Evaluating and Managing Infant Aphakia with Gas Permeable Lenses

Nathan Cheung, OD, FAAO

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Disclosure Statement:
Nothing to disclose
Infant Aphakia
Why should we use rigid gas permeable lenses?
POLL Question

• Who fits contact lenses for infant aphakes?
  a) Yes, I do
  b) No, I don’t
POLL Question

• What lenses do you use?
  a) RGP
  b) Silsoft
  c) Soft Contact Lens
Goal of this Presentation

- review the latest literature
- step wise instructional approach to fitting
- argument for why RGP lenses should be used
Infant Aphakia
Anatomy
Axial Length in Pediatric Eyes

- 20 full term infants measured using through-the-eyelid biometry at 4, 12, 26, 36 and 52 +/- 2 weeks.
- 17.03mm +/- 0.382mm at 4 weeks of age
- 19.91 +/- 0.602mm at 52 weeks of age
- greatest change in axial length of 1.191mm +/- 0.406mm occurred within the first 12 weeks of life
- The smallest change in axial length of 0.96mm occurred from 9 to 12 months of age with the smallest range 0.142 +/- 0.96mm.
- the greatest change in axial length occurs with the first 12 weeks of life and that axial length change slows down between the ages of 9 and 12 months.

- 20 eyes were measured
- Extrapolated mean axial length at birth 16.8mm
  - 20mm at 12 months of age
  - 21mm at 4 years of age
- Axial length changes rapidly in the noncataractous eyes the first 18 months of life.

Longitudinal changes in axial length and lens thickness in infants. Abstract from AAOPT Donald Mutti et al.
- At age 3 months Axial Length 19.66 ± 0.76 mm, respectively.
- Between 3 and 9 months, significant increases occurred in ACD, VCD, and AL


**Figure 1.** Axial length measurements using the standard applanation technique in an office setting.
Axial length in children with congenital cataracts

- 44 eyes; 1.5 months to 8 years old
- AL measured with contact biometry at the time of cataract surgery
- Mean age 27.3 months: Mean AL 20.63 +/- 2.11mm; Mean K 44.94 +/- 2.44mm

- 59 patients with unilateral cataract
- Found no difference between axial length growth or corneal flattening between operated and non-operated eyes

- Took a look at axial length following cataract surgery and IOL implantation
- They found no statistical significance between operated and non operated eyes
- The AL followed a normal pattern

- 42 infants with unilateral cataracts. Had refractions for first 4 years of life
  - 1st year of life: +30.75-26.36D
  - 24 months: +23.02D
  - 36 months: +21.19D
  - 48 months: +20.86D
- Rate of change per month
  - 1-6 months: 0.43D/month
  - 6-12 months: 0.37D/month
  - 12-18 months: 0.30D/month
  - 18-24 months: 0.24D/month
  - >24 months: 0.19D/month

• 200 infants, handheld topography,
  – 1.6 days, 3 months, 6 months
• Birth: 48.5 (48.2-48.89; 95% CI 41.4-56.0D) and astigmatism 6D (5.6-6.3D)
  – Mean astigmatism at 3mm was 6.4D (6-6.8 D 95%CI)
  – At 5 mm was 5.9D (5.4-6.3D)
• 6 months: 43.0 (41.3-43.1 95%CI) and 2.3D of astigmatism (1.2-3.2D)
• 56 premature infants born 24–32 weeks of gestational age
• K’s 65.83D at 28 weeks to 49.38D at 42 weeks Post conceptual age
• CCT decreased from 794 à 559 um
• Only 2 other studies about CCT in premature infants
  • Autzen and Bjornstrom- 13 infants with age < 33 weeks
    o 0.656 +/- 0.103 mm at 5 days of life
    o 0.654 +/- 0.084mm at 20 days
    o 0.566 +/- 0.064 mm at 110 days
  • No difference between the first and third postnatal week.
  • 3 months, same thickness as a full term newborn
  • No correlation was found between gestational age at CCT
  • Kirwan et al- 35 premature infants (70 eyes)
  • Born at gestational age ranging 23-32 weeks in four post conceptual age groups
    o 0.691 +/- 0.087; 0.648 +/- 0.072; 0.605 +/- 0.059; 0.564 +/- 0.034
    o 8.0 +/- 2.8; 5.6 +/- 3.9; 4.6 +/- 0.5
  • Full term newborns CCT: 0.581 +/- 0.047; 0.573 +/- 0.052; 0.585 +/- 0.052mm
  o Reach adult CCT by 3 years
• Cook et al. K’s: 5.80mm/58.25D at 32 weeks PCA à 6.8mm/49.5D at 40 weeks
• Friling et al. K’s: 63.3 and 57.3D in patients < 32 weeks; 58.3 and 53.9D in patients 32-36 weeks PCA, 54.0D and 50.7D in patients more than 36 weeks PCA
• Gordon and Donzis 51.2D in full term newborns

• Large corneal thickness is related to corneal hydration
• Corneal transparency develops during fetal life, fetal cornea is translucent rather than transparent and is more hydrated than in an adult
  • Condensation begins in the posterior stroma during fetal maturatio
  • Most anterior stromal lamellae formed, corneal transparency reaches adult quality
  • Water content of the cornea decreases

<table>
<thead>
<tr>
<th>TABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keratometric and Pachymetric Mean Values and Standard Deviations for Each PCA Week</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PCA (wkl)</th>
<th>Keratometry (D)</th>
<th>Pachymetry (um)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>28 (n = 6)</td>
<td>65.83</td>
<td>0.94</td>
</tr>
<tr>
<td>29 (n = 4)</td>
<td>64.69</td>
<td>1.62</td>
</tr>
<tr>
<td>30 (n = 6)</td>
<td>63.23</td>
<td>1.37</td>
</tr>
<tr>
<td>31 (n = 8)</td>
<td>62.31</td>
<td>2.09</td>
</tr>
<tr>
<td>32 (n = 12)</td>
<td>59.86</td>
<td>2.62</td>
</tr>
<tr>
<td>33 (n = 18)</td>
<td>55.50</td>
<td>2.61</td>
</tr>
<tr>
<td>34 (n = 30)</td>
<td>54.88</td>
<td>2.92</td>
</tr>
<tr>
<td>35 (n = 26)</td>
<td>53.79</td>
<td>2.23</td>
</tr>
<tr>
<td>36 (n = 46)</td>
<td>53.03</td>
<td>2.51</td>
</tr>
<tr>
<td>37 (n = 38)</td>
<td>52.52</td>
<td>1.85</td>
</tr>
<tr>
<td>38 (n = 42)</td>
<td>50.30</td>
<td>1.98</td>
</tr>
<tr>
<td>39 (n = 28)</td>
<td>50.45</td>
<td>2.41</td>
</tr>
<tr>
<td>40 (n = 14)</td>
<td>50.32</td>
<td>1.94</td>
</tr>
<tr>
<td>41 (n = 20)</td>
<td>48.73</td>
<td>1.84</td>
</tr>
<tr>
<td>42 (n = 12)</td>
<td>49.38</td>
<td>2.33</td>
</tr>
</tbody>
</table>

PCA = post-conceptual age; D = Sphere; SD = standard deviation.
* The number of measurements for each PCA is shown in parentheses.
Infant Aphakia Literature

- Historical Aphakia Studies
- Infant Aphakia Treatment Study
  - Summaries of some of the IATS published papers
  - Highlight landmark study on the IATS CL experience that was published in 2016

• 25 eyes: +31.00D (+18.75-+40.00D), BC: 46.75 (41.00-49.00D)

• Most large BC adjustments occurred (> 1D) occurred during first 3 months after surgery

• GP lenses can change every 2-3 months, so it is important to follow them closely to make the expected/unexpected parameter changes
• Shaugnessy MP et al. Rigid gas-permeable contact lenses are a safe and effective means of treating refractive abnormalities in the pediatric population. The CLAO journal, October 2001. 27 (4): 195-201.
• Retrospective chart review of 12 children fit into RGP CL
• RGP's more difficult fitting process and adaptation period
• High oxygen permeability, low bacterial and protein adherence and ability to correct astigmatism
• Easier to insert with fewer handling abilities (small diameter and increased rigidity)
• More economical than soft and silicone lenses
• Lens comfort asking caregivers: redness, tearing or eye rubbing
• RGP are about 1/3 the wholesale cost of a Silsoft
• Average replacement of 2.18 lenses per 6 months, or about 4 lenses a year

• Evaluate the use of silsoft, chart review from 1992-1999

• Patients got CL 5-12 days after surgery, f/u q month for first year, q 2 months 2nd year, then every 3 months thereafter.
  – 51 children/ 83 eyes.
  – 19.4 +/- 18 months
  – CL wear duration per lens: 26 +/- 11 weeks
  – Mean CL usage: 5.8 years
  – Mean CL loss: 0.98/year
• IOL over CL
  – Less cost
  – Elimination of difficulties associated with CL insertion and removal
  – Less aphakic uncorrected treatment with lens loss or inconsistent use
  – Elimination of the need for parents to meticulously care for CL
• Parents still need to patch with either method
• Disadvantage of IOL
  – Post-operative iritis requiring high dose of topical steroid
  – IOL subluxation
  – Iris capture
  – May still need glasses over-top
• Initial stress level for CL insertion was high, but it decreases over time
• Unable to detect any demographic factors that will predict CL failure
• More stress levels due to patching therapy than CL use, and patching therapy never got better for the child over time
• CL cost was a bigger stress than CL insertion and removal
  – But caregivers would still want CL over glasses
  – Patients lose a CL once every 9.2 months
  – 44% needed glasses on top of CL

*Menicon Z: Dk 189 Fatt. (189,163, 250 depending on method used)

**Holden and Mertz- minimal oxygen requirements, less than 4% was 87 +/- 3.3 x 10^-9**
**34.3 +/- 5.2 x 10^-9, exceed 4% swelling, but return to normal thickness**
**Daily wear: 24.1 +/- 2.7 x 10^-9**
**Center thickness of lens to define oxygen permeability**
**The lens uses a spherical, single cut central optic zone, blended multicurve peripheral system and larger overall diameter than most RGP lenses**
**Lens permeability, thickness profile, good tear exchange**


CLEW creates a stressful environment
- Chronic pressure, mechanical stress, lens-induced hypoxia
- Standard soft disposable lenses with eyes closed for an hour increase oxygen permeability by 40% and when the same lenses are worn overnight for 2 weeks: increases 99%
- RGP wear: reduction in epithelial barrier function directly related to hypoxia exposure
  - Medium DK 28x10^-9 Dk/t and High DK 53x10^-9
- Epithelium permeability increased with wearing lenses overnight
- Suggested: lenses with the highest oxygen permeability and fastest rate of tear exchange are preferred to minimize disruption of the corneal epithelial layer
Infant Aphakia Treatment Study (IATS)

- Randomized, Multicenter (12 sites) clinical trial
- 114 infants with unilateral cataract surgery (1-6 months of age)
  - IOL implantation VS Contact Lens
    - Patients with IOL implantation had spectacles to correct residual refractive error
- Main Outcome Measure
  - Grating acuity at 12 months
  - HOTV visual acuity at 4.5 years
    - Performed by the same masked travelling examiner that travelled to all the sites
Infant Aphakia Treatment Study (IATS) (NCT00321234)

**Study Description**

The study has been completed.

**Sponsor**

Emory University

**Collaborators**

Georgia Institute of Technology

**Information provided by**

Amy K. Kaplan, MD, Emory University

**Study Details**

- **NCT00321234**
- **First received: September 13, 2005**
- **Last updated: July 27, 2006**
- **Last verified: July 27, 2006**

**Objectives**

- **Primary Objective:**
  - Visual Acuity (Early Treatment for Retinopathy of Prematurity [ETROP]) at 4.5 years
  - **Secondary Objectives:**
    - Stereoacuity (Early Treatment for Retinopathy of Prematurity [ETROP]) at 4.5 years
    - **Intervention:**
      - Aphakic Contact Lens
      - Aphakic Intraocular Lens

**Measured Values**

<table>
<thead>
<tr>
<th>Participants Analyzed</th>
<th>Aphakic Contact Lens</th>
<th>Aphakic Intraocular Lens</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Units: Participants]</td>
<td>57</td>
<td>55</td>
</tr>
</tbody>
</table>

**Visual Acuity - Subjective Assessment at Age 4.5 Years**

<table>
<thead>
<tr>
<th>[Units: LogMAR units]</th>
<th>0.90</th>
<th>0.90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (Inter-Quartile Range)</td>
<td>0.30 to 1.60</td>
<td>0.40 to 1.73</td>
</tr>
</tbody>
</table>


### Table 1. IATS Inclusion/Exclusion Criteria

**Inclusion Criteria**
1. Visionally significant congenital cataract (≥3 mm central opacity) in 1 eye.
2. Aged 29 d to <7 mo (<210 d) at time of cataract surgery.
3. At least 41 postconceptional weeks at time of cataract surgery.
4. Written informed consent provided by parent or legal guardian agreeing that patient could be randomized in operating room if EUA confirmed that patient was eligible for study.

**Exclusion Criteria**
1. Cataract was known to be due to trauma or acquired as adverse effect of treatment administered postnatally.
2. Corneal diameter <5 mm.
3. Intraocular pressure ≥29 mm Hg.
4. PVP causing stretching of the ciliary processes or tractional detachment of retina.
5. Active uveitis or signs suggestive of previous episodes of uveitis.
6. Child was product of preterm pregnancy (<36 wk gestational age).
7. Retinal disease that may limit visual potential of eye.
8. Previous intracocular surgery.
9. Optic nerve disease that may limit visual potential of eye.
10. Fellow eye that would limit disease that might reduce its visual potential.
11. Child had medical condition that might interfere with visual acuity testing at age 12 mo or 4½ y.
12. Child was not able to return to IATS clinical center for regular follow-up examinations.

### Table 2. Baseline Characteristics of IATS Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CL  (n=57)</th>
<th>IOL  (n=57)</th>
<th>Total (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at surgery, median (25th-75th percentile)</td>
<td>1.8 (1.1-2.1)</td>
<td>1.9 (1.2-2.5)</td>
<td>1.8 (1.2-2.3)</td>
</tr>
<tr>
<td>Category of age at surgery, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-4 wk</td>
<td>26 (45.6)</td>
<td>26 (45.6)</td>
<td>52 (45.6)</td>
</tr>
<tr>
<td>5-6 wk</td>
<td>17 (29.8)</td>
<td>16 (28.1)</td>
<td>33 (28.1)</td>
</tr>
<tr>
<td>7 wk to 3 mo</td>
<td>8 (13.9)</td>
<td>10 (17.5)</td>
<td>18 (16.1)</td>
</tr>
<tr>
<td>3.1 to 5.0 mo</td>
<td>6 (10.5)</td>
<td>7 (12.3)</td>
<td>13 (11.4)</td>
</tr>
<tr>
<td>5.1 to &lt;7 mo</td>
<td>3 (5.2)</td>
<td>4 (7.0)</td>
<td>7 (6.1)</td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>32 (56.1)</td>
<td>31 (54.1)</td>
<td>63 (55.6)</td>
</tr>
<tr>
<td>Race, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>49 (86.6)</td>
<td>48 (84.5)</td>
<td>97 (85.1)</td>
</tr>
<tr>
<td>Black</td>
<td>2 (3.5)</td>
<td>3 (5.3)</td>
<td>5 (4.3)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0.0)</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>9 (15.8)</td>
<td>10 (17.5)</td>
<td>19 (16.7)</td>
</tr>
<tr>
<td>Private insurance, No. (%)</td>
<td>27 (47.4)</td>
<td>22 (39.6)</td>
<td>49 (43.0)</td>
</tr>
<tr>
<td>Qualified for Medicaid, No. (%)</td>
<td>17 (29.8)</td>
<td>22 (39.6)</td>
<td>39 (34.2)</td>
</tr>
<tr>
<td>Pupil diameter, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cataract eye</td>
<td>3.5 (3.0)</td>
<td>3.3 (2.9)</td>
<td>3.4 (3.0)</td>
</tr>
<tr>
<td>Fellow eye</td>
<td>3.5 (3.0)</td>
<td>3.3 (2.9)</td>
<td>3.4 (3.0)</td>
</tr>
<tr>
<td>Corneal diameter, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cataract eye</td>
<td>10.6 (10.7)</td>
<td>10.6 (10.7)</td>
<td>10.6 (10.7)</td>
</tr>
<tr>
<td>Fellow eye</td>
<td>10.8 (10.7)</td>
<td>10.8 (10.7)</td>
<td>10.8 (10.7)</td>
</tr>
<tr>
<td>IOP, mm Hg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cataract eye</td>
<td>12.7 (4.9)</td>
<td>11.8 (4.9)</td>
<td>12.2 (4.9)</td>
</tr>
<tr>
<td>Fellow eye</td>
<td>12.9 (4.9)</td>
<td>12.9 (4.9)</td>
<td>12.9 (4.9)</td>
</tr>
<tr>
<td>Keratometry, D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cataract eye</td>
<td>46.4 (2.7)</td>
<td>46.4 (2.7)</td>
<td>46.4 (2.7)</td>
</tr>
<tr>
<td>Fellow eye</td>
<td>45.5 (2.9)</td>
<td>45.4 (1.9)</td>
<td>45.5 (1.9)</td>
</tr>
<tr>
<td>Axial length, mm</td>
<td>0.1 (0.1)</td>
<td>0.1 (0.1)</td>
<td>0.1 (0.1)</td>
</tr>
<tr>
<td>Cataract eye</td>
<td>0.1 (0.1)</td>
<td>0.1 (0.1)</td>
<td>0.1 (0.1)</td>
</tr>
<tr>
<td>Fellow eye</td>
<td>0.1 (0.1)</td>
<td>0.1 (0.1)</td>
<td>0.1 (0.1)</td>
</tr>
<tr>
<td>Refraction error of fellow eye, D</td>
<td>2.4 (1.9)</td>
<td>2.3 (2.2)</td>
<td>2.3 (2.2)</td>
</tr>
</tbody>
</table>

Abbreviations: EUA, examination under anesthesia; IATS, Infant Aphakia Treatment Study; PVP, persistent vitreous detachment.

**Notes:**
- Unless otherwise indicated, data are expressed as mean (SD).
- Considered part of the white matter group.
• The Infant Aphakia Treatment Study: Further on intra- and postoperative complications in the intraocular lens group. JAAPOS. 2015 April; 19(2):101-103.

• No significant difference in VA in infants with unilateral congenital cataract <7 months

• Significant more intraoperative and postoperative adverse events

• Was post-op steroid application enough?
  – Initially suggested to use QID, most some went up to 6x/day for 4 weeks
  – Others used subconj injection of steroids
  – No difference in adverse events between the two groups (pupillary membranes)

• What’s the prevalence of glaucoma and did it increase with ciliary sulcus fixation IOL
  – 11/57 19% in IOL and 9/57 in CL that develop glaucoma
  – Does not increase

• “In conclusion, we maintain that most children with a unilateral congenital cataract should be left aphakic and treated with a contact lens until the family and surgeon decide that secondary IOL implantation is indicated. However, when family circumstances make primary IOL implantation a better option, we recommend that these surgeries be performed by experienced infant cataract surgeons given the high rate of intraoperative and postoperative adverse events associated with this surgical procedure.”
### Table 2

Number of Patients with Postoperative Adverse Events by Treatment Group

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CL (57 Patients)</td>
<td>IOL (57 Patients)</td>
</tr>
<tr>
<td>Lens Reprolifiation into Visual Axis</td>
<td>2 (4%)</td>
<td>23 (40%)</td>
</tr>
<tr>
<td>Pupillary Membrane</td>
<td>2 (4%)</td>
<td>16 (28%)</td>
</tr>
<tr>
<td>Corectopia</td>
<td>1 (2%)</td>
<td>16 (28%)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>9 (16%)</td>
<td>11 (19%)</td>
</tr>
<tr>
<td>Glaucoma Suspect</td>
<td>11 (19%)</td>
<td>5 (9%)</td>
</tr>
<tr>
<td>Contact Lens Related Adverse Events</td>
<td>10 (18%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Vitreous Hemorrhage</td>
<td>2 (4%)</td>
<td>5 (9%)</td>
</tr>
<tr>
<td>Retinal Hemorrhage</td>
<td>2 (4%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Hyphema</td>
<td>1 (2%)</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>Retained Cortex</td>
<td>2 (4%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Retinal Detachment</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Endophthalmitis</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Pathosis Bulbi</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Corneal Edema &gt;30 days</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Wound Leak / Dehiscence</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>IOL Capture</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>At Least 1 Adverse Event</td>
<td>32 (56%)</td>
<td>46 (81%)</td>
</tr>
</tbody>
</table>

### Table 3

Number of Patients with Additional Intraocular Surgical Procedures By Treatment Group

<table>
<thead>
<tr>
<th>Type of Surgical Procedure</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CL (57 Patients)</td>
</tr>
<tr>
<td>Clearing Visual Axis Opacities</td>
<td>8 (14%)</td>
</tr>
<tr>
<td>Glaucoma Surgery</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Repair Retinal Detachment</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Repair Wound Dehiscence</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>IOL Exchange</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Indecatomy / Indotony</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Lysis of Vitreous Wicks</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Secondary IOL</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>At Least 1 Surgical Procedure</td>
<td>12 (21%)</td>
</tr>
</tbody>
</table>

*Multiple surgical procedures could have been done during the same episode. Examinations under anesthesia only or strabismus surgery only are not included.*

To see if IOL implantation prevent strabismus from developing, less frequently

112 children- 91 had strabismus

- 56 had esotropia of 2-70 PD
- 30 had exotropia of 3-50PD

Similar percentage of patients in CL and IOL group (86% vs 77%)

Esotropia more common than exotropia 2:1

Better VA in operated eye and higher levels of stereopsis associated with lower rates of strabismus

### Table 1. Double alignment by 5 years of age

<table>
<thead>
<tr>
<th>Distribution</th>
<th>n (%)</th>
<th>Tilted</th>
<th>Prism</th>
<th>Intermittent</th>
<th>Constant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esotropia</td>
<td>112 (7)</td>
<td>7 (7)</td>
<td>0</td>
<td>1 (1)</td>
<td>110 (99)</td>
</tr>
<tr>
<td>Exotropia</td>
<td>30 (7)</td>
<td>1 (3)</td>
<td>0</td>
<td>0 (0)</td>
<td>30 (100)</td>
</tr>
<tr>
<td>Pure hypertropia</td>
<td>0 (0)</td>
<td>0</td>
<td>0</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

### Table 2. Double alignment at distance versus by age 5 years

<table>
<thead>
<tr>
<th>Distribution</th>
<th>n (%)</th>
<th>Distance 15 cm</th>
<th>Distance 50 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esotropia</td>
<td>112 (7)</td>
<td>7 (7)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Exotropia</td>
<td>30 (7)</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pure hypertropia</td>
<td>0 (0)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### Table 3. Ophthalmic referral to visual acuity by age 5 years

<table>
<thead>
<tr>
<th>Visual acuity</th>
<th>Referral to Ophthalmic Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.30-0.40</td>
<td>5/12 (42%)</td>
</tr>
<tr>
<td>0.15-0.20</td>
<td>5/12 (42%)</td>
</tr>
<tr>
<td>0.05-0.15</td>
<td>5/12 (42%)</td>
</tr>
<tr>
<td>0.00-0.05</td>
<td>5/12 (42%)</td>
</tr>
</tbody>
</table>

Notes:

- 17% of patients developed strabismus.
- Of the 29 of 114 infants (25%) that had strabismus at enrollment, 19 were boys. 10 of

• At 1 year, no difference in median visual acuity in unilateral congenital cataract and IOL
• 5 fold increase in additional intraocular operations in IOL group- remove visual axis opacities
• 5 fold increase in iris prolapse during cataract surgery in IOL group
• The Infant Aphakia Treatment Study Group. A Randomized Clinical Trial Comparing Contact Lens to Intraocular Lens Correction of Monocular Aphakia during Infancy: HOTV Optotype Acuity at Age 4.5 Years and Clinical Findings at Age 5 years. JAMA Ophthalmol. 2014 June; 132 (6):676-682.

• No significant difference in median visual acuity

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>Treatment</th>
<th>CL (57 patients)</th>
<th>IOL (55 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/20 to &lt; 20/40</td>
<td>13 (23%)</td>
<td>6 (11%)</td>
<td></td>
</tr>
<tr>
<td>20/40 to &lt; 20/80</td>
<td>9 (16%)</td>
<td>14 (25%)</td>
<td></td>
</tr>
<tr>
<td>20/80 to &lt; 20/200</td>
<td>7 (12%)</td>
<td>8 (15%)</td>
<td></td>
</tr>
<tr>
<td>20/200 or worse</td>
<td>28 (49%)</td>
<td>27 (49%)</td>
<td></td>
</tr>
</tbody>
</table>

• No treatment group difference in behavioral functioning as measured by child behavior checklist. Poorer visual acuity associated with more externalizing behavior

• Caregiver stress was strongest predictor of behavioral function

• Poor visual acuity was weakly correlated with behavior

• Congenital cataracts 1.2-6.0 per 10 000 live births
  – Unilateral or bilateral, may be isolated or part of systemic disorder

• 14% of infants with ocular findings that would include them into PFV

• 4% systemic disorder at initial presentation
  – Down’s Syndrome, cerebral atrophy, delayed maturation, conradi-hunermann syndrome

• Unilaterality does not exclude presence of associated vigilance for development of other systemic disorders

• Follow up- systemic disease:
  – Stickler syndrome, pyridoxine-dependent epilepsy, congenital rubella syndrome
  – Prevalence of associated systemic disease is low for unilateral cataract
Russell B. et al. The infant aphakia treatment study contact lens experience to age of 5 years. Eye & Contact Lens 2016; 0:1-6.

- 114 patients \( \rightarrow \) 57 CL treatment for aphakia
  - 57: 2 had nonamblyopic NLP or LP vision after surgery, so no optical correction
  - 3 received IOL between ages 1-5
  - 52
    - 24 SE (46%)
    - 11 GP (21%)
    - 17 (33%) used a mixture of both at some point in time
  - Only 3 sites fitted GP lenses routinely
  - 37 eyes were first fitted with SE lenses
    - Completing the study
      - 14 in 7.5, 14 in 7.7 and 7 in 7.9, 9 wearing powers \( \leq +20 \)D
      - 2 patients fitted with Cooper Proclear soft lens when \( < +20 \)
      - 3 cases of CL failure, all with SE- needed IOL implantation
        - Caregiver couldn’t do I and R
  - 41 patients wearing SE at one point in time
    - 28 wore for continuous wear (7-21 nights)
    - 6 daily wear basis
    - 3 alternated between daily and continuous wear
    - No documentation for 4 patients
    - GP lenses worn on daily wear basis
- Median age of cataract surgery for CL: 1.8 months (1.1-3.1 months)
  - 32(56%) female and 49 (86%) were white
Median logMAR +0.90 (+0.30 to -1.60)
• SE: +0.70 logMAR (+0.30 to -1.2)
• GP: +2.03 logMAR (+0.20 to -2.28)

**TABLE 1.** Categories of Visual Acuity at 5 Year According to the Type of CL Worn

<table>
<thead>
<tr>
<th>Type of CL Worn, n (%)</th>
<th>Visual Acuity</th>
<th>RGP (n=12)</th>
<th>Silisoft (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/20 or better</td>
<td>20/40 to 20/80</td>
<td>4 (33)</td>
<td>9 (20)</td>
</tr>
<tr>
<td>20/40 to 20/80</td>
<td>0</td>
<td>9 (20)</td>
<td></td>
</tr>
<tr>
<td>20/80 to 20/200</td>
<td>0</td>
<td>7 (16)</td>
<td></td>
</tr>
<tr>
<td>20/200 or worse</td>
<td>8 (67)</td>
<td>6 (13)</td>
<td></td>
</tr>
</tbody>
</table>

*The P value for Fisher's exact test comparing the percentages in the visual acuity categories between the two groups.
LogMAR values for Snellen acuities: +0.00: 20/20; +0.30: 20/40; +0.60: 20/80; +1.00: 20/200.

**TABLE 2.** Mean Central Keratometric Power (D) at 1 and 5 Years of Age for Treated and Fellow Eyes for 46 Patients With Measurements at Both Age 1 and Age 5

<table>
<thead>
<tr>
<th>Age</th>
<th>Treated Eye</th>
<th>Fellow Eye</th>
<th>Difference</th>
<th>P</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>44.5 (1.9)</td>
<td>43.5 (1.5)</td>
<td>1.0 (1.9)</td>
<td>0.001</td>
<td>0.4 to 1.6</td>
</tr>
<tr>
<td>5 years</td>
<td>44.5 (1.7)</td>
<td>43.5 (1.4)</td>
<td>1.0 (1.9)</td>
<td>0.008</td>
<td>0.2 to 1.4</td>
</tr>
<tr>
<td>Change</td>
<td>-0.14 (0.8)</td>
<td>0.06 (1.1)</td>
<td>-0.2 (1.3)</td>
<td>0.29</td>
<td>-0.6 to 0.2</td>
</tr>
</tbody>
</table>

Of the 57 patients randomized to the CL group, there were 46 patients who had K readings at both the age 1 year EUA and the clinical exam at age 5 years. The mean (±SD) age at the age 1 year EUA was 11.0±0.4 months and was 59.9±0.7 months at the age 5 years clinical exam. The mean time between the 2 measurements was 48.9±0.7 months.

Values are mean (standard deviation).

*The P value for the paired t test comparing the means of the treated and fellow eyes. The difference was calculated as (Treated − Fellow).
*The 95% confidence interval (CI) for the difference between the means of the treated and fellow eyes.
*The change was calculated as (Age 5 − Age 1) and therefore negative values indicate a decrease in average central keratometric power.

**TABLE 4.** Keratometric Astigmatism at Ages 1 and 5 Years

<table>
<thead>
<tr>
<th>Age</th>
<th>Measure</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year (n=52)</td>
<td>Astigmatism</td>
<td>1.62 (0.58)</td>
<td>0.00 to 3.00</td>
</tr>
<tr>
<td></td>
<td>Steep Meridian</td>
<td>45.40 (2.54)</td>
<td>42.00 to 51.87</td>
</tr>
<tr>
<td></td>
<td>Flat Meridian</td>
<td>43.78 (2.14)</td>
<td>40.30 to 51.03</td>
</tr>
<tr>
<td>5 years (n=51)</td>
<td>Astigmatism</td>
<td>2.00 (1.00)</td>
<td>0.34 to 4.01</td>
</tr>
<tr>
<td></td>
<td>Steep Meridian</td>
<td>45.34 (3.60)</td>
<td>41.07 to 52.00</td>
</tr>
<tr>
<td></td>
<td>Flat Meridian</td>
<td>43.34 (3.16)</td>
<td>39.02 to 49.78</td>
</tr>
<tr>
<td>Change* (n=46)</td>
<td>Astigmatism</td>
<td>0.40 (1.28)</td>
<td>-3.12 to 5.58</td>
</tr>
</tbody>
</table>

*The change was calculated as Year 5 − Year 1 so that negative values indicate a decrease in astigmatism.
• Average number of lenses needed annually per patient: 10 in year 1; 9 in year 2; 7 in year 3; 5 in years 4 and 5
• SE are the first choice in pediatric CL professionals
  • Ease of fitting
  • High power availability
  • Excellent oxygen permeability
• Standard of 7.5mm (90%)
• Most required refitting at 3 years old due to increased deposit formation requiring more frequent replacements
  • Deposit formation related to lipid composition and lipid thickness changes
  • Increased palpebral fissure size
  • Increased Blink rate
• Evaluating fit of SE lenses
  • Require the application of fluorescein
  • Use of cobalt blue light source
  • Good centration
  • Complete corneal coverage
  • Good fit along limbus for tear exchange
• CL: $25331 and supply cost of $7728
• IOL: $27090 and supply cost of $3204
• Only 3/13 sites did GP fittings and on 12 eyes
• Mean GP BC at baseline: 47.62 +/- 2.62
  • At 12 months: 47.00 +/- 3.50
  • At 5 years: 44.31
• GP fitting requires more time and expertise to fit
• Mean corneal curvature at birth: 47-48.50
  • When globe radius enlarges and corneal curvature flattens to adult ~43

• Adverse Events
  • 13 CL-related adverse events
    • 7 in first post-operative year
    • 1 GP in situ broken GP
    • All SE lenses and overnight wear
  • 6 bacterial keratitis
  • 2 corneal ulcer
  • 3 with recurrent postkeratitis
IATS- Concerns

• Concerns for IOL implantation
  – Higher frequency of postoperative complications

• Concerns for Contact Lens use
  – Poor cooperation with inserting and removing the lenses
  – High cost of contact lenses
  – High rate of lost lenses
  – Difficulty of fitting steep corneas of infants
  – Bacterial keratitis
Silsoft

- Elastofilcon, 0.2% Water, Dk 340.0, Dk/t 71
- Cast molding ASTM D143475 method
- BC: 7.5 (45), 7.7 (43.75), 7.9 (42.75)
- D: 11.30mm
- Powers: +23 to +32 (3D steps)
- Optical Zone: 7.0mm
- Center Thickness: 0.51-0.71mm
Corneal Curvature

Keratometry measurements in preterm and full term newborn infants

R Friling, D Weinberger, I Kremer, R Avisar, L Sirota, M Snir

Corneal Topography of Neonates and Infants

Sherwin J. Isenberg, MD; Madeline Del Signore, RN; Anthony Chen, MD; Jefferey Wei, MD; Peter D. Christenson, PhD

Corneal Curvature and Thickness Development in Premature Infants

Silvana De Silva, MD; Fulvio Parentin, MD; Paola Michieletto, MD; Stefano Pensiero, MD
Silsoft versus RGP

• Pros and cons
  – RGPs customizable to Base Curve and Power
  – Comparing oxygen permeability: DK, DK/T, tear exchange
  – Fitting difficulties
  – Handling difficulties
Fitting Infants with an RGP

- Obtaining a fitting set
  - Or ordering a trial lens from known K values from surgery
- Which lens to start off with
  - Graph of corneal curvature and predictive lens parameters
- Insertion techniques
- Fluorescein staining patterns
  - Adjusting the lens/BC of the lens based off of staining patterns
- Over-retinoscopy to finalize power
  - Find your vertex distance (tape measure)
    - Highly unlikely you will be able to maintain your normal working distance with these infants
Which lens to start off with

Insertion techniques
Insertion

- Place non-dominant hand over child’s forehead
- Pull up on upper lid
- Slide the contact lens underneath the top lid
Removal

• Secure the head with hand in place
• Place one finger on the top lid and pull up at the base of the lashes
• Pull the bottom lid down, maintaining a small amount of pressure the eye
• Gently apply pressure
Insertion and Removal techniques

- Great video resource with Cincinnati Children’s Hospital and Medical Center
  - https://www.cincinnatichildrens.org/health/a/aphakia
  - http://seraph.cchmc.org/MediasiteEX/Play/ddc4055d5667400f91cce0cc547a56e4
Fluorescein staining patterns
Over-retinoscopy to finalize power

- Find your vertex distance (tape measure)
  Highly unlikely you will be able to maintain your normal working distance with these infants
Sample Calculations

– Example: +33 trial lens and you get a +5.00 over-retinoscopy (33cm working distance)
  • +35.00 Lens would be needed to make the infant corrected for infinity/distance
  • However, you would want a +38.00 lens if you wanted to over-correct the infant with a +3.00 near ADD
Adjusting the fit

• Ordering lenses
  – SAM and FAP
  – GOAL: 2.00 to 3.00D of over correction

• GOAL: 2.00 to 3.00D of over correction
  – Decrease over correction as they age
  – By age 2, visual/optical set-up for them to be plano at distance with a +2.50- +3.00ADD
Sample Calculations- Poll Question

- Example: +33 trial lens on a 1 month old aphake and you get a -1.00 over-retinoscopy at (40 cm working distance); and the lens was 1.5D too steep
  
a) +32.00  
b) +33.00  
c) +34.00  
d) All I know is that today is a Saturday
Follow up schedule

- Follow up in 1-2 week after getting new CL
- Follow up in 1 month
- Follow up q3 months until about 2-3 years of age
- Every 4-6 months thereafter
Actual Patient Cases

- Exam information will be displayed
What can my baby see?
### Conversions from Cycles/cm to Snellen Equivalents

<table>
<thead>
<tr>
<th>Cycle/cm</th>
<th>Test Distance</th>
<th>9.5cm</th>
<th>19cm</th>
<th>38cm</th>
<th>55cm</th>
<th>84cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td>20/57</td>
<td>20/40</td>
<td>20/23</td>
<td></td>
<td>20/16</td>
<td>20/11</td>
</tr>
<tr>
<td>26</td>
<td>20/84</td>
<td>20/59</td>
<td>20/33</td>
<td></td>
<td>20/24</td>
<td>20/15</td>
</tr>
<tr>
<td>19</td>
<td>20/110</td>
<td>20/81</td>
<td>20/45</td>
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<td>20/32</td>
<td>20/21</td>
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<tr>
<td>13</td>
<td>20/170</td>
<td>20/120</td>
<td>20/66</td>
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<td>20/44</td>
<td>20/31</td>
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<tr>
<td>9.8</td>
<td>20/220</td>
<td>20/160</td>
<td>20/89</td>
<td></td>
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<td>20/41</td>
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<tr>
<td>6.5</td>
<td>20/340</td>
<td>20/240</td>
<td>20/130</td>
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<td>20/63</td>
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<td>4.8</td>
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<td>20/180</td>
<td></td>
<td>20/130</td>
<td>20/84</td>
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<tr>
<td>3.2</td>
<td>20/680</td>
<td>20/490</td>
<td>20/270</td>
<td></td>
<td>20/190</td>
<td>20/136</td>
</tr>
<tr>
<td>2.4</td>
<td>20/910</td>
<td>20/650</td>
<td>20/360</td>
<td></td>
<td>20/260</td>
<td>20/170</td>
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<tr>
<td>1.6</td>
<td>20/1400</td>
<td>20/970</td>
<td>20/540</td>
<td></td>
<td>20/380</td>
<td>20/250</td>
</tr>
<tr>
<td>1.3</td>
<td>20/1700</td>
<td>20/1200</td>
<td>20/670</td>
<td></td>
<td>20/470</td>
<td>20/310</td>
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<tr>
<td>0.86</td>
<td>20/2500</td>
<td>20/1800</td>
<td>20/1000</td>
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<td>20/470</td>
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<td>20/3300</td>
<td>20/2400</td>
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<td>20/630</td>
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<td>0.43</td>
<td>20/4800</td>
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<td>20/940</td>
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<tr>
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<td>--------------</td>
<td>--------</td>
<td>------</td>
<td>------</td>
<td>------</td>
<td>------</td>
</tr>
</tbody>
</table>
Parting Words

- Infant Aphakia is a very difficult condition to manage
- Lots of time and effort is required at every visit
- Close follow up is needed to ensure correct refractive error
- Patching is critical
- Things change and it’s OK
One size fits all?
What do our kids deserve?
References/Reading Material

- Drews-Botsch CD et al. Predictors of adherence of occlusion therapy three months after cataract extraction in the infant aphakia treatment study. J AAPOS 2012 April; 16 (2):150-155.
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