29.4	12.2 (6.9) 1.8-25.1	7	2	
Group 2b N=8	49.6 (6.3) 42-60	29.4 (16.1) 12-59	8.6 (6.6) 0-19.1	73.4 (7.7) 63.8-85.7	44.9 (18.4) 15.4-74	14.5 (7.6) 3.8-27.5	5	3	

- Five of 6 reimplantation cases come from Group 2b cases
- Group 2b cases were 9 years older on average but most notably had **45** years of hearing loss compared with Group 1 and 2a subjects who had 26 and 22 years of hearing loss, on average
- Degree of change in LF hearing was no different between Group 2a and 2b (~50 dB on average)

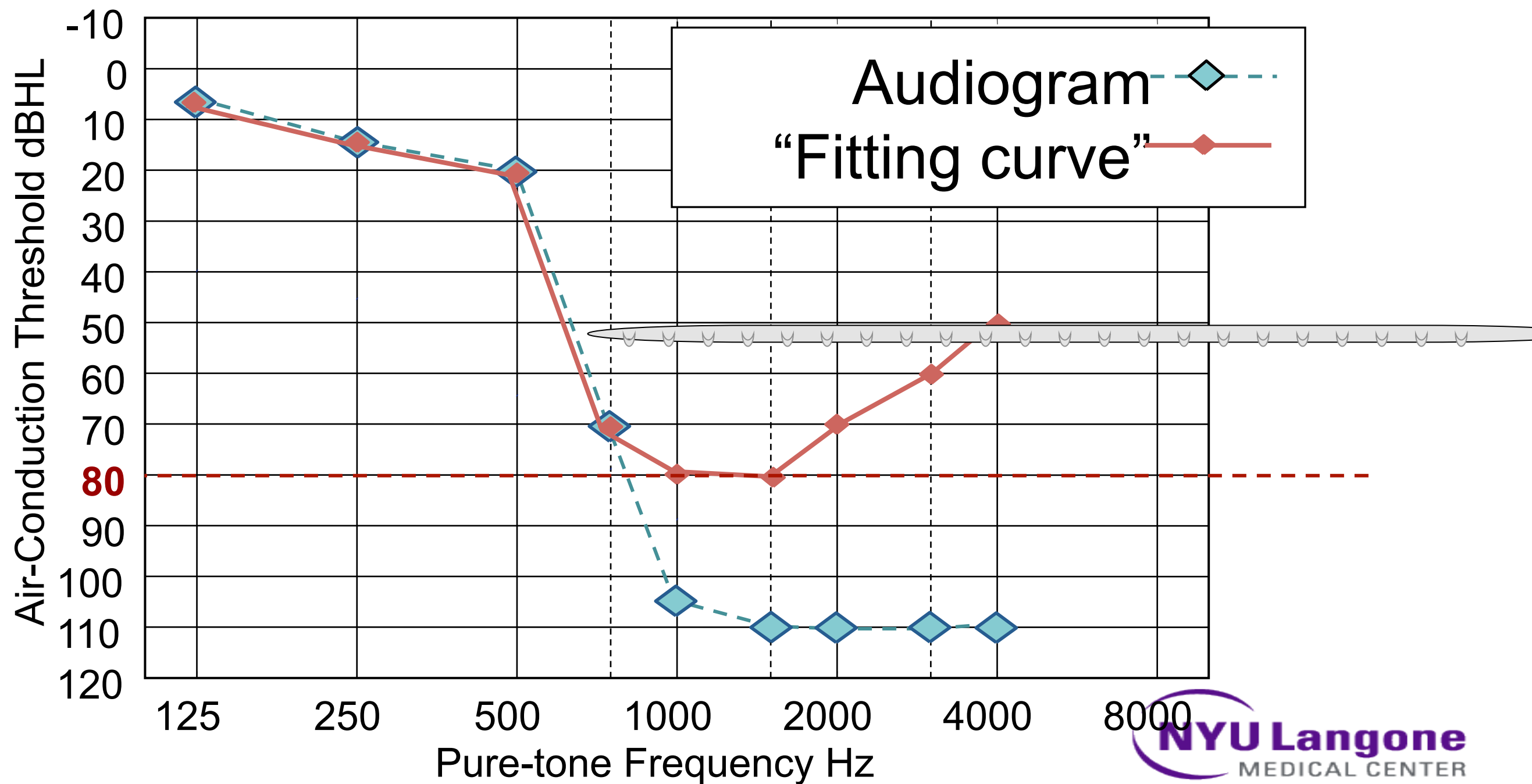
Group 2b Status

- 5 of the 8 Group 2b subjects elected reimplantation to address performance concerns
- 1 of the 8 Group 2b subjects was very satisfied with their performance and showed improved speech scores for both CNC and AzBio when using both ears
- 1 of the 8 Group 2b subjects passed away for reasons unrelated to the device

Overall Conclusions

- Older subjects with very long durations of overall HF hearing loss should be considered with caution
 - *Trend* towards higher risk of significant loss
 - Most significant loss occurs, with long duration of preoperative hearing loss, don't appear to benefit from electrical stimulation

HA fittings for “dead regions”



Considerations

- Look at low frequency start point - start at 50 and lose 30dB.....
- Also look at high frequencies, detection vs dead
- Duration of S/P HF hearing loss, “are there ganglion cells to stimulate?”
- Patient age
- Male Gender