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Efficacy of Myopia Control Contact Lenses (BHVI Extended Depth of Focus Contact Lens and MiSight) in a Contralateral Study Design

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Purpose:To determine the effectiveness of myopia control contact lenses (CL) using a contralateral study design.
Methods: Prospective, 12 month, randomised clinical trial of 95 children (10.8 ± 1.5; 7 to 14 yrs) with myopia (-1.99± 0.68D; -0.71 to -3.68D) assigned to 3 groups: Group I: bilateral single vision CL (n=30); Group II: contralateral single vision CL versus MiSight (n=31); and Group III: contralateral single vision CL versus BHVI extended depth of focus CL; n=34. Spherical equivalent (SE) refractive error was determined using cycloplegic autorefraction at baseline and 6 monthly intervals. Axial length (AL) measurements were conducted at baseline and 3 monthly intervals. In Groups II and III, there was a cross-over of the test and control CL between eyes after six (6) months and CL wear continued for further 6 months. Change in SE and AL was analysed for the first and second 6 month periods (herein referred to as first and second period). Differences in progression over time and between CL types were analysed using paired t-test. Significance was p<0.05.
Results: For Group I, changes in SE and AL for the first and second periods were -0.41 ± 0.28D/0.13 ±0.09mm and -0.25±0.27/0.16±0.09mm. In comparison, change in SE and AL for MiSight versus controls in Group II was -0.23 ±0.33/0.08±0.08 versus -0.38 ± 0.27D/0.16 ±0.10mm for first period and -0.18 ±0.17/0.08±0.07 versus -0.26 ± 0.18D/0.14 ±0.08mm for the second period. Change in SE and AL in Group III, i.e. BHVI EDOF versus control eyes was -0.26 ±0.26/0.06±0.09 versus -0.42 ± 0.22D/0.15 ±0.07mm for the first period and -0.11 ±0.20/0.05±0.09 versus -0.30 ± 0.15D/0.16 ±0.09mm for the second period. The paired contralateral efficacy in slowing myopia with MiSight was not different to BHVI EDOF for both SE and AL (p=0.12, p=0.28). Considering changes in AL alone and across both the first and second periods, 84% and 97% of MiSight and EDOF CL wearing eyes progressed ≤ than their contralateral control eyes (p=0.11).
Conclusions: With bilateral wear of single vision CL, change in SE was slightly less over the second compared to first period but change in AL was similar between the two periods. Change in SE and AL with contralateral wear of single vision CL was similar to that of bilateral wear of single vision CL. Both BHVI EDOF and MiSight contact lenses were effective in slowing eye growth in the majority of eyes and significantly, the reduction in progression was similar between the two CL.

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Current and Emerging Pharmaceutical Interventions for Myopia

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Purpose: To summarise the pharmaceutical interventions for myopia at clinical and pre-clinical stages in the last decade and discuss challenges for pre-clinical drugs to progress to clinical trials.
Methods: A literature review was performed to identify all clinical trials and pre-clinical studies from 2008-2018 involving pharmaceutical agents and myopia progression.
Results: 20 trials were identified: 13 active, 5 completed and 2 with unknown status. Atropine and 7-methylxanthine were effective while other agents such as ketorolac tromethamine, riboflavin and BHVI2 (an experimental drug) are being investigated. In animals, 30 pharmaceutical interventions significantly reduced myopia progression and were classified into 6 categories based on the proposed mechanisms of myopisation: anti-muscarinic, dopaminergic, anti-inflammatory, intraocular pressure lowering, natural extracts and miscellaneous. However, several drugs were injected intravitreally or subconjunctivally.
Conclusions: The invasive nature of some pre-clinical agents prevents their advancement towards clinical trials. Nonetheless, they provide valuable insight into the poorly-elucidated process of myopisation. Atropine remains the most well-studied and effective drug while others are being investigated. Future pre-clinical interventions should be studied in combination with atropine to optimise the treatment of myopia.

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Myopia Controle for Europeans: Evidence-based Protocol

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Purpose: Treatment options for myopia control in children with progressive myopia are emerging. Clinicians and eye care providers are implementing these into clinical practice, but standard of care is lacking. We have developed a protocol for myopia control incorporating all scientific evidence.
Protocol: Target for myopia control are axial length and refractive error. Children are examined every 6 months. Before intervention, risk factors as outdoor exposure and myopia family history are assessed, children are fully examined, and axial length is plotted on the growth curve (Tideman et al. Acta Ophthalmol 2018) to identify expected growth and risk of high myopia. First, lifestyle recomendations including 2 hours daily outdoor exposure are provided. Children who present with axial length on the 75th percentile or more on the growth chart receive an initial treatment of atropine eye drops 0.5%, and they receive multifocal pheochromatic glasses to compensate for side effects. Children below the 75th percentile are started on low dose atropine, ortho-K, or multifocal lenses in accordance with the wishes and feasibility of the patient and parents. When no decline of progression (with shift to lower percentile on the growth chart) is observed under the initial treatment, treatment is altered to a higher dose of atropine, or a combination of optical and pharmaceutical interventions.
Treatment success: Applying this protocol to 300 children in the clinic, we achieved 70% reduction of myopia progression; 72% managed to stay on the myopia control regimen for at least 3 years.

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Two-Year Clinical Trial of the Low-concentration Atropine for Myopia Progression (LAMP) Study: 0.05% atropine remained the optimal concentration for myopia control

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Purpose: The ATOM 2 study demonstrated a significantly better efficacy of 0.01% atropine during the second year when compared with the first year. In this study, we aimed to evaluate the efficacy and safety of 0.05%, 0.025%, and 0.01% atropine over a 2-year period to determine which is the optimal concentration for longer-term myopia control.
Design: A randomized, double-masked trial, extended from the Low-Concentration Atropine for Myopia Progression (LAMP) study.
Participants: The children originally randomized to receive atropine 0.05%, 0.025%, 0.01%, or placebo once daily in both eyes in the LAMP study phase 1 were invited to join this extended trial (phase 2). Finally, 383 children who completed 1-year follow up in phase 1 were enrolled.
Methods: In phase 2, children of the placebo group in phase 1 were switched to receive 0.05% atropine from the beginning of the second year follow up, while those in the 0.05%, 0.025%, and 0.01% atropine groups remained the same regimen for two years. Cycloplegic refraction (spherical equivalent, SE), axial length (AL), accommodation amplitude, pupil diameter, and best-corrected visual acuity were measured at 4-month interval. A questionnaire for quality of visual function was administered at the end of the second year. Generalized estimating equations (GEEs) were used to adjust the inter-eye interaction.
Main outcome measure: Changes in SE and AL, and their differences among groups.
Results: Over the 2-year period, the mean SE progression was 0.55±0.84D, 0.85±0.73D, 1.11±0.86D, and 0.99±0.79D in 0.05%, 0.025%, 0.01% atropine, and switch-over groups, respectively, with mean AL increase by 0.39±0.34mm, 0.50±0.33mm, 0.58±0.39mm, and 0.58±0.33mm. Comparing with the first year, the second-year efficacy of 0.05% and 0.025% remained similar, but mildly improved in the 0.01% atropine group. For the phase 1 placebo group, the myopia progression was significantly reduced after switching to 0.05% atropine (SE change 0.16D at second year vs 0.79D at first year, p<0.001; AL change 0.15mm at second year vs 0.41mm at first year, p<0.001). Accommodation loss, change in pupil size, vision acuity, and vision-related quality of life in all concentrations remained similar to the first year results. All concentrations remained well tolerated during the 2-year period.
Conclusions: Over two years, atropine eye drop at 0.05% is the optimal concentration that has been tested for slowing myopia progression.

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