What Do We Need to Understand to Improve Contact Lens Comfort?

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Disclosure

- Retired from Alcon Laboratories but have no stock or options from Alcon, or stock or options in Novartis.
- Consultant to Alcon Laboratories
- Consultant to NavaBay Pharmaceuticals
- Previously employed by Bausch and Lomb, Wesley-Jessen and Paco Pharmaceutical Services
- Hold Stock in Merck
What is our experience with comfort during Contact Lens wear?

2010
Percent of Dropouts for Comfort/Fit

What is our experience with comfort during Contact Lens wear?

2004
Estimated Rate of US Contact Lens Dropouts-2004

New Contact lens wearers 3.8 million/yr

<table>
<thead>
<tr>
<th>Soft Contact Lens Wearer base</th>
<th>30.2 million (54% &gt; 35 years old)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Lens Dropouts</td>
<td>3.0 million (10%)</td>
</tr>
</tbody>
</table>

Growth of Contact Lens Wearers 2.7% (not counting refits)

Source: AC Nielson Household Panel, Consumer Surveys, Alcon estimates 2004
Who are our patients and what do they wear?

2011
2011 Distribution of Lenses and Wear Schedules

Percent of Wearers

Type of materials fitted

Nichols J, Contact Lenses 2011. Contact Lens Spectrum 1/20/2012; Article ID=106550
Average Age of Fits of Contact Lenses

<table>
<thead>
<tr>
<th>Region</th>
<th>Average Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>31</td>
</tr>
<tr>
<td>US</td>
<td>32</td>
</tr>
<tr>
<td>Canada</td>
<td>33</td>
</tr>
<tr>
<td>UK</td>
<td>34</td>
</tr>
<tr>
<td>Australia</td>
<td>35</td>
</tr>
<tr>
<td>Sweden</td>
<td>37</td>
</tr>
</tbody>
</table>
What have been the approaches to improving comfort?

- Materials design and mechanical properties
- Contact Lens fit
- Cleaning
- Disposability
- Surface/Lens Treatments
- Care Systems
In order to design a product, there must be a way to measure the outcome of the design.
How have we been measuring comfort and are there better ways?

- Comfort Scales
  - Simple 0-5, 0-50, 0-100
  - Anchored with intermediate points defined
Simple Comfort Scales

Measured at instant in time

0 5
Uncomfortable Cannot feel lens
Simple Comfort Scales

Measured at instant in time (1 min)

Uncomfortable

Cannot feel lens

N=6 (12 eyes) each measurement

Simple Comfort Scales

Measured at instant in time (6hrs)

N=6 (12 eyes) each measurement

Simple Comfort Scales

Clinical Data for Lens A

- N=50 patients, 2 weeks of wear

At baseline 32% found lenses comfortable at the end of the day.

After 2 weeks with lens A, 91.5% found the lens to be comfortable.
Interpreting Comfort Data from Contact Lens Wearers

Brennan et al, Dryness and End-of-Day Comfort with Silicone Hydrogel Lenses; TFOS 2007
Interpreting Comfort Data from Contact Lens Wearers

Patient Dropout

E-O-D Comfort

Area of above the curve

Comfort Ceiling

20 points

Brennan et al, Dryness and End-of-Day Comfort with Silicone Hydrogel Lenses; TFOS 2007
What is the minimum difference we can detect with these scales?
What is the minimum difference we can detect with these scales?
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Anchored Comfort Scales

Anchored Comfort Scales

How have we been measuring comfort and are there better ways?

- **Comfort Scales**
  - Simple 0-5, 0-50, 0-100
  - Anchored with intermediate points defined

- **Multiple Scales**
  - Scales to measure a variety of comfort Attributes
Use of Likert Scales

- Measures of responses to specific statements.
- Able to discriminate specific responses.
- Used to understand comfort and other lens wear responses over time.

Examples
- “My lenses feel comfortable all day.”
- “My lenses are moist feel moist from Insertion to Removal.”
- “My lenses are comfortable at the end of the day.”
- My lenses feel fresh

2. Garofalo R. Lemp J. Clinical Trial Experience with Opti-Free PureMoist MPDS. Contact Lens Spectrum Sept 2011;
Likert Measurement Scale

1 2 3 4 5

Strongly Agree  Agree  Neither Agree nor Disagree  Disagree  Strongly disagree
All Patients

Uncontrolled Product Use

N= 9,412

% Agree/Strongly Agree

- All Day Comfort: Baseline 73.6, Two Weeks Use 87.9
- Lenses Moist From Insertion to Removal: Baseline 46.7, Two Weeks Use 78.6
- Comfortable at the end of the Day: Baseline 46.9, Two Weeks Use 76.8

Data on file Alcon Laboratories, Inc.
All Day Comfort
Lenses Moist From Insertion to Removal
Comfortable at the end of the Day

Data on file Alcon Laboratories, Inc.
Asymptomatic SiHy Lens Wearers

Comfort From Insertion To Removal

At the end of a 90 day clinical study when using test product
Patients undecided are not included and data may not equal 100%
Lenses replaced on manufacturer’s recommended schedules

Data on file Alcon Laboratories, Inc.
<table>
<thead>
<tr>
<th>Statement</th>
<th>Asymptomatic Product A v. Control*</th>
<th>Symptomatic Product A v. Control*</th>
<th>Asymptomatic Product B v. Control*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhances lens comfort/comfortably wear lenses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable end of day/all day/long lasting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feel moist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentle on eyes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision clear end of day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insertion comfort</td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Removal comfort</td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Feel fresh</td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Like handling</td>
<td></td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

= No significant difference  + p<0.05

Data on file Alcon Laboratories, Inc.

*Same control in all 3 studies
### Lenses Feel Moist*

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>8-10 hrs</th>
<th>10-12 hrs</th>
<th>12-14 hrs</th>
<th>14-16 hrs</th>
<th>+16 hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.9</td>
<td>2.0</td>
<td>1.8</td>
<td>1.9</td>
<td>1.6</td>
</tr>
<tr>
<td>Agree</td>
<td>2</td>
<td>2.0</td>
<td>1.8</td>
<td>1.9</td>
<td>1.6</td>
</tr>
<tr>
<td>Neither Agree nor Disagree</td>
<td>3</td>
<td>2.0</td>
<td>1.8</td>
<td>1.9</td>
<td>1.6</td>
</tr>
<tr>
<td>Disagree</td>
<td>4</td>
<td>2.0</td>
<td>1.8</td>
<td>1.9</td>
<td>1.6</td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>5</td>
<td>1.9</td>
<td>2.0</td>
<td>1.8</td>
<td>1.9</td>
</tr>
</tbody>
</table>

N=31 N=39 N=68 N=87 N=39

*Response to Likert item:
“When I Use This Solution, My Lenses Feel Moist”

At the end of a 90 day clinical study when using Product B

Data on file Alcon Laboratories, Inc.
Agreement by lens to Likert Statement: “I can Comfortably wear my lenses.” after 90 days

With better measurement systems and technologies, we are making progress providing better lens comfort.

Thank you