BAD SCIENCE

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Many slides from this presentation were taken (with permission) from an earlier talk by Bob Carlyon

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Those slides are not included in this summary. You can see them (and many other ones) by watching the original , very informative and highly entertaining presentation at http://to.ly/loCT

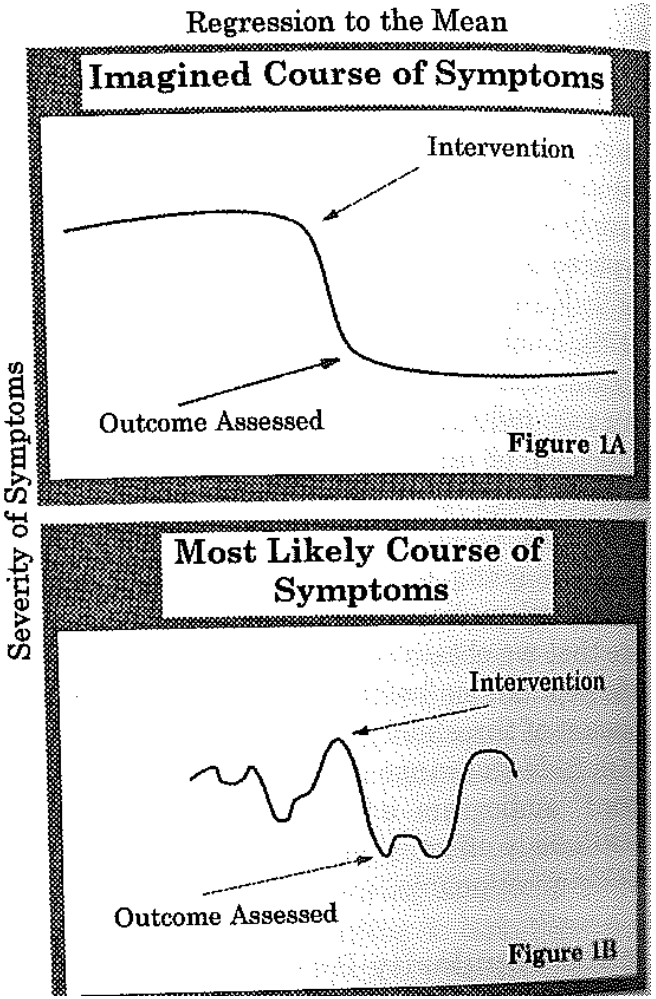
Other slides were inspired by a chapter written by Anne Marie Tharpe ("Treatment Fads Versus Evidence-Based Practice")

Improvement with treatment

- Does this mean the treatment works?
- Possible reasons for improvement
  - Regression to the mean
  - Nonspecific effects of treatment
  - Specific effects of treatment
- In the first two cases, we see improvement despite ineffective treatment
- How can this happen?

Regression to the mean

- Fluctuation unrelated to treatment
- Seeking care when symptoms are worse
- Natural course of the disease (cold, tinnitus, many others)



Hawthorne effect

- Subjects modified their behavior when they are being studied, but not in response to any particular experimental manipulation.
- Original study: Hawthorne Works. Were workers more productive with high or low levels of light? Cleaner workstations? Relocated workstations?
- Answer: All of the above

Expectation Effect

- Clinician or patient expectations can influence apparent results
- Some factors
  - Paying a significant amount of money
  - Trip to a distant location
  - Elegant, expensively appointed offices
- If we expect a treatment to work, we are more likely to perceive that it is working

Placebo effect

- Includes all effects discussed before
- Placebo: "A substance or procedure… that is objectively without specific activity for the condition being treated" (Moerman and Jonas, 2002)
- About 70% of patients respond excellently or well to placebo regardless of presenting complaint (Roberts et al., 1993)

Placebo effect

- 44% of patients with duodenal ulcer (Roberts et al., 1993)
- 64% of patients with miofascial pain disfunction (Goodman et al., 1976)
- 70-80% of patients with herpes simplex (Roberts et al., 1993)

Some tools to minimize these problems

- Randomization
- Use of control conditions
- Blinding
- Appropriate experimental design and analysis

An example of two studies from the same data set

- **Language development in children implanted with the Clarion Cochlear Implant**
  - McConkey A, Bollard PM, Green J
  - *The Annals of Otology, Rhinology & Laryngology;* Apr 1999; 108

Subjects

- 23 pediatric Clarion users
  - All prelingually deafened
  - Average time of implantation 3 years 2 months

Methods-test

- Data Collection
  - RDLS administered
    - Preoperatively with hearing aids
    - Approx. 6 months after receiving their Clarion implant
      - Actual average amount of time between test intervals: 6.6 months
  - RDLS score converted to language age

Methods-outcome measure

- Data Analysis
  - Change in age-equivalent scores that occurred between the 2 test intervals was divided by *actual amount of time that passed between those intervals*
  - This calculation was converted to percent:
    - (Months of language growth)/(months of time between preimplantation test and second test)

Results

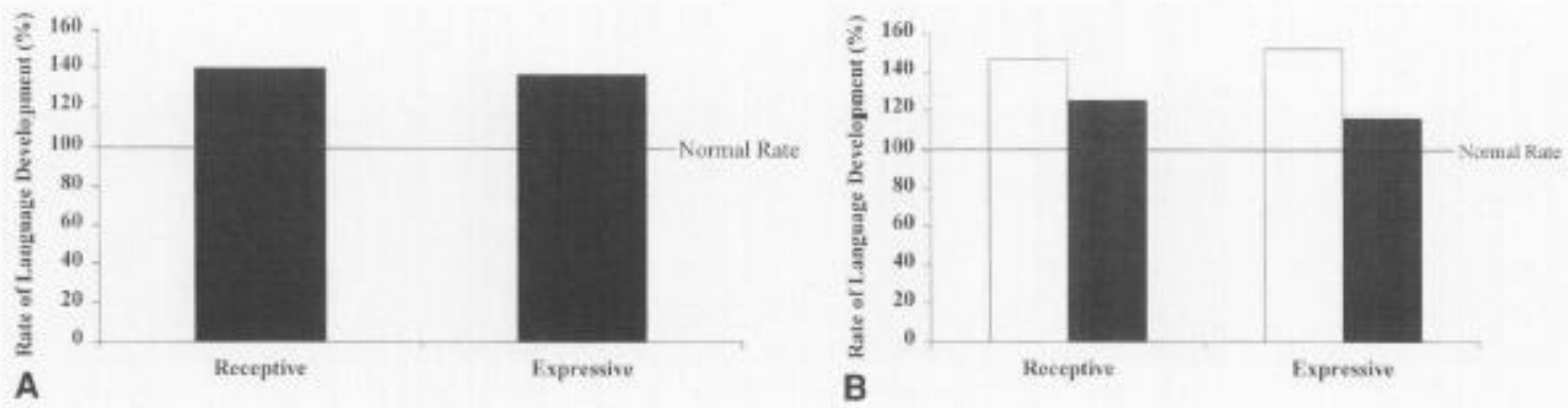


Fig 2. Rate of language development after 6 months of Clarion use. Solid horizontal line illustrates growth rate expected of normal-hearing child. A) Averaged across 23 subjects. B) Broken down by communication mode. Open bars — oral communication subjects; black bars — total communication subjects.

Results

- Results
  - Average rate of improvement for receptive language
    - 140%
  - Average rate of improvement for expressive language
    - 139%
  - Thus, mean rate of language progress for implanted children was approximately 40% faster than expected for normal-hearing peers of same language age
    - Not found to be statistically different from normal hearing rate

Results- above average language development

- Conclusions
  - Clarion children, on average, progressed at a rate that exceeded that of normal hearing children of the same language age during first 6 months of implant use

Another study

- **Language Development in Children Who Are Prelingually Deaf Who Have Used the SPEAK or CIS Stimulation Strategies Since Initial Stimulation**
  - Svirsky MA, Chute PM, Green J, Bollard P, Miyamoto RT.
  - *The Volta Review*, 102(4): 199-213

Subjects

- 44 pediatric CI users
  - 25 Clarion users
    - **Same database as previous study**
  - 19 Nucleus users
  - All profoundly to totally deaf, at birth or before 3 years
  - Received cochlear implants before age 6
  - Programmed with CIS or SPEAK stimulation strategies since the initial day of stimulation

Methods

- Data Collection
  - RDLS administered
    - Preoperatively with hearing aids
    - Clarion users: approx. 6 months after receiving their implant
      - Actual average amount of time between test intervals: 8.6 months
      - **Children had used their implants for only 6.4 months of this period**
    - Clarion and Nucleus users: approx. 12 months after receiving implant
  - RDLS score converted to language age

Methods-outcome measure

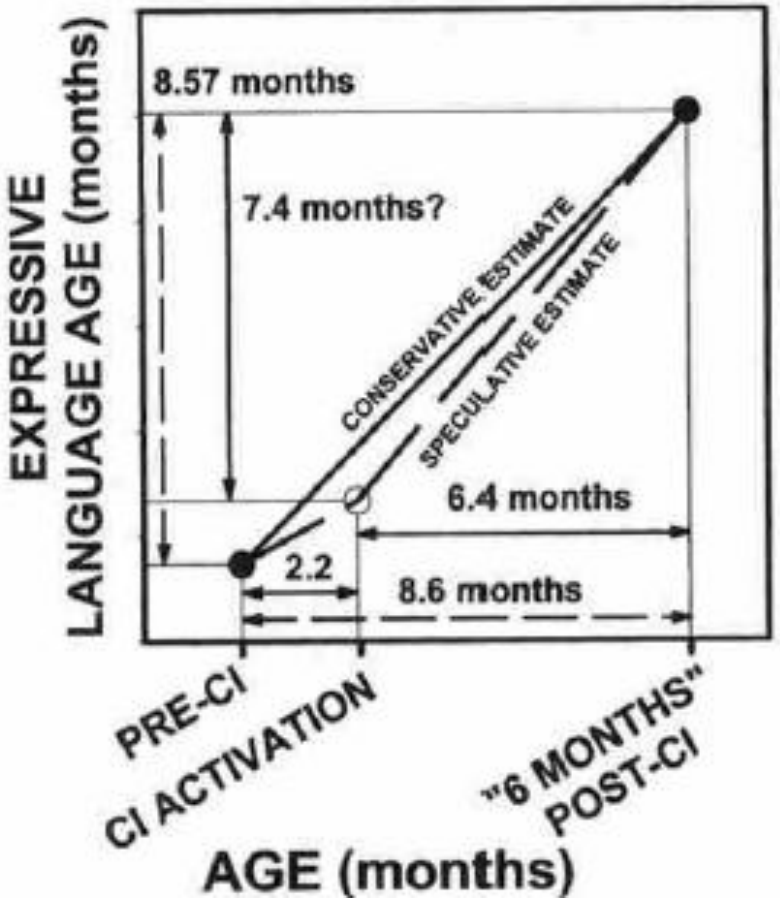
- Data Analysis
  - Change in age-equivalent scores that occurred between the 2 test intervals was divided by actual amount of time that passed between those intervals
  - This calculation was converted to percent:
    - (Months of language growth)/(months of time between preimplantation test and second test)

Data analysis

- Data analysis
  - Problem: average time between first 2 testing intervals was 8.6 months, but children had used their implants for only 6.4 months of that period
  - Reasonable assumption: language slopes would have been higher if children had had their devices active during all 8.6 months
  - Solution: make a second estimation of language growth
    - Assume subjects increased their language age at a rate of 50% between preimplantation and activation (avg 2.3 months)

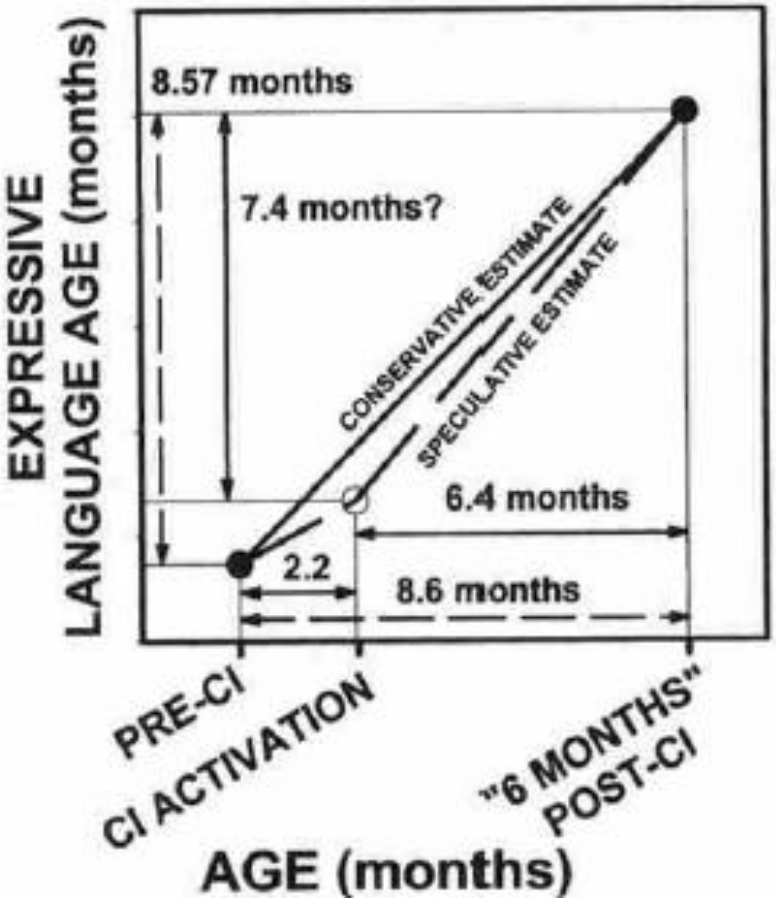
Activation time

- Clarion group



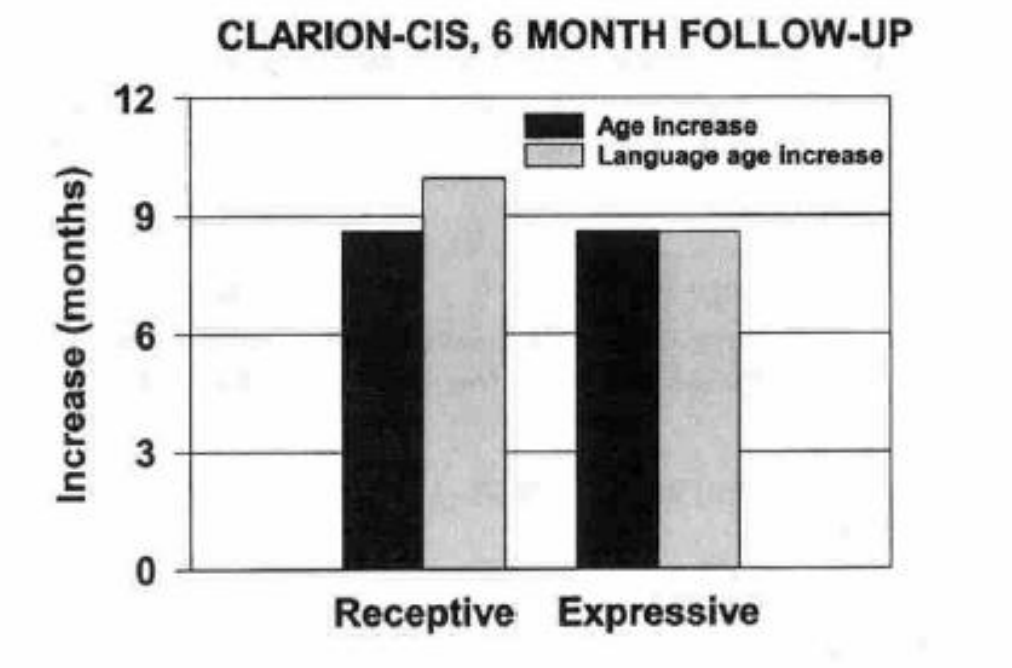
- Black circles
  - Changes in actual values of expressive language and chronological age
- White circle
  - Estimate of expressive language at exact time of CI activation
  - Assumed language skills increased at 50% normal rate during the average 2.2 months between first testing and time of initial stimulation

Two slopes



- 2 slopes presented
  - Conservative
  - Speculative
    - Approximately 120%

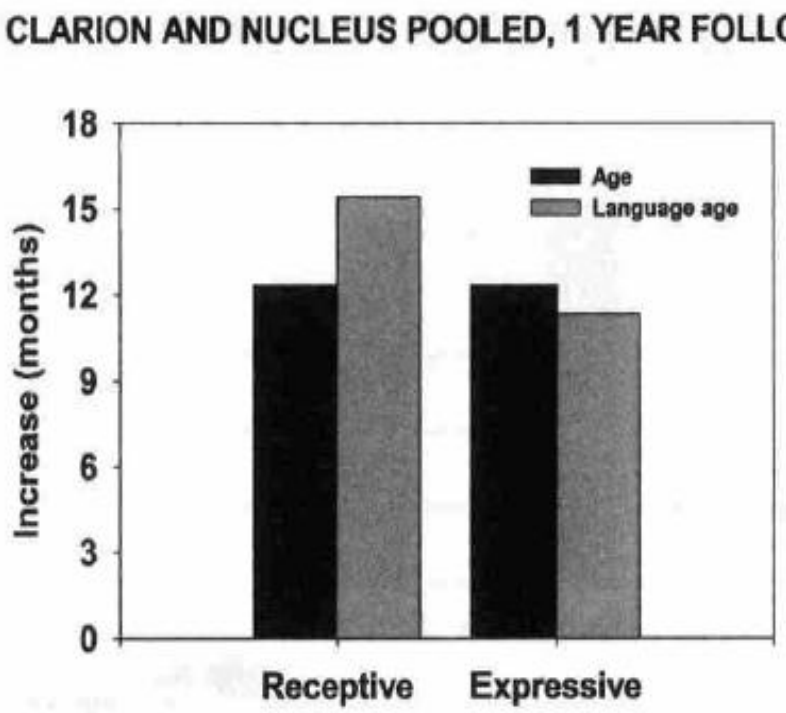
Results



-Changes from preimplantation testing interval to first postimplantation testing interval

-Ratio of gray to black represents conservative estimate of language slope

Results



- Pooled average changes in age and language age
- Day of initial stimulation to 12-month implantation interval
- **"SPECULATIVE" ESTIMATE OF LANGUAGE SLOPE**
  - Language age was not actually measured on the day of initial stimulation

Conclusions

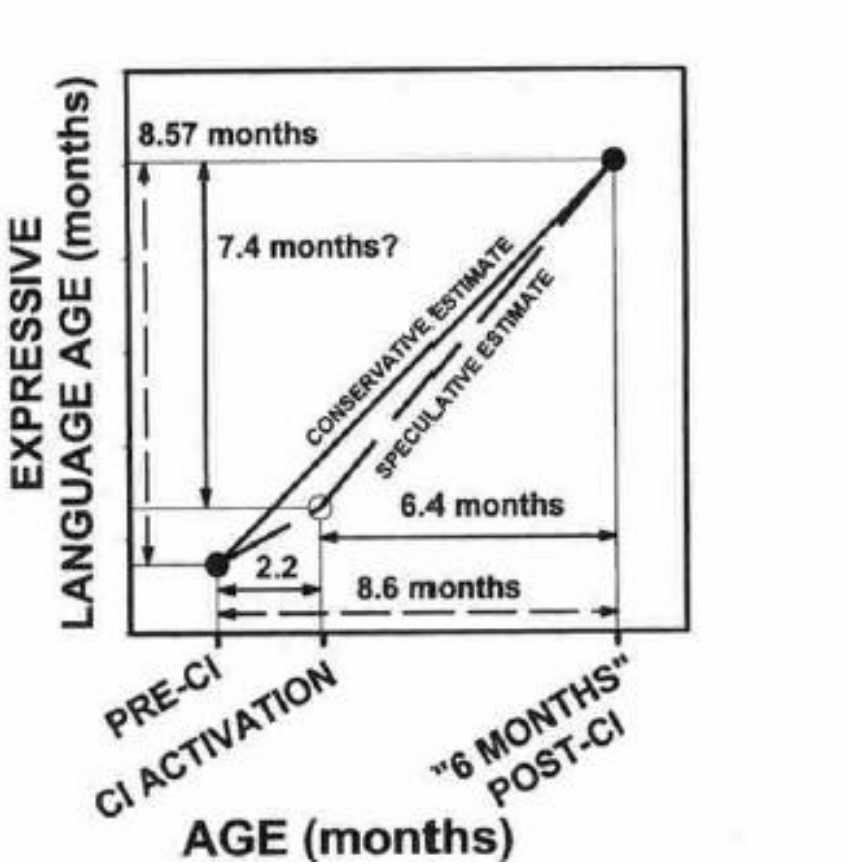
- Conclusions
  - Postimplantation language development proceeded at a pace that was comparable to that shown by children with normal hearing of similar initial language skills
  - Language gap present at implantation did not increase after children started using the device

Discrepancies in 6 month Clarion analyses despite same database (+/- 2 children)

McConkey et al.	Svirsky et al.
■ Rates of about 140%	• Conservative rates of 115% and 104% for receptive and expressive language, respectively • Speculative rates of 104% and 123% for receptive and expressive language, respectively
■ Increases of 9 months for both receptive and expressive language	• Increases of 9.95 and 8.57 months for receptive and expressive language, respectively
■ Elapsed time: **6.6 months** ▪ **Likely time elapsed between initial stimulation and 6-month test session**	• Elapsed time: **8.6 months** – **Time elapsed between test sessions**

Incorrect comparison

- Comparing language gains from initial test to second test to the time that elapsed from activation time until 6-month post-implantation interval is inappropriate
- Assumes that no increase in language skills occurred between preimplantation test and time of CI activation



FINAL COMMENTS

- There may be apparent improvement in response to a treatment even when the treatment is actually ineffective.
- It's easy to root around in a complex data set, and then get excited over interesting "findings"
- Most scientists are honest, but differ in how tough they are on themselves
- Easier to trust findings when:
- Obvious statistical errors are absent
- Significance level is high
- Exactly same dependent variables used in multiple

FINAL COMMENTS

- Easier to trust findings when:
  - Obvious statistical errors are absent
  - Significance level is high
  - Exactly same dependent variables used in multiple papers from same lab
  - Obvious a priori what test should be
  - Crossing interactions
  - Direction of causality is addressed
  - Most common problems are easy to spot

FINAL COMMENTS

- Remember there are different levels of evidence in clinical research, and the highest levels automatically eliminate many sources of error.
- There are also many ways to overinterpret data in basic research.
- Peer-reviewed studies, especially from more prestigious journals, are more trustworthy.
- But, as we will see in the next talk, definite recommendations found in the peer-reviewed literature may sometimes be baseless.