



Cochlear Implant Study

Simone Moore



Study Background

- Initiated by Bruce Gantz, MD and colleagues at the University of Iowa in 1999, as an FDA regulated feasibility study
- Multicenter study launched in 2002
 - 25 subjects implanted in the US
- Study broadened in 2005 to include additional surgeons/sites and up to 100 subjects total
 - 58 subjects implanted in the US
- As of March 6, 2007:
 - Study closed to enrollment
- Subject Group:
 - 87 total



Hybrid S12



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Definitions

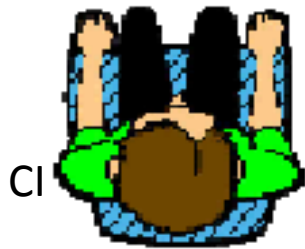
- **Ispilateral:** one hearing aid



- **Bilateral:** two hearing aids



- **CI Alone:** cochlear implant, no hearing aids



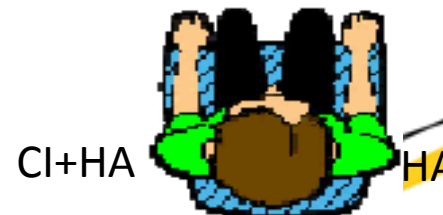
- **Hybrid:** cochlear implant + hearing aid in same ear, nothing in the other



- **Bimodal:** cochlear implant + hearing aid in other ear



- **Combined:** cochlear implant + hearing aids in both ears

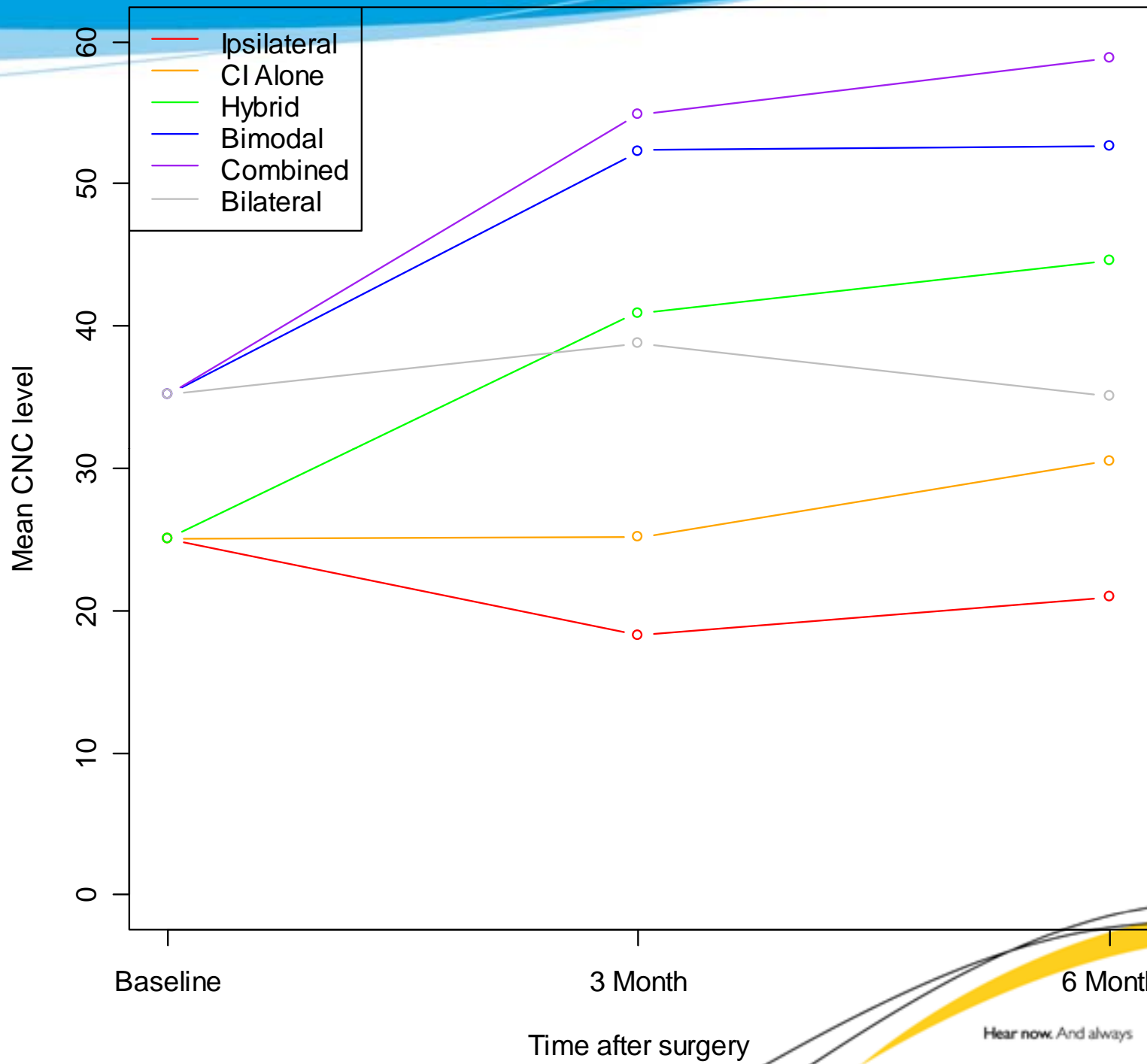


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Definitions

- **Consonant Nucleus Consonant (CNC) Test:**
 - Nucleus means vowel
 - It consists of 10 lists of 50 monosyllabic words (i.e. bat, cat, hat, had, mad, sad, bad, boy, toy, etc.)
 - Each person reads two word lists per setting for a total of 100 words
 - The score that you will see is the number of words correct out of 100
 - Test is performed every three months in each setting



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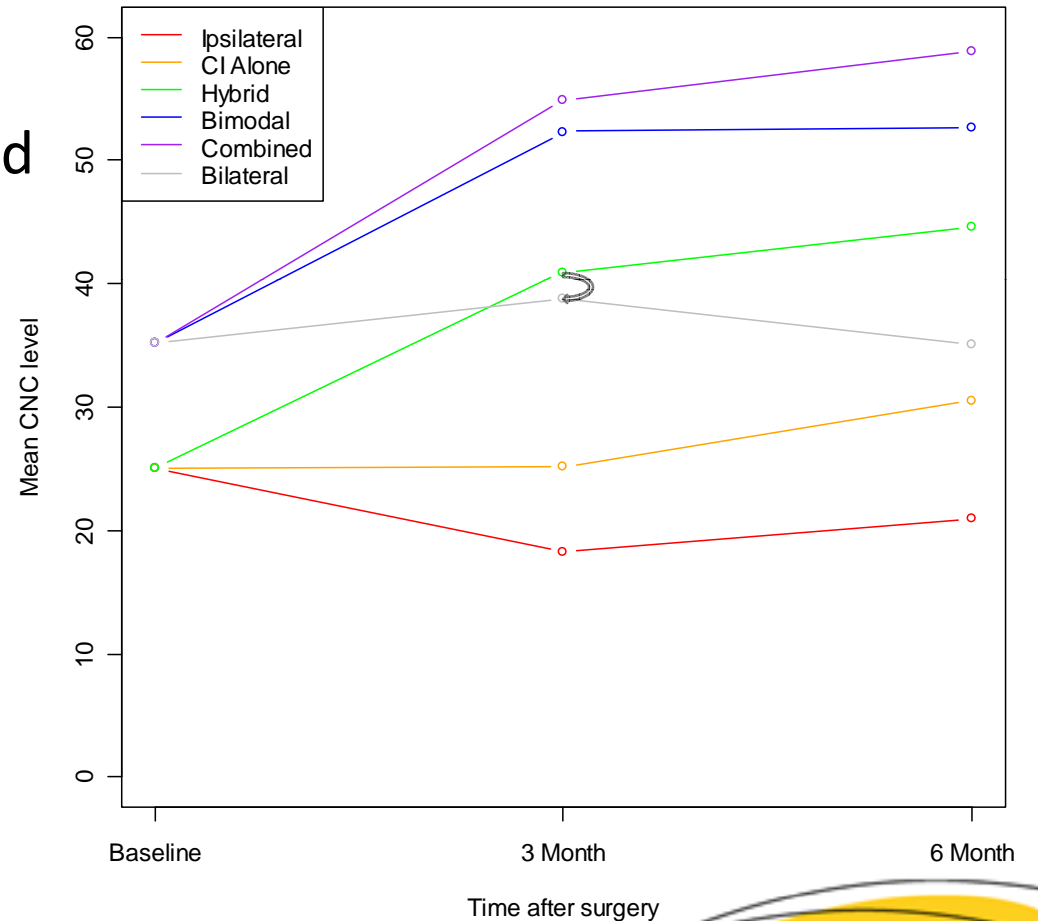


Paired T-Tests for CNC Scores

- T-test:
 - Comparison of 2 settings
- Parameters:
 - $x_2 - x_1 = \text{diff}$
 - $\begin{cases} H_0 : \text{diff} = 0 \\ H_A : \text{diff} \neq 0 \end{cases}$
 - $\alpha = 0.05$
 - 95% Confidence Interval
- At Time=0
 - $t = -7.9541$, $p \approx 0.000$
 - Conf. Int. = $-12.53, -7.52$
 - 0 is not within the Conf. Int. so we can reject the null
 - Therefore the two scores have a statistically significant difference

Paired T-Tests for CNC Scores

- At time=3 months
 - 15 tests were performed
 - Null rejected in all but one test: hybrid to bilateral
 - $t=0.8683$, $p=0.389 > 0.05$
 - Conf. Int. = $-3.347, 8.445$
 - Therefore all scores except hybrid and bilateral have statically significant difference

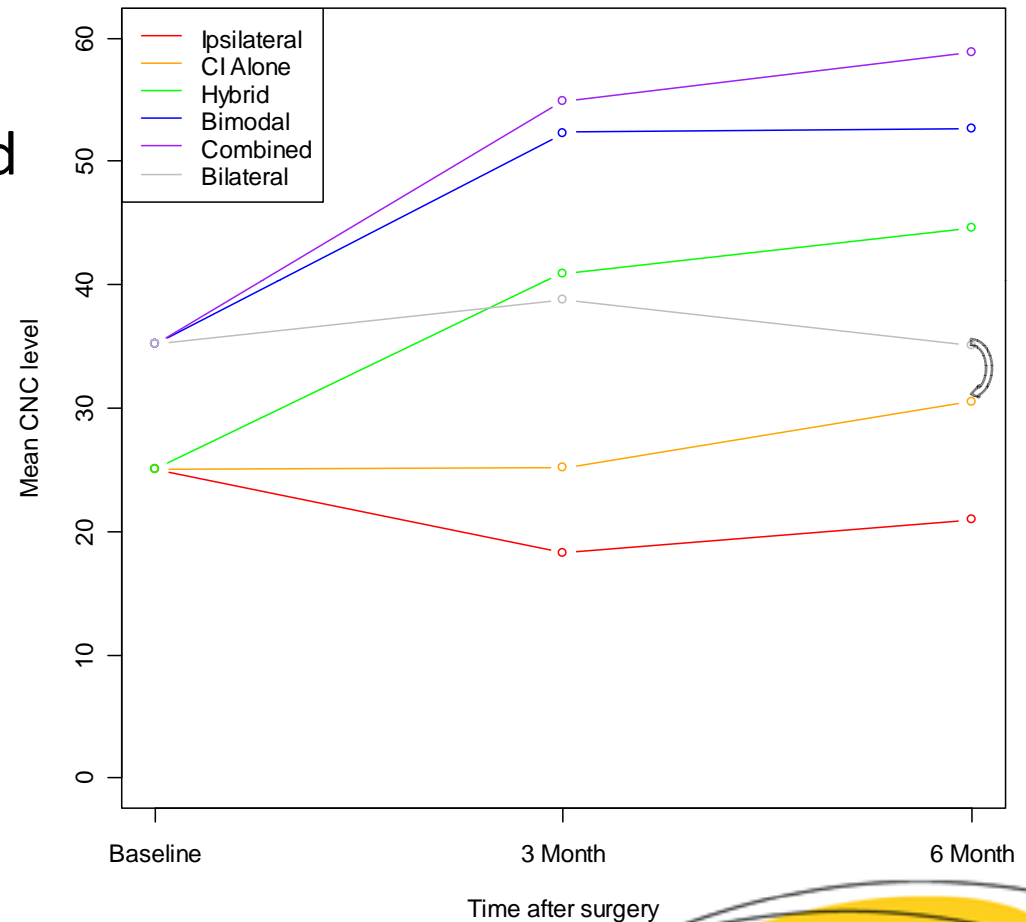


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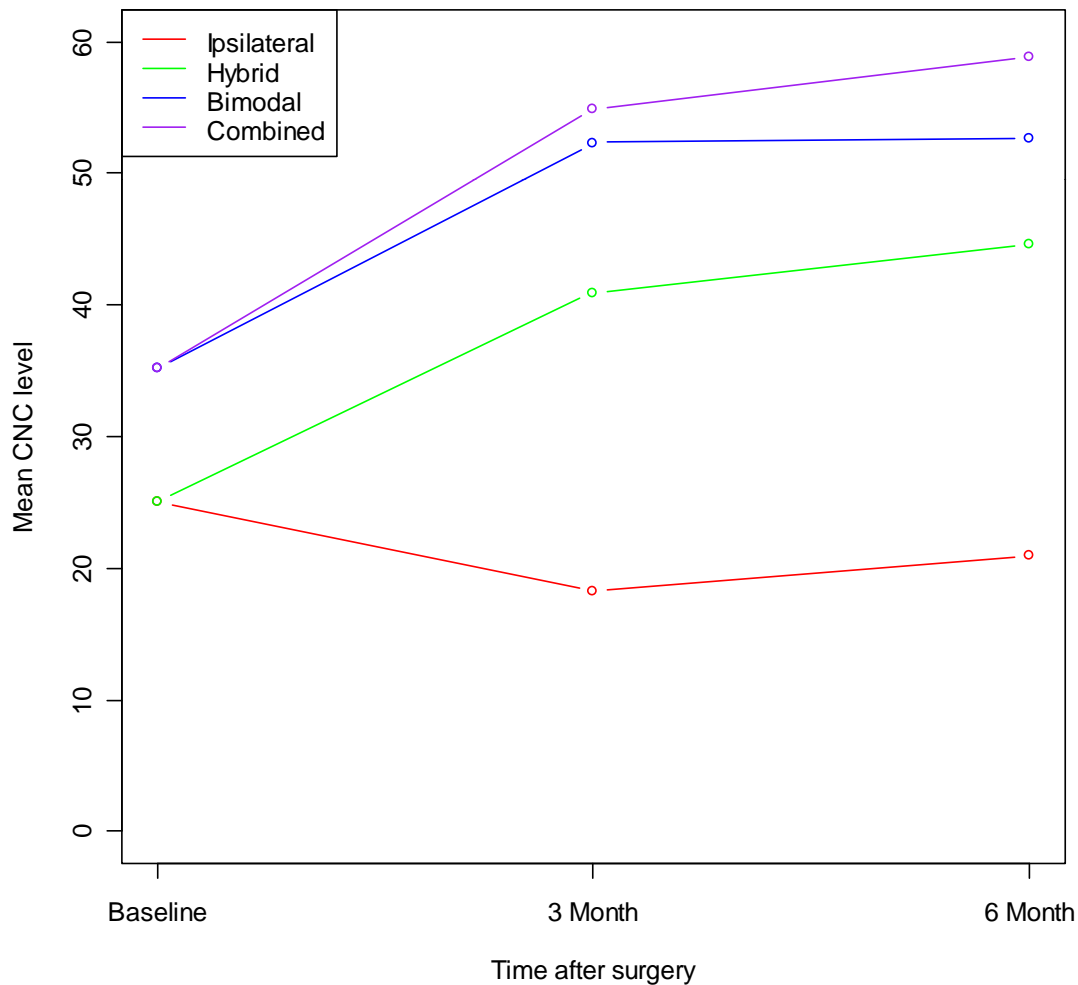
Paired T-Tests for CNC Scores

- At Time=6 months
 - 15 tests were performed
 - Null rejected in all but one test: CI alone to bilateral
 - $t=-1.975$, $p=0.0535 > 0.05$
 - Conf. Int. = $-13.362, 0.103$
 - Therefore all scores except CI alone and bilateral have statically significant difference



Paired T-Tests for Time

- We examine change over time for same setting.



- Ipsilateral, hybrid, bimodal and combined all reject the null for the difference of baseline to 3 months and baseline to 6 months
- No test rejects the null for 3 to 6 months
- Tests show that most change occurs from baseline to three months



Linear Regressions

- Linear Regression: create a linear model with β coefficients that reflect the relationship between the y variable and x variable that it is attached to
- General Equation:
 - $Y = \beta_0 + \beta_1 * X_1 + \beta_2 * X_2 + \beta_3 * X_3 + e$
 - Where:
 - Y = 6 month CNC score
 - X_1 = baseline CNC score
 - X_2 = age at implantation
 - X_3 = age at onset of hearing loss

Linear Regressions

| | Intercept (β_0) | β_1 | β_2 | β_3 |
|--------------|-------------------------|-----------|-----------|-----------|
| Ipsilateral | 12.83739 | 0.88337* | -0.24905 | 0.02345 |
| CI Alone | 42.9668 | 0.8997* | -0.7240* | 0.2578 |
| Hybrid | 58.2815 | 0.7292* | -0.7281* | 0.3290 |
| Bimodal | 42.6735 | 0.6597* | -0.4603* | 0.4207* |
| Combined | 54.7264 | 0.5928* | -0.4553* | 0.3104 |
| Bilateral | 8.31329 | 0.83055* | -0.14247 | 0.18975 |
| Significance | | 6/6 | 4/6 | 1/6 |

*indicates statistical significance ($p < 0.05$)



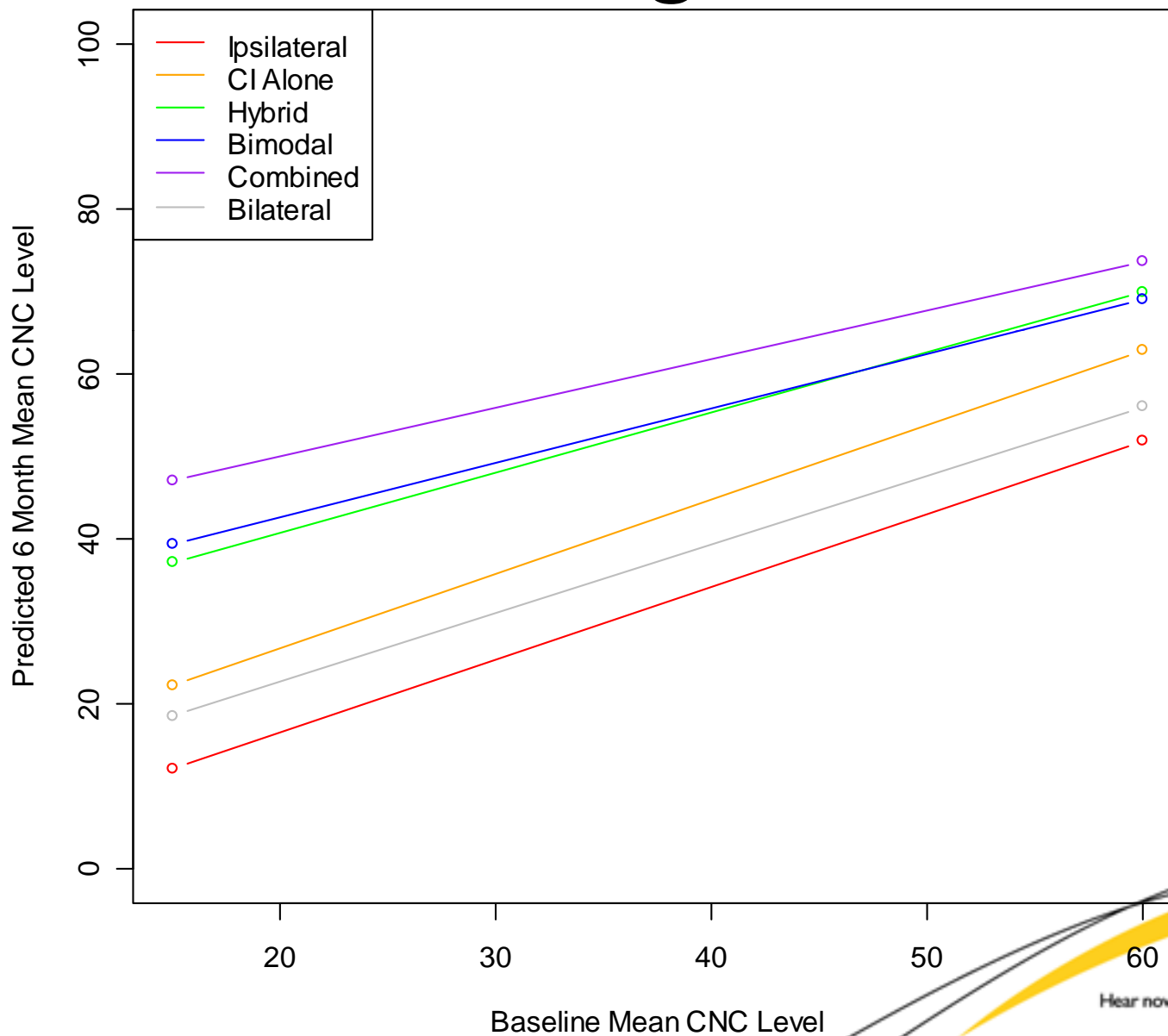
Linear Regressions

Relationship to 6 month CNC score:

- β_1 indicates that the baseline score has positive relationship
- β_2 indicates that the age at onset of hearing loss has a negative relationship
- β_3 indicates that the age at implantation of device has a positive relationship



Linear Regressions



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Conclusions

The combined and bimodal settings seem to be effective. The combined setting has the highest score results overall, and the difference between the score of the combined and bimodal settings was statistically significant at three and six months. We can conclude that combined setting is the most effective.



Acknowledgements

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Improvements

- A lot of missing data
- More complex tests or analysis
- Data from all time points is being analyzed