The Story Begins……

- In the late 19th century, Orthoptics invented by:
  - Ophthalmologists – Worth, Maddox …!!
- 20's and 30's: Optometry starts to adopt orthoptics
- 1928: OEP is born, orthoptics becomes vision training
- 30's and 40's: research shows CI more prevalent with reading and learning problems
- In the 50's-60's over 50% of OD's say they offer some form of VT
- 60's and 70's: Organized Medicine starts to criticize VT as unscientific

Financial Disclosures

- None
Is CI Just a Psychological Problem?

- Numerous OMD articles starting in 1896 (Duane): CI often psychogenic; “nervous weakness and neurasthenia” common causes

CI – all in your head???

- Mellick (1950) Br J Ophth: 47/63 (76%) of CI’s have “neurotic tendencies”, no definition!
- Massey (2000) Br Orth J: 19 CI’s ages 13 to 45, higher scores on “short-term neuroticism scale” than “normals”
  - Reduction in anxiety post-Tx from “habituation to hospital setting” or “reassuring nature of Tx process”

1980’s

- VT is part of the Optometric Family, but……
Does VT Really Work???

Convergence Insufficiency Tx in the 80’s
- CI Treatments: pencil push-ups, base-in prism, home VT, in-office VT
- Research: In-office VT - case studies and retrospective studies
- No data on anything else
- AAO continued with AAP in issuing position papers against VT
- VT OD’s still claim that VT can improve reading and school performance

Intriguing optometric studies
- Garzia et al, Effects of nearpoint visual stress on psycholinguistic processing in reading, JAOA, 1988,60:38-44.
One Small Problem.....

- Only used optometry students!!!
1995

- Mitch Scheiman, Len Press and Sue Cotter replaced Ralph Garzia, Mike Wesson
- 5 different optometry schools
- Started looking critically at the literature

Many Smaller Questions First

- How to define CI?
- Prevalence?
- How is NPC measured and from what part of the eye/head?
Also....

- What’s the reliability of our tests?
- Are the norms valid?
- How is success of treatment measured?

Next 7 Years......

- Series of 9 pilot studies
- Setting the stage for a bigger study
The History and Science of CI  
Michael Gallaway, OD

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### CI Symptom Survey (CISS)

**Expected: <16**

<table>
<thead>
<tr>
<th>Question</th>
<th>Frequency</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do your eyes feel tired when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do your eyes feel uncomfortable when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you have headaches when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you feel sleepy when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you lose concentration when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you have double vision when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you see the words move, jump, swim or appear to float on the page when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you feel like you read slowly?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do your eyes ever hurt when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do your eyes ever feel sore when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you feel a “pulling” feeling around your eyes when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you notice the words blurring or coming in and out of focus when reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you lose your place while reading or doing close work?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Do you have to re-read the same line of words when reading?</td>
<td>Never</td>
<td>0</td>
</tr>
</tbody>
</table>

**Total Score:** __

---

### Severity of CI

- **2 sign CI:** ≥ 4 more XP at near than distance, reduced PFV or reduced NPC
- **3 sign CI:** all of the above
- **Increased symptoms with 3 sign CI**

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Rouse and CIRS Study Group, Frequency of CI in optometry clinic settings. OVS, 1998.
The History and Science of CI
Michael Gallaway, OD

<table>
<thead>
<tr>
<th>Treatment Patterns for CI, 2002*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Optometrists 563/863 (58%) responded</td>
</tr>
<tr>
<td>Ophthalmologists 196/863 (23%) responded</td>
</tr>
</tbody>
</table>


1999
- Compared in-office to home VT; non-treatment control
- In-office VT more successful than home VT or no treatment
- No placebo treatment or masked examiner

1998
- CIRS becomes Convergence Insufficiency Treatment Trial (CITT) Planning Committee
- Mitch Scheiman - Chair, Mike Rouse, Eric Borsting, Sue Cotter, Jeff Cooper, Rick London, Paul DeLand, Lynn Mitchell
- Randomized Clinical Trial needed
Research Studies: Quality of Design

- Randomized Clinical Trial
  - Placebo controlled, masked examiners, well-defined groups, statistically powered
  - Allows for generalization
- Prospective Study
  - Masked
  - Unmasked
- Retrospective Chart review
- Case Report

Randomized Clinical Trial

- Prevalent condition
- No consensus on treatment
- NEI: Have to show you can make it happen
Convergence Insufficiency Treatment Trial (CITT): Pilot Study

A Randomized Trial of Vision Therapy vs. Pencil Push-Ups for Convergence Insufficiency in Children

Supported by:
NIH-NEI R21 EY113164-01
Funded Oct 2000, $150,000

CITT Pilot: Specific Aims

- PCO, OSU, SCCO, SUNY, Pacific, UH
- 47 children, ages 9 to 18 with CI
- 12 weeks of treatment, Compare Pencil Push-ups, Office based VT, and In-office Placebo Treatment
- Is there a difference between treatments in improving patient symptoms and visual findings?

CITT Pilot Study

- OBVT clinically and statistically better than both pencil push-ups and placebo, improved visual findings and symptoms
- Pencil push-ups no better than placebo
- 90% of subjects who received placebo thought it was real VT
A Big Step….

- Kushner (2005): CITT results … “should dispel the beliefs of those naysayers who believe that CI is not a real entity and that all perceived benefit of treatment is a result of a placebo effect.”

Base In Prism RCT

  - BI not effective for treatment of symptomatic CI in children
  - No better than placebo at improving Sx or signs

Ready for the Big Dance!

- Pilot studies done to clarify many previous questions
- Successful CITT Pilot: excellent recruitment and retention, effective placebo therapy
- Recruited 3 ophthalmological sites, and added new optometric sites
- 2002 and 2003, denied by NEI

Convergence Insufficiency Treatment Trial (CITT)

$6.1 million grant Funded by the NEI: October 2004

Study Design

- Multi-center, placebo-controlled, single-masked, randomized clinical trial
- Designed to compare the benefits of Pencil Push-up therapy and Vision Therapy/Orthoptics.
- 221 subjects aged 9 to <18 years with CI enrolled over 18 months
  - 9 sites (collaborative): 6 optometry, 3 ophthalmology
Study Design

- Four treatment groups
  - Home-based Pencil Push-up Therapy
  - Home-based Pencil Push-ups with Computer Vision Therapy (HTS)
  - Office-based Vision Therapy
  - Office-based Placebo Vision Therapy

All subjects received 12 weeks of treatment

Home-based groups
- 15 minutes, 5 days/week
- Weekly phone appointments with therapist

Office-based groups
- Weekly, 60 minute, in-office treatment sessions
- 15 mins home therapy procedures, 5 days/week
- Masked exams at 4, 6, 12 weeks & 6, 12 months
CITT Results

- 99% completed 12 week outcome exam
- Over 3500 visits with <2% missed visits
- Office Based VT significantly greater improvements in Sx, NPC and BO vergences than other three treatments
- Both home treatments no better than placebo

Randomized Clinical Trial of Treatments for Symptomatic Convergence Insufficiency in Children

Objective: To compare home-based treatment among four treatment groups (cycloplegics, prism, vision therapy, control) in children between 6 to 12 years old with a diagnosis of symptomatic convergence insufficiency.

Methods: A randomized, double-blind, placebo-controlled trial of 4 treatment groups for convergence insufficiency was compared.

Results: In 12 weeks of treatment, the VT group showed significantly greater improvements in Sx, NPC, and BO vergences compared to other treatment groups.

Application to Clinical Practice: VT should be considered as a viable treatment option for children with symptomatic convergence insufficiency.

Long-Term Effectiveness of Treatments for Symptomatic Convergence Insufficiency in Children

Objective: To evaluate the long-term stability of improvements in symptoms and signs in children treated with cycloplegics, prism, or vision therapy for symptomatic convergence insufficiency.

Methods: A prospective, multicenter, randomized, controlled trial of 4 treatment groups was performed.

Results: Over a 3-year follow-up period, the VT group showed sustained improvements in Sx, NPC, and BO vergences compared to other treatment groups.

Application to Clinical Practice: VT should be considered as a long-term treatment option for children with symptomatic convergence insufficiency.
What About Attention and Reading?

- NEI: first had to prove that VT works

We didn’t know the best ways to study reading and attention
- Back to the drawing board: more pilot studies
- Collaborate with experts in reading/ADHD

Measuring ADHD behaviors in children with symptomatic accommodative dysfunction or convergence insufficiency: a preliminary study

Joe Berting, B.A., Michael Romo, G.S., M.S., and Ray Yiu, O.D.

Journal of the American Optometric Association, Volume 76, Number 4

JAOA, 2005
2009

- CITT RS Group: Pilot study of impact of VT for CI on reading and attention
- 44 CI’s, ages 9 to 17, no control, no $$
- 16 weeks of OBVT
- Conners, Child Behavior Check List and reading tests 8 weeks after Tx

- Improved reading comprehension, no change in fluency.

20 years after the idea was initially proposed....
- And after 1 rejection from NEI (now 2 strikes and you’re out!)....

CITT Attention and Reading Trial
CITT-ART

- Funded by National Eye Institute May 1, 2014- April 2019
- $8 M total funding
- Study Chair: Mitch Scheiman, OD, PhD
The History and Science of CI
Michael Gallaway, OD

CITT-ART Ex Committee

- Mitch Scheiman, OD, PhD, Study Chair
- Susan Cotter, OD, MS
- Marjean Taylor Kulp, OD, MS
- Eric Borsting, OD, MEd
- Lynn Mitchell, MS
- Chris Chase, PhD
- L. Eugene Arnold, MD, MEd
- Carolyn Denton, PhD
- MaryAnn Redford, DDS, MPH

Participants

- 9 Clinical Sites / Principal Investigators
  1. SUNY, Erica Ellis, OD
  2. OSU, Marjean Kulp, OD
  3. SCCO/Ketchum, Sue Cotter, OD
  4. PCO/Salus, Michael Gallaway, OD

Sites / PI's

5. NOVA, Stacey Coulter, OD
6. UAB, Kristine Hopkins, OD
7. Akron Children’s Hospital, Rich Hertle, MD
8. Bascom Palmer, Susanna Tamkins, OD
9. Ingryd Lorenzana, OD, Private practice, Chicago
### Study Design

- Children ages 9-14 with symptomatic CI
- Subjects randomized to 16 weeks of treatment with either:
  - office-based vision therapy with home reinforcement (OBVAT)
  - office-based placebo therapy with home reinforcement (OBPT)

### Study Design

- Outcomes (reading and attention) assessed after 16 weeks of treatment
- One year follow up

### Reading Outcome Measures

- Primary outcome measure: Reading Comprehension on Wechsler Individual Achievement Test III (WIAT-III)
- Also, listening comprehension, word reading, pseudoword decoding, and oral reading fluency on WIAT-III
Secondary Outcome Measures

- GMRT: Gates-MacGinitie Reading Test
- RCBM: Reading curriculum based measures
- CBM Maze
Attention Measures

• SNAP-IV: Swanson Nolan and Pelham Teacher and Parent Rating Scale
• SWAN: Strengths and Weaknesses of ADHD Symptoms and Normal Behavior Rating Scale (parents)
• D2 Test of Attention

Quality of Life Measures

• Homework Problems Checklist
• Academic Behavior Survey
Does VT Improve Reading and Attention?

Sometime in 2018 - 24 Years Later, We'll Find Out!

Impact of CITT

- Gold Standard evidence: 3 RCT’s show that office based VT is the most effective Tx for CI, improves both Sx and Signs of CI
- Pencil push-ups/ home VT no better than placebo
- Recent PEDIG RCT compared pencil push-ups to computerized home VT: neither better than placebo

- St. Christopher’s Hospital for Children, Philadelphia; Children’s Hospital of Phila (CHOP)

CI & VT: What’s Next?
What are the Neural Substrates for VT?

- Is VT “biologically plausible”?
- Maybe CI really is in your head!

Tara Alvarez, PhD
Mitch Scheiman, OD PhD

- Functional Mechanisms of Neural Control in Convergence Insufficiency
- Current NEI funded RCT, cross-over design with young adult CI’s and normals, placebo controlled
- Objective eye movement measures to assess vergence adaptation, slow and fast components of disparity vergence
- fMRI to assess cortical changes
The History and Science of CI
Michael Gallaway, OD

CICON – CI in CONcussion

- Multi-center RCT, Submitted to NEI in Jan 2017
  - 5 Children’s Hospitals/4 Colleges of Optometry, 1 Ophthalmology site
    - Salus / Children’s Hospital of Philadelphia
    - Boston Children’s Hospital
    - UAB
    - Akron Children’s Hospital
    - SCCO/Ketchum
- Specific Aim – To compare the effectiveness of 12 weeks of OBVT, OBPT, standard community care for adolescents 11-17 years with PCS and symptomatic CI.

The Dream

- Early visionaries provided the leadership

- For VT to be widely accepted as scientifically valid and clinically useful to help a wide range of patients optimize visual function and improve their lives

- Has public perception about VT changed?

Thank you!
Mgallaway@salus.edu