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COURSE

Important Trials in Paediatric Ophthalmology and Strabismus

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PEDIG Amblyopia Studies

- Amblyopia Treatment Studies (ATS) carried out by the Pediatric Eye Disease Investigator Group (PEDIG)
- ATS1-13 published so far
- Moderate Amblyopia – 20/80 or better in amblyopic eye
- Severe Amblyopia- 20/100- 20/400

http://pedig.jaeb.org/Publications.aspx
https://www.aao.org/asset.axd?ID=58e48e5b-e5ac-4386-adec-ef9ad39533f1

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ATS Findings-Summary

- Occlusion is as effective as Pharmacological therapy for Moderate Amblyopia (ATS1)
- Minimal time (2 hours) patching is as effective as Part time (6 hours) occlusion for Moderate Amblyopia (ATS 2B)
- Part time (6 hours) occlusion is as effective as Full time occlusion for Severe Amblyopia (ATS 2A)

http://pedig.jaeb.org/Publications.aspx
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ATS Findings-Summary

- Weekend Atropine is as effective as Daily Atropine for Moderate Amblyopia (ATS 4)

- Distance activities as effective as those at Near while undergoing occlusion (ATS 6)

http://pedig.jaeb.org/Publications.aspx
https://www.aao.org/asset.axd?ID=58e48e5b-e5ac-4386-adec-ef9ad39533f1

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Myopia

- Significant global public health concern
- Associated ocular comorbidities of retinal detachment, macular choroidal degeneration, premature cataract and glaucoma

Incidence of RD	Myopia
0.015%	Less than 4.74D
0.07%	≥ 5 D
3.2%	≥ 6 D

- 9 X risk of macular degeneration for ≥ 5D

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Atropine in the Treatment of Myopia study (ATOM)

- Randomized, double-masked, placebo-controlled trial involving 400 Singapore children (n=346 completed 2 year trial)

- Showed that 1% atropine eye drops instilled nightly in one eye over a 2-year period reduces myopic progression significantly in children by 77% (0.28 D in the atropine eye versus 1.2 D in non-treated eyes).

Chua WH, Balakrishnan V, Chan YH, et al. Atropine for the treatment of childhood myopia. Ophthalmology 2006;113:2285-2291.

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ATOM study (contd.)

- The atropine group's mean axial length remained essentially unchanged, whereas the placebo group's mean axial length increased

- Increased rate of myopia progression following the cessation of atropine treatment in the ATOM study subjects but overall less myopia at 3 years

Chua WH, Balakrishnan V, Chan YH, et al. Atropine for the treatment of childhood myopia. Ophthalmology 2006;113:2285-2291.

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ATOM-2

- 400 Asian children (aged 6-12 years) with myopia of 2.00 D or worse in each eye were randomized to atropine 0.01%, 0.1%, and 0.5% groups OD for 2 years
- Similar reduction in myopic progressions
- When atropine stopped for 12 months after 24 months of treatment (phase 2 of ATOM2), there was a rapid increase in myopia in children originally treated with higher concentrations of atropine, whereas those receiving the lowest concentration of 0.01% showed minimal change
- Children who had myopia progression during phase 2 were restarted on atropine 0.01% for a further 24 months (phase 3).
- The lower myopia progression in the 0.01% group persisted during phase 3, with overall myopia progression and change in axial elongation at the end of 5 years being lowest in this group

Chia A, Lu QS, Tan D. Five-Year Clinical Trial on Atropine for the Treatment of Myopia 2: Myopia Control with Atropine 0.01% Eyedrops. Ophthalmology. 2016 Feb;123(2):391-9.

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MOTAS and ROTAS Studies

- Monitored and Randomized Occlusion Treatment of Amblyopia Studies
- Participants were instructed to dose for 6 hours/day (MOTAS) or randomized to 6 or 12 hour/day (ROTAS).
- Dose was monitored continuously using an occlusion dose monitor (ODM)
- 152 patients recruited

Stewart CE, Moseley MJ, Stephens DA, Fielder AR. Treatment dose-response in amblyopia therapy: the Monitored Occlusion Treatment of Amblyopia Study (MOTAS). Invest Ophthalmol Vis Sci. 2004;45:3048–54.
Stewart CE, Stephens DA, Fielder AR, Moseley MJ. Objectively monitored patching regimens for treatment of amblyopia: randomised trial. BMJ. 2007;335:707.
Wallace MP, Stewart CE, Moseley MJ, Stephens DA, Fielder AR; Monitored Occlusion Treatment Amblyopia Study (MOTAS) Cooperatives; Randomized Occlusion Treatment Amblyopia Study (ROTAS) Cooperatives. Compliance with occlusion therapy for childhood amblyopia. Invest Ophthalmol Vis Sci. 2013 Sep 17;54(9):6158-66.

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MOTAS and ROTAS Studies

- This study shows that compliance with patching treatment averages less than 50%

- Age, sex, amblyopia type, and severity were not associated with compliance

Stewart CE, Moseley MJ, Stephens DA, Fielder AR. Treatment dose-response in amblyopia therapy: the Monitored Occlusion Treatment of Amblyopia Study (MOTAS). Invest Ophthalmol Vis Sci. 2004;45:3048–54.
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Newcastle Control Score

Table 1 The Newcastle control score

Score	*Component*
Home control	
0	Squint/monocular eye closure never noticed
1	Squint/monocular eye closure seen occasionally (<50% of time child observed for distance)
2	Squint/monocular eye closure seen frequently (>50% of time child observed for distance)
3	Squint/monocular eye closure seen for distance and near fixation
Clinic control near	
0	Manifest only after cover test and resumes fusion without the need for blink or refixation
1	Blink or refixate to control after cover test
2	Manifest spontaneously or with any form of fusion disruption without recovery
Clinic control distance	
0	Manifest only after cover test and resumes fusion without the need for blink or refixation
1	Blink or refixate to control after cover test
2	Manifest spontaneously or with any form of fusion disruption without recovery

NCS total = home + clinic near + clinic distance.
A score of 3 or greater was taken to indicate a requirement for treatment intervention.

**** This topic was a VIVA station in 2015 FRCOphth exam ****

Haggerty H, Richardson S, Hrisos S, Strong NP, Clarke MP. The Newcastle control score: a new method of grading the severity of intermittent distance exotropia. Br J Ophthalmol 2004; 88: 233–235.