## Summary of PEDIG Amblyopia Studies

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A, atropine penalization; P, occlusion (patching); O, optical correction; M, moderate amblyopia (20/40-20/80); M*, moderate amblyopia (20/40 – 20/100); M/S, moderate-severe amblyopia (20/40 – 20/250); S, severe amblyopia (20/100 – 20/400)
A Randomized Trial of Atropine vs Patching for Treatment of Moderate Amblyopia in Children

Objective: To compare patching (≥ 6 hours to all waking hours/daily) vs. atropine (1 drop/daily) to treat strabismic and/or anisometropic amblyopia

Number enrolled: 419
Age: 3 – < 7
Amblyopia severity: Moderate (20/40-20/100) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Amblyopic eye visual acuity at 6 months

Results: • Amblyopic eye visual acuity improved an average of 3.16 lines in patching group and 2.84 lines in atropine group
  • Amblyopic eye visual acuity was ≥ 20/30 and/or improved ≥ 3 lines in 79% of patching group and 74% of atropine group
  • Visual acuity improvement was initially faster in patching group but after 6 months the difference was clinically insignificant
  • Treatment effect between the groups did not vary with age, type of amblyopia, or depth of amblyopia

Conclusions: Patching or atropine produced similar improvements in amblyopic eye visual acuity


Two-Year Follow-up of a 6-Month Randomized Trial of Atropine vs Patching for Treatment of Moderate Amblyopia in Children

Objective: To compare patching (≥ 6 hours to all waking hours/daily) vs. atropine (1 drop/daily) for 6 months followed by best clinical care for 18 months to treat strabismic and/or anisometropic amblyopia

Number enrolled: 363
Age: 3 – < 7
Amblyopia severity: Moderate (20/40-20/100) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Amblyopic eye visual acuity at 2 years

Results: • One third of patients were still being treated for amblyopia
  • Change in treatment:
    84% of patching group and 78% of atropine group continued with same treatment
    28% of patching group and 25% of atropine group switched treatment
    21% of patching group and 18% of atropine group were treated with both
  • Amblyopic eye visual acuity improved an average of 3.70 lines in patching group and 3.60 lines in atropine group
  • Amblyopic eye visual acuity was ≥ 20/30 and/or showed improvement of ≥ 3 lines in 86% of patching group and 83% of atropine group
  • Mean amblyopic eye visual acuity in both groups was 20/32, 1.80 lines worse than sound eye visual acuity
• Amblyopic eye visual acuity of 20/25 was achieved in 51% of patching group and 49% of atropine group
• Treatment effect between the groups did not vary with age, type of amblyopia, or depth of amblyopia
• No difference between the groups in adverse effects on sound eye visual acuity, ocular alignment, or stereoacuity

Conclusions: At 2 years, patching or atropine for 6 months followed by best clinical care for produced similar improvements in amblyopic eye visual acuity


The Effect of Amblyopia Therapy on Ocular Alignment

Objective: To evaluate the change in ocular alignment with patching vs. atropine to treat anisometropic and/or strabismic amblyopia

Number enrolled: 357
Age: 3 – < 7
Amblyopia severity: Moderate (20/40-20/100) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Change in ocular alignment (no deviation, 1 – 8 Δ, > 8Δ) at 2 years
Results: • New strabismus developed in 18% of patching group and 16% of atropine group
  • Only 2 patients in patching group and 3 patients in atropine group developed strabismus > 8Δ
  • Microtropia progressed to deviation > 8Δ in 13% of patching group and 15% of atropine group and resolved in 38% of the patching group and 35% of the atropine group
  • Strabismus > 8Δ improved in 46% of patching group and 47% of atropine group and resolved in 13% of patching group and 16% of atropine group

Conclusions: Patching or atropine produced similar rates of deterioration and improvement of ocular alignment


The Effect on Refractive Error of Unilateral Atropine as Compared With Patching for the Treatment of Amblyopia

Objective: To evaluate the change in sound eye refractive error with patching vs. atropine to treat anisometropic and/or strabismic amblyopia

Number enrolled: 282
Age: 3 – < 7
Amblyopia severity: Moderate (20/40-20/100) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Change in sound eye refractive error at 2 years
Results: • Mean spherical equivalent of the sound eye at baseline was +2.58 D in patching group and +3.13 D in atropine group
• Mean change in sound eye refractive error was +0.08 D in patching group and +0.10 D in atropine group
• Mean change in sound eye refractive error was -0.60 D in children who only received patching and -0.21 D children who only received atropine
• Only 11% of patching group and 17% of atropine group had a change in sound eye refractive error > 1 D

Conclusions: Atropine compared to patching was not associated with an adverse effect on sound eye refractive error


Impact of Patching and Atropine Treatment on the Child and Family in the Amblyopia Treatment Study

Objective: To assess the quality of life and psychosocial impact of patching vs. atropine to treat anisometropic and/or strabismic amblyopia

Number enrolled: 364
Age: 3 – < 7
Amblyopia severity: Moderate (20/40-20/100) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Amblyopia Treatment Index overall and subscale (adverse effects, treatment compliance, and social stigma) scores based on a 5-point scale at 5 weeks

Results: • Both treatments were well tolerated
  • Atropine received more favorable (lower) overall and subscale scores than patching
  • Overall score was 2.52 in patching group vs. 2.02 in atropine group
  • Adverse effects of treatment score was 2.35 in patching group vs. 2.11 in atropine group
  • Difficulty with compliance score was 2.46 in patching group vs. 1.99 in atropine group
  • Social stigma score was 3.09 in patching group vs. 1.84 in atropine group
  • Age, cause of amblyopia, and depth of amblyopia showed little relationship with overall score

Conclusions: Both patching and atropine were well tolerated although atropine received more favorable scores


A Randomized Trial of Patching Regimens for Treatment of Moderate Amblyopia in Children

Objective: To compare 2 hours vs. 6 hours of daily patching combined with 1 hour of concurrent near visual activities to treat strabismic and/or anisometropic amblyopia

Number enrolled: 189
Age: 3 – < 7
Amblyopia severity: Moderate (20/40-20/80) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Amblyopic eye visual acuity at 4 months
Results: • Amblyopic eye visual acuity improved an average of 2.40 lines in each group
  • Amblyopic eye visual acuity was ≥ 20/32 and/or showed improvement of ≥ 3 lines in 62% of patients in each group
  • Course of visual acuity improvement similar between the groups
  • Treatment effect between the groups did not vary with age, type of amblyopia, or depth of amblyopia
  • No difference between the groups in adverse effects on sound eye visual acuity, ocular alignment, or stereoacuities
  • Both treatment groups were well tolerated, but the 6-hour group had worse social stigma scores on the Amblyopia Treatment Index
Conclusions: 2 hours or 6 hours of daily patching combined with 1 hour of near visual activities produced similar improvements in amblyopic eye visual acuity

A Randomized Trial of Prescribed Patching Regimens for Treatment of Severe Amblyopia in Children
Objective: To compare 6 hours vs. full-time (all but 0 to 1 waking hours) daily patching combined with 1 hour of concurrent near visual activities to treat strabismic and/or anisometropic amblyopia
Number enrolled: 175
Age: 3 – < 7
Amblyopia severity: Severe (20/100-20/400) with sound eye visual acuity ≥ 20/40
Outcome measure: Amblyopic eye visual acuity at 4 months
Results: • Amblyopic eye visual acuity improved an average of 4.80 lines in 6-hour group and 4.70 lines in full-time group
  • Amblyopic eye visual acuity showed improvement of ≥ 3 lines in 86% of 6-hour group and 82% of full-time group
  • Course of visual acuity improvement similar between the groups
  • Treatment effect between the groups did not vary with age, type of amblyopia, or depth of amblyopia
  • Patients with worse amblyopic eye visual acuity (20/200-20/400) and younger children (< 5 years) showed more improvement in amblyopic eye visual acuity
  • No difference between the groups in adverse effects on ocular alignment or stereoacuity
  • Sound eye visual acuity was 0.50 lines better in the 6-hour group vs. 0.10 lines in the full-time group
  • Both treatment groups were well tolerated and the scores on the Amblyopia Treatment Index were similar between the groups
Conclusions: 6 hours or full-time daily patching combined with 1 hour of near visual activities produced similar improvements in amblyopic eye visual acuity.


Treatment of Anisometropic Amblyopia in Children With Refractive Correction
Objective: To evaluate refractive correction to treat previously untreated anisometropic amblyopia at 5-week intervals until visual acuity stabilized or amblyopia resolved (spectacle phase of 2-phase trial).

Number enrolled: 84
Age: 3 – < 7
Amblyopia severity: Moderate-Severe (20/40-20/250) with interocular acuity difference of ≥ 3 lines and anisometropia ≥ 0.50 D spherical equivalent and/or ≥ 1.50 D astigmatism.

Outcome measure: Maximum improvement in amblyopic eye visual acuity.

Results:
• Amblyopic eye visual acuity improved an average of 2.90 lines.
  • 77% improved ≥ 2 lines.
  • 27% had resolution of amblyopia.
  • 83% stopped improving after 10 weeks but continued improvement was noted up to 30 weeks.
  • Treatment effect between the groups was related to better baseline amblyopic eye visual acuity and smaller amounts of anisometropia but was not related to age or type of anisometropia.
  • Further improvement (21/34 patients) and resolution (6/34 patients) of amblyopia were noted in patients with a residual interocular difference of ≥ 2 lines randomized to the spectacle correction control group of the second phase of this study - A randomized trial to evaluate 2 hours of daily patching for strabismic and anisometropic amblyopia in children.

Conclusions: Refractive correction alone can improve amblyopic eye visual acuity and resulted in the resolution of amblyopia in almost 1/3 of patients.


Treatment of Strabismic Amblyopia With Refractive Correction
Objective: To evaluate refractive correction to treat previously untreated strabismic amblyopia at 5-week intervals until visual acuity stabilized or amblyopia resolved (spectacle phase of 2-phase trial).

Number enrolled: 12
Age: 3 – < 7
Amblyopia severity: Moderate-Severe (20/40-20/250) with interocular acuity difference of ≥ 3 lines and anisometropia ≤ 0.75 D spherical equivalent or ≤ 1.25 D astigmatism.
Outcome measure: Maximum improvement in amblyopic eye visual acuity

Results: • Amblyopic eye visual acuity improved an average of 2.20 lines
  • 75% improved ≥ 2 lines
  • 25% had resolution of amblyopia
  • Improvement was noted up to 25 weeks
  • Further improvement (3/5 patients) of amblyopia, but not resolution, of amblyopia was noted in patients with a residual interocular difference of ≥ 2 lines randomized to the spectacle correction control group of the second phase of this study - A randomized trial to evaluate 2 hours of daily patching for strabismic and anisometropic amblyopia in children
  • Could not exclude possibility that change in strabismus angle, learning or age effect, regression to the mean, or chance could account for some of the visual acuity improvements

Conclusions: Refractive correction alone may improve amblyopic eye visual acuity and resulted in the resolution of amblyopia in 1/4 of patients


A Randomized Trial to Evaluate 2 Hours of Daily Patching for Strabismic and Anisometropic Amblyopia in Children

Objective: To compare 2 hours of daily patching combined with 1 hour of concurrent near visual activities vs. spectacle correction/observation control group to treat strabismic and/or anisometropic amblyopia (randomization phase of 2-phase trial)

Number enrolled: 180
Age: 3 – < 7
Amblyopia severity: Moderate-Severe (20/40-20/400) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40 already in optimal correction ≥ 16 weeks or completed spectacle phase (previous 2 studies)

Outcome measure: Amblyopic eye visual acuity at 5 weeks and at scheduled intervals until no further improvement

Results: • Amblyopic eye visual acuity improved an average of 1.10 lines in patching group vs. 0.50 lines in control group at 5 weeks
  • Amblyopic eye best-measured visual acuity at any visit improved an average of 2.20 lines in patching group vs. 1.30 lines in control group
  • Treatment effect between the groups did not vary with age, type of amblyopia, depth of amblyopia, prior amblyopia treatment, or participation in spectacle phase of the study
  • No difference between the groups in adverse effects on sound eye visual acuity, ocular alignment, or stereoacuity

Conclusions: After treatment with spectacle correction, 2 hours of patching improved amblyopic eye visual acuity

A Randomized Pilot Study of Near Activities Versus Non-Near Activities During Patching Therapy for Amblyopia

Objective: To compare whether children prescribed 2 hours of daily patching combined with near vs. non-near activities would perform those activities and to estimate the effect of these activities to treat strabismic and/anisometric amblyopia

Number enrolled: 64
Age: 3 – <7
Amblyopia severity: Moderate-Severe (20/40-20/400) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Time spent performing near activities and amblyopic eye visual acuity at 4 weeks

Results: • Mean number of hours spent on near activities/day was 1.60 hours in near activities group vs. 0.20 hours in non-near activities group
• Mean hours patched/day was 2.00 in near activities group and 1.90 in non-near activities group
• Amblyopic eye visual acuity improved an average of 2.60 lines in near activities group vs. 1.60 lines in non-near activities
• This treatment effect was seen in patients with severe amblyopia (3.70 lines in near activities group vs. 1.20 lines in non-near activities group) but not in those with moderate amblyopia (1.70 in near activities group and 1.40 non-near activities group)

Conclusions: Children instructed to perform near activities spent more time performing near activities and preliminary data suggest that performing near activities may be beneficial in treating amblyopia


A Randomized Trial of Atropine Regimens for Treatment of Moderate Amblyopia in Children

Objective: To compare daily vs. weekend (Saturday and Sunday) atropine to treat strabismic and/or anisometric amblyopia

Number enrolled: 168
Age: 3 – <7
Amblyopia severity: Moderate (20/40-20/80) with interocular acuity difference of ≥ 3 lines and sound eye visual acuity ≥ 20/40
Outcome measure: Amblyopic eye visual acuity at 4 months

Results: • Amblyopic eye visual acuity improved an average of 2.30 lines in each group
• Amblyopic eye visual acuity was ≥ 20/25 or ≥ sound eye visual acuity in 47% of daily group and 53% of weekend group
• Course of visual acuity improvement similar between the groups
• Treatment effect between the groups did not vary with age, type of amblyopia, depth of amblyopia, iris color, sound eye refractive error, or prior amblyopia treatment
• No difference between the groups in adverse effects on sound eye visual acuity, ocular alignment, or stereoacuity
• Both treatment groups were well tolerated, but the weekend group had worse compliance scores on the Amblyopia Treatment Index and reported more light sensitivity

Conclusions: Daily or weekend atropine produced similar improvements in amblyopic eye visual acuity


Risk of Amblyopia Recurrence After Cessation of Treatment
Objective: To assess stability of visual acuity improvement after cessation of treatment other than spectacle correction for strabismic and/or anisometropic amblyopia

Number enrolled: 156
Age: 3 – <8
Amblyopia severity: Moderate-Severe (20/40 or worse) with interocular acuity difference of ≥ 3 lines initially with amblyopic eye visual acuity improvement ≥ 3 lines during continuous amblyopia treatment for the previous 3 months (≥ 2 hours daily patching or ≥1 drop atropine/week)

Outcome measure: Recurrence of amblyopia (≥ 2 line decrease in visual acuity from enrollment) during the first year after cessation of treatment

Results: • 24% of children had amblyopia recurrence within 1 year after stopping therapy
  • Recurrence rate similar in patients who stopped patching or atropine
  • Most recurrences occur within the first 13 weeks after discontinuation of treatment
  • Recurrence based on treatment/weaning groups (maximum patching hours/patching hours stopped at enrollment):
    14% in low-intensity non-weaned (2 hours/2 hours)
    14% in moderate-intensity weaned (6 – 8 hours/2 hours)
    42% in moderate-intensity non-weaned (6 – 8 hours/6 – 8 hours)

Conclusions: One-fourth of successfully treated children experienced a recurrence within the first year off treatment and the risk of recurrence was greater when moderate-intensity patching was not weaned


Factors Associated with Recurrence of Amblyopia on Cessation of Patching
Objective: To evaluate additional factors associated with recurrence of amblyopia after cessation of treatment other than spectacle correction for strabismic and/or anisometropic amblyopia

Number enrolled: 69
Age: 3 – <8
Amblyopia severity: Moderate-Severe (20/40 or worse) with interocular acuity difference of ≥ 3 lines initially with amblyopic eye visual acuity improvement ≥ 3 lines during continuous amblyopia treatment for the previous 3 months (≥ 2 hours daily patching or ≥1 drop atropine/week)
Outcome measure: Recurrence of amblyopia (≥ 2 line decrease in visual acuity from enrollment) during the first year after cessation of treatment

Results: • Risk of recurrence was higher with
  Better amblyopic eye visual acuity at cessation of treatment
  Greater number of lines improved at cessation of treatment
  Less interocular acuity difference at cessation of treatment
  Previous amblyopia recurrence
• Risk of recurrence was NOT associated with
  Age at diagnosis or cessation of treatment
  Ocular alignment at cessation of treatment
  Randot stereoacuity at cessation of treatment

Conclusions: A higher risk of recurrence was noted in the most successfully treated children and there was absence of protection from recurrence with orthotropia and excellent stereopsis


Randomized Trial of Treatment of Amblyopia in Children Aged 7 to 17 Years

Objective: To evaluate amblyopia treatment (2 – 6 hours daily patching combined with 1 hour of concurrent near visual activities in both the 7 – 12 year old subgroup and 13 – 17 year old subgroup PLUS daily atropine in the 7 – 12 year old subgroup only) vs. optical correction only to treat strabismic and/or anisometropic amblyopia

Number enrolled: 507
Age: 7 – 17
Amblyopia severity: Moderate-Severe (20/40-20/400) with sound eye visual acuity ≥ 20/25
Outcome measure: Number of responders to treatment (improvement of amblyopic eye visual acuity ≥ 10 letters/2 lines) by 24 weeks

Results: • One-fourth of optical correction group responded to treatment in both subgroups
  • 53% in 7 – 12 year old subgroup vs. 25% in 13 – 17 year old subgroup were responders
  • In the 13 – 17 year old subgroup, responder rate in treatment group increased to 47% in those who were not previously been treated for amblyopia vs. 16% in those who were previously treated for amblyopia
  • Most patients, including responders, were left with a residual visual acuity deficit
  • Intractable, constant diplopia did not occur in any patient

Conclusions: • Optical correction alone can improve amblyopia in patients 7 – 17 years old
  • Amblyopia treatment can further improve visual acuity in patients aged 7 to 12 years old even if amblyopia has been previously treated and in patients aged 13 – 17 years old when amblyopia has not been previously treated but appears to be of little benefit if amblyopia has been previously treated

Stability of Visual Acuity Improvement Following Discontinuation of Amblyopia Treatment in Children Aged 7 to 12 Years

Objective: To assess stability of visual acuity improvement after cessation of treatment other than spectacle correction for strabismic and/or anisometropic amblyopia

Number enrolled: 80
Age: 7 – 12
Amblyopia severity: Moderate-Severe (20/40-20/400) with sound eye visual acuity ≥ 20/25 initially with amblyopic eye visual acuity improvement ≥ 10 letters (2 lines)

Outcome measure: Amblyopic eye visual acuity decrease ≥ 10 letters (2 lines) during the first year off of treatment

Results: • 7% had amblyopic eye visual acuity decrease ≥ 10 letters (2 lines)
  • 82% maintained an increase of amblyopic eye visual acuity ≥ 10 letters (2 lines) from pretreatment visual acuity
  • No patients had worse visual acuity than their pre-treatment visual acuity

Conclusions: Visual acuity improvement after amblyopia treatment in patients aged 7 to 12 years old was maintained in most children for at least 1 year after treatment


Treatment of Bilateral Refractive Amblyopia in Children Three to Less Than 10 Years of Age

Objective: To determine the amount and time course of binocular visual acuity improvement during treatment of bilateral refractive amblyopia

Number enrolled: 113
Age: 3 – < 10
Amblyopia severity: Moderate-Severe (20/40-20/400) with ≥ 4 D spherical equivalent hyperopia and/or ≥ 2 D astigmatism in each eye

Outcome measure: Binocular visual acuity at one year

Results: • Mean binocular visual acuity improved an average of 3.9 lines from 20/63 to 20/25
  • For moderate amblyopia (20/40-20/80), mean visual acuity improvement was 3.4 lines
  • For severe amblyopia (20/100), mean visual acuity improvement was 6.3 lines
  • Cumulative probability of binocular visual acuity ≥ 20/25 was:  21% at 5 weeks
  46% at 13 weeks
  59% at 26 weeks
  74% at 52 weeks

Conclusions: Treatment of bilateral refractive error with optical correction improved binocular visual acuity with most improving to ≥ 20/25 within one year