Digital Binocular Therapy for Amblyopia

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Amblyopia

- A unilateral or bilateral reduction of BCVA not caused directly by any structural abnormality of the eye or the posterior visual pathways
- Most common cause of vision loss in children (2-4% in North America)
- Preventable and reversible with appropriate and early treatment

Types of Amblyopia:

- Strabismic
- Refractive
- Stimulus Deprivation

Treatment

- Eliminate any obstacle to vision (deprivation type)
- Correct any significant refractive error or ocular misalignment
- Force use of the amblyopic eye

Force the use of amblyopic eye

- Patching
  - Full time vs Part time
  - Different types of patches

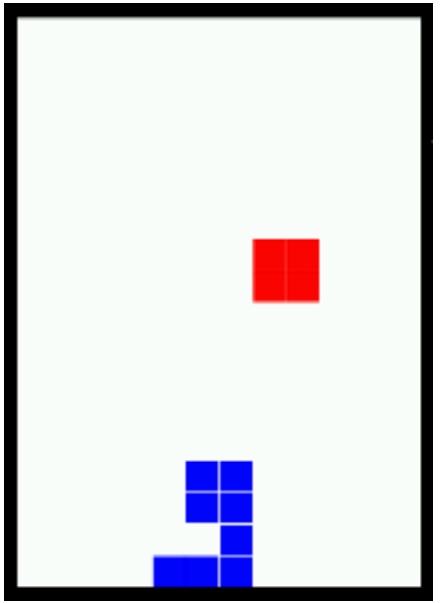
Force the use of amblyopic eye

- penalization
  - Pharmacologic (Atropine drops)
  - Optical (fogging)

- Binocular treatment
  - Dichoptic
  - VR

Dichoptic Therapy

- A novel binocular therapy for amblyopia
- Designed to promote binocular vision by rebalancing visual stimuli between the eyes



ATS 18: Binocular iPad Game vs Patching

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ATS 18: Binocular iPad Game vs Patching

- Amblyopia = VA 20/40 to 20/200
- n= 385 children, age 5-12 years
- Strabismic, Anisometropic, combined mechanism
- Randomized to 4 months of:
  - Binocular iPad game for 1 hour a day
  - Patching of the fellow eye for 2 hours a day

ATS 18: Binocular iPad Game vs Patching

- Improvement of amblyopic eye VA at 16 weeks:
  - Binocular group: 1.05 lines
  - Patching group: 1.35 lines

} exceeded the prespecified noninferiority difference limit

- Only 22% of the binocular game group performed more than 75% of the prescribed treatment !

- Adverse effects (including diplopia) were uncommon and of similar frequency between groups
- Improvement in stereopsis was the same in both groups

ATS 20: Binocular Dig Rush Game vs glasses

- To test dichoptic binocular treatment
- To compare the efficacy of:
  - Binocular game treatment (1 hr/day, 5 days/week)
  - Spectacle correction only

ATS 20: Binocular Dig Rush Game vs glasses

- Older cohort (7-12 yrs old)
- Major eligibility criteria:
  - Age 7 to 12 years
  - Amblyopia associated with:
    - anisometropia (≥1.00 D difference between eyes in spherical equivalent)
    - strabismus (<5 PD at near by SPCT)
    - both
  - Visual acuity
    - Amblyopic eye: 20/40 to 20/200
    - Fellow eye: 20/25 or better
    - IOD ≥ 3 logMAR lines

ATS 20: Older cohort (7-12 yrs old): results

- 138 randomized to binocular rx VS only glasses
- Amblyopic-Eye VA improvement (letter score):
  - At 4 weeks:
    - Binocular rx: 1.3
    - Glasses only: 1.7
  - At 8 weeks:
    - Binocular rx: 2.3
    - Glasses only: 2.4

ATS 20: Older cohort (7-12 yrs old): results

- Stereo: No difference (no improvement)
- Adherence of >75% of prescribed game play was:
  - Reported by parent, 4 weeks: 68%, 8 weeks: 74%
  - Recorded by device, 4 weeks: 58%, 8 weeks: 56%
  - Control group who were offered treatment after completing the study, only 15% adhered to treatment!

ATS 20: Older cohort (7-12 yrs old): results

- Adverse event:
  - The number of participants with a new heterotropia and/or worsening of a pre-existing tropia of >10 PD was 13% in both groups at 8 weeks
- Points to consider:
  - 96% of patients enrolled had been previously treated for amblyopia
  - No dose-response relationship between duration of game play and improvement in VA
  - Are younger patients more likely to response to treatment?

ATS 20: Binocular Dig Rush Game vs glasses

- Younger cohort (4-<7 yrs old)
- To compare the efficacy of:
  - Binocular game treatment (1 hr/day, 5 days/week)
  - Spectacle correction only

ATS 20: Younger cohort (4-<7 yrs old): results

- 182 randomized to binocular rx VS only glasses
- Amblyopic-Eye VA improvement (Log MAR lines):
  - At 4 weeks (significant):
    - Binocular rx: 1.1
    - Glasses only: 0.6
  - At 8 weeks: (not significant)
    - Binocular rx: 1.3
    - Glasses only: 1

ATS 20: Younger cohort (4-<7 yrs old): results

- Adherence of >75% of prescribed game play was:
  - Recorded by device, 4 weeks: 47%, 8 weeks: 42%

Luminopia

- Virtual reality machine with dichoptic binocular treatment
- To compare the efficacy of:
  - Luminopia device with glasses (1 hr/day, 6 d/week)
  - Spectacle correction only
- Streams movies and TV shows from licensed partners

Luminopia

- 105 randomized to binocular rx VS only glasses
- Age 4-7 yrs
- Amblyopic-Eye VA improvement (lines):
  - At 12 weeks:
    - Binocular rx: 1.8
    - Glasses only: 0.8
- Adherence with the prescribed treatment was 88.2% at 12 weeks
- No significant side effects recorder

CureSight

- Dichoptic digital therapeutic with eye tracking function that blur and reduce the contrast of the fellow eye's fovea

- To compare the efficacy of:
  - CureSight device (90 min/day, 5 d/week)
  - Patching 2hrs/day, 7 d/week

- Streams any media content on the internet

CureSight

- 103 child (age 4-8) randomized to binocular rx VS patching
- Amblyopic-Eye VA improvement (LogMAR):
  - At 16 weeks:
    - Binocular rx: 0.28
    - Patching rx : 0.23
- Adherence with the prescribed treatment was 91% at 16 weeks
- No significant side effects recorder