Moving beyond current contact lenses for comfortable vision

Mr Nick Dash Optometrist

Owner: Visual Edge Optometrists
Honorary Lecturer: University of Cardiff
CEO: Sports Vision Institute
Nick Dash
Declaration of Association

Advisor to
Adidas Eyewear
Accuvision (Corneal Specialists)
Bausch & Lomb
British Olympic Association
ECB: England and Wales Cricket Board
Moving beyond current contact lenses for comfortable vision

PAST (1970s)

NEXT GENERATION
The Evolution of Soft Contact Lens Materials

- 1508: Da Vinci sketches 
  - Da Vinci sketch of a corneal neutralization concept

- 1823: Astronomer Sir John Herschel creates first written description of a contact lens

- 1880s: First contact lenses produced

- 1936: First corneal lens

- 1948: First hydrogel lens

- 1959: First silicone hydrogel lens

- 1999: First HyperGel (TM)

- 2012: HyperGel (TM)
Hydrogel 1970s

- highly successful due to high water content and increased comfort
- Water loving ~ hydrophilic

<table>
<thead>
<tr>
<th>Corneal Lenses</th>
<th>Hydrogel Lenses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disadvantages</strong></td>
<td><strong>Advantages</strong></td>
</tr>
<tr>
<td>Lack of oxygen permeability</td>
<td>Improved Vision Correction</td>
</tr>
<tr>
<td>Not Comfortable</td>
<td>Increased Comfort</td>
</tr>
<tr>
<td>Not Safe</td>
<td>Increased Health</td>
</tr>
</tbody>
</table>
Silicone Hydrogel 1999

**Expected Advantages over Hydrogel**

- Higher oxygen transmissibility
- Increased Comfort
- Reduced Corneal Infection
- Reduced Hypoxia-Related issues
- Decreased Contact lens wear drop out
Why is Oxygen Important?

- For ECPs, oxygen is often synonymous with ‘health’

- Transmitting oxygen from atmosphere to central anterior cornea helps maintain normal metabolic activity
  - Peripheral cornea gets oxygen from limbal vessels
  - Posterior layers receive oxygen from aqueous humor

- A measure of a CL’s physiologic performance relates to the amount of oxygen reaching the cornea
### Requirements for daily wear

<table>
<thead>
<tr>
<th>Author</th>
<th>Dk/t</th>
<th>Flux</th>
</tr>
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<tbody>
<tr>
<td>Holden and Mertz 1984</td>
<td>24</td>
<td>87%</td>
</tr>
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<td>92%</td>
</tr>
<tr>
<td>Papas 1998</td>
<td>125</td>
<td>98%</td>
</tr>
</tbody>
</table>
Reduction in Hyperaemia with Silicone Hydrogel lenses

Baseline low Dk wear

1 month SiH EW

Images reproduced with permission of the Centre for Contact Lens Research
### Requirements for daily wear

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<td>92%</td>
</tr>
</tbody>
</table>
## Requirements for extended wear

<table>
<thead>
<tr>
<th>Author</th>
<th>Dk/t</th>
<th>Flux</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holden and Mertz 1984</td>
<td>87</td>
<td>92%</td>
</tr>
<tr>
<td>Harvitt and Bonanno 1999 (1)</td>
<td>125</td>
<td>96%</td>
</tr>
</tbody>
</table>
Is Dk/t the most useful measure of O₂ availability to cornea?

There are some widely varying estimates of critical oxygen tension when Dk/t used as measure

Do we see clinical difference in oedema between SiH lenses?

Does Oxygen Flux better model potential movement O₂ into epithelium?
Oxygen Flux

**Table 1. Oxygen transmissibility and flux for a range of representative contact lenses**

<table>
<thead>
<tr>
<th>Lens</th>
<th>Dk/t(^1)</th>
<th>Open eye flux(^2)</th>
<th>% of maximum</th>
<th>Closed eye flux(^2)</th>
<th>% of maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>100µm thick HEMA lens</td>
<td>7.5</td>
<td>3.95</td>
<td>52%</td>
<td>1.50</td>
<td>25%</td>
</tr>
<tr>
<td>Acuvue 2</td>
<td>26</td>
<td>6.65</td>
<td>88%</td>
<td>4.09</td>
<td>68%</td>
</tr>
<tr>
<td>Acuvue Advance</td>
<td>86</td>
<td>7.31</td>
<td>97%</td>
<td>5.55</td>
<td>92%</td>
</tr>
<tr>
<td>PureVision</td>
<td>110</td>
<td>7.37</td>
<td>98%</td>
<td>5.68</td>
<td>94%</td>
</tr>
<tr>
<td>Focus Night &amp; Day</td>
<td>175</td>
<td>7.44</td>
<td>99%</td>
<td>5.84</td>
<td>97%</td>
</tr>
<tr>
<td>No lens</td>
<td>Infinite</td>
<td>7.54</td>
<td>100%</td>
<td>6.04</td>
<td>100%</td>
</tr>
</tbody>
</table>

\(^1\): Manufacturers’ values for -3.00DS lenses. \(^2\): Units are µl cm\(^{-2}\) h\(^{-1}\)

Dk/t is the ability of the lens to allow oxygen to pass through it (units x10\(^{-9}\))

Oxygen flux is an indication of the volume of oxygen that actually reaches the cornea (units of surface area and time)

Morgan & Brennan, 2004  Feb 04Optician
These data are for -3.00Ds lenses Morgan and Brennan 2004.
The Success of Silicone Hydrogel

- Silicone Hydrogel lenses have become the lens type of choice for:

SiHy lenses represent about 3 out of every 4 new fits in the U.S.
Challenges with Current Materials

The science behind incorporating silicone into contact lenses was based on increasing oxygen transmissibility.

- Are all patients benefiting from this addition of silicone?
  - Silicone hydrogels aren’t for everyone
  - Challenges exist just as they do for hydrogel lenses
  - Number wearers remains the same
Non-oxygen related clinical observations

- Infection
- Inflammation
- Corneal staining
- Discomfort
  - Modulus
  - Design
  - Lubricity
Silicone Hydrogel = Success

- Total number of contact lens wearers remains relatively unchanged
- Are SiHy lenses the answer?
- No growth in Overall Market
- Down grading Si content in major lens
  - The Dk/t value for Narafilcon A (Europe) is 118.
  - Dk/t value of Narafilcon B TrueEye (USA) 65.
UK contact lens penetration with little year on year growth, while drop out rates also remaining largely unchanged

- Contact lens drop out rates remain largely unchanged at c.10% per annum over a similar time frame
Contact Lens Drop-outs

Kids (6-12)  Teens (13-17)  Young Adults (18-30)  Adults (31-44)  Older Adults (45-64)  Seniors (65+)

35%  45%  54%  76%

% VC

2.1%  3.0%  3.1%  5.1%

% CL Users

2.1% of 838K  3.0% of 1053K  3.1% of 640K

Annual Dropout Rate (% of user base - US, EU)

Discomfort is, by far, the single primary reason for drop-out among new fits, i.e. those who wore contacts for 1 year or less (52%, vs. 28% among those who wore 5+ years).

Convenience issues contribute disproportionately to drop out in the first five years of wear (55% vs. 37% among those wearing 5+ years).
Recent research suggests drop out rates as high as 30.4%

Most common reason more than 50% is comfort and visual comfort

66% of wearers have concerns about comfort, 23% suggest it is a major concern

SiH has failed to grow the market

56% of drop outs had not sought any further advice from their ECP (Naroo et al)
$500 Million Invested in CL Research

Current Materials Fail to Address all our patients needs
What percent of patients report suffering from glare or halos?

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halo</td>
<td>34%</td>
</tr>
<tr>
<td>Glare</td>
<td>53%</td>
</tr>
<tr>
<td>Tired eyes</td>
<td>69%</td>
</tr>
<tr>
<td>Sensitive eyes</td>
<td>36%</td>
</tr>
<tr>
<td>Itchy eyes</td>
<td>40%</td>
</tr>
<tr>
<td>Dry eyes</td>
<td>38%</td>
</tr>
<tr>
<td>Eye strain</td>
<td>58%</td>
</tr>
<tr>
<td>Red eyes</td>
<td>33%</td>
</tr>
<tr>
<td>Puffy or swollen eyes</td>
<td>22%</td>
</tr>
<tr>
<td>Pain inside your eyes</td>
<td>19%</td>
</tr>
<tr>
<td>Headaches after near work</td>
<td>29%</td>
</tr>
<tr>
<td>Blurry or hazy vision</td>
<td>39%</td>
</tr>
<tr>
<td>Watery eyes</td>
<td>27%</td>
</tr>
<tr>
<td>Burning sensation in the eyes</td>
<td>19%</td>
</tr>
</tbody>
</table>
Spherical aberration and image quality

- Spherical aberration is the inability of the eye to focus light rays passing simultaneously through the center and the periphery of the eye.
- The retinal image appears blurred because the peripheral light rays are focused anterior to the retina.
- Spherical aberration can be a barrier to high-quality vision in low light, resulting in blurred vision, halos and glare.
SCL Materials and Optical Quality

- Dependent on
  - Surface quality after hydration and during dehydration
  - Shape regularity after hydration during dehydration
- Dehydration and blurred images
- Visual Comfort
What factors contribute to dehydration and “Dehydration Blur”?

Individual Factors
- Decreased oxygen transmission
- Tighter fitting lenses
- Change in lens power
- Increased surface deposits

Environmental Factors

Lens Factors

Dehydration Blur
Even with all the recent advances in contact lenses, significant unarticulated comfort and vision challenges persist.

The phenomena of dry and tired eyes and blurry vision, in particular, results in a significant increase of awareness – highlighting key hidden needs.
Result is a negative impact on the lens wearing experience.

lenses fail to deliver comfortable vision

Symptom Impact on Wearing Experience

Negative Impact on Wearing Experience (% Agree)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>% Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Eyes</td>
<td>71%</td>
</tr>
<tr>
<td>Blurry Vision</td>
<td>70%</td>
</tr>
<tr>
<td>Tired Eyes</td>
<td>65%</td>
</tr>
<tr>
<td>Itchy Eyes</td>
<td>63%</td>
</tr>
<tr>
<td>Sensitive Eyes</td>
<td>60%</td>
</tr>
<tr>
<td>Glare</td>
<td>56%</td>
</tr>
<tr>
<td>Halos</td>
<td>55%</td>
</tr>
<tr>
<td>Red Eyes</td>
<td>52%</td>
</tr>
<tr>
<td>Watery Eyes</td>
<td>49%</td>
</tr>
</tbody>
</table>

Negative Impact on Comfort (% Agree)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>% Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Eyes</td>
<td>79%</td>
</tr>
<tr>
<td>Tired Eyes</td>
<td>71%</td>
</tr>
<tr>
<td>Blurry Vision</td>
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<td>Watery eyes</td>
<td>52%</td>
</tr>
<tr>
<td>Red Eyes</td>
<td>52%</td>
</tr>
<tr>
<td>Glare</td>
<td>49%</td>
</tr>
<tr>
<td>Halos</td>
<td>47%</td>
</tr>
</tbody>
</table>
Very strong patient responses to the leading conditions

**Symptom Feeling/Association**

- **How do Dry Eyes make you feel?**
  - Frustrated, annoyed, irritated, tired, uncomfortable
  - Need, want, dry, drops, upset, contacts, take-out-contacts

- **How does Blurry vision make you feel?**
  - Frustrated, tired, uncomfortable
  - Feel, need, nervous, eyes, take-out-contacts

- **How do Tired Eyes make you feel?**
  - Tired, uncomfortable, sleepy, want, eyes
  - Exhausted, close, need, headache

Wearers express strong physical and emotional associations.
High correlation between symptoms, which can negatively impact the CL wearing experience...

- Dryness
- Symptoms
- Tired Eyes
- Blurry Vision
Accumulation of symptoms throughout the day

TIME OF SYMPTOM OCCURRENCE POST PROMPTED

(Percentage)

when waking
Baseline
in the morning
4 hours
at noon
8 hours
in the afternoon
12 hours
in the evening
16 hours

| blur | tired eye | dry eye |
Are your lens-wearing patients as satisfied as you think?

What can be done to make a difference?

• Maximize “comfortable vision”
  ➢ provide end-of-day comfort
    ▪ lens hydration
  ➢ provide clear vision
    ▪ correct aberrations
    ▪ no dehydration blur
Factors influencing lens comfort

Material Properties*:
- Modulus
- Water content
- Bound water profile

Lens Design*:
- Edge configuration
- Lens thickness profile
- Back surface design

What about oxygen?
- Requires study that controls material and lens design factors while changing oxygen profile
- Hypoxia paradox

$500 Million Invested in CL Research

Current Materials Fail to Address all our patients needs
Coffee morning with Brian
Beyond Current Contact Lens Materials

Wouldn’t it be great if a daily disposable lens material could be designed in a way that is inspired by the biology of your eyes?

What if we could do all this without adding silicone to the lens?
Bio-inspiration: a discipline that studies and learns from nature’s best ideas to generate breakthrough products and technologies

Blueprints Based on the World Around Us

Blueprints Based on the Eye

*Pseudophakic accommodation and evidence of forward movement as the primary mechanism of action of Crystalens have been demonstrated in multiple studies using objective and subjective methods. (www.crystalens.com)
Mimics actions of the lipid layer of the tear film

- Prevents dehydration, to retain moisture better than the leading daily disposable lens
- Maintains shape
- Maintains consistent optics

4 Twenty-two subjects participated in a randomized, double-masked, contra lateral eye study to evaluate water loss of Biotrue ONEday, 1-Day Acuvue Moist, 1-Day Acuvue TruEye contact lenses. After 4, 8, 12, and 16 hours of wear, lenses were removed and immediately weighed (wet weight). The lenses were then completely dried and reweighed (dry weight). The percent water loss was then calculated for each lens from the wet and dry weights.
• Lipid layer of our tear film contains natural surfactants
• A surfactant is added to material formulation, and is an integral part of HyperGel™
• Surfactant is permanently enriched at outer surface during manufacturing process

\[
\text{lens polymer} + \text{ surfactant} \rightarrow \text{HyperGel}^{\text{TM}}
\]
The Next Generation Material

- **The Answer:** HyperGel™ (nesofilcon A)

- The best features of hydrogel lenses (high water & comfort)
- The best features of silicone hydrogel lenses (oxygen the eye needs for healthy daily lens wear)
- Bio-inspired lens that goes beyond hydrogel and silicone hydrogel
Introduction

During the course of lens wear, contact lenses lose water content, which may not only lead to discomfort, but also potentially to reducing retinal image quality through lens surface instability.

Lens surface stability is affected by the magnitude of water loss and the rate of water loss across the lens diameter. Slow and consistent water loss across a lens may help to maintain the shape characteristics that impact lens fit and the optical surface of the lens, which may provide greater visual stability with typical blink rates.

The objective of this study was to understand the lens shape dynamics during off-eye dehydration of one investigational and three commercially available daily disposable contact lenses.

Methods

Four -3.00D power lenses of each product type (etafilcon A, 43%; narafilcon B, 48%; nelfilcon A, 69%; investigational lens, 78%) were allowed to dehydrate in an ambient environment for 20 minutes to observe the physical shape changes over time. All 16 lenses were allowed to dehydrate at the same time. (The average indoor temperature was 72°F with a RH of 30% at the time of the experiment).

Each lens was taken from the package and blotted to remove excess packaging solution. A photo was taken every 2 minutes over the 20 minute period.

Four pair of photos for each lens type (time 0 and time 20 min) were presented to 12 subjects to rate whether the lens shape in image A as compared to image B was similar or different using a 10 point rating scale where 1 corresponded to "Extremely Similar" and 10 corresponded to "Extremely Different".

A one-way ANOVA showed a statistically significant difference (p<0.0001) between the investigational lens (A) compared to nelfilcon A (D), narafilcon B (C) and etafilcon A (B), where the mean rating scores were 1.9, 8.8, 8.4 and 6.8, respectively, indicating that the test lens, after 20 minutes looked "extremely similar" to the time 0 image.

Results

Although changes were happening throughout the 20 minute period, all 3 commercially available contact lens materials showed significant edge "fluting" as a result of lens dehydration at the end of the 20 minute test period, while the investigational contact lens material did not.

Additionally, four pair of photos for each lens type (time 0 and time 20 min) were presented to 12 subjects who rated whether the lens shape of image A compared to image B was similar or different, using a 10 point rating scale where 1 corresponded to "Extremely Similar" and 10 corresponded to "Extremely Different".

A one-way ANOVA showed a statistically significant difference (p<0.0001) between the investigational lens (A) compared to nelfilcon A (D), narafilcon B (C) and etafilcon A (B), where the mean rating scores were 1.9, 8.8, 8.4 and 6.8, respectively, indicating that the test lens, after 20 minutes looked "extremely similar" to the time 0 image.

Traditional clinical literature and belief suggests that higher water content lenses dehydrate more than lower water content lenses. In this study, the highest water content lens material demonstrated a more consistent lens shape over the 20 minute dehydration period compared to narafilcon B, 48%; nelfilcon A, 69%; and etafilcon A, 43% lenses, suggesting that the investigational material may have unique properties relative to water content retention. Further research is warranted to understand the impact of dehydration driven lens shape change on vision, comfort and fitting performance in-vivo.
Dehydration and Lens Shape Change

- **Methodology:**
  - Laboratory experiment
  - Ambient room conditions
  - Images captured every 2 minutes

- **Gross Shape change:**
  - Diameter
  - Edge scalloping

- nesofilcon A
  - 78% water content
  - Images at 0 mins and 20 mins

- etafilcon A
  - 43% water content
  - Images at 0 mins and 20 mins

- narafilcon B
  - 48% water content
  - Images at 0 mins and 20 mins

- nelfilcon A
  - 69% water content
  - Images at 0 mins and 20 mins
In-vivo Dehydration

Retain moisture and shape\(^6\)

Maximum moisture on the eye\(^5\)

**In vitro** lens shape retention over 20 minutes\(^6\) (laboratory testing)

![Lens shape comparison](image)

**Clinical dehydration comparison after 16 hours of wear**\(^5\)

![Graph showing lens water content](image)

- **1-Day ACUVUE Moist**
  - Water content: 53.1%
  - Water content after 16 hours of wear: 44.6%
- **1-Day ACUVUE TruEye**
  - Water content: 76.4%
  - Water content after 16 hours of wear: 78%

---

5 Twenty-two subjects participated in a randomized, double-masked, contra lateral eye study to evaluate water loss of Biotrue ONEday, 1-Day Acuvue Moist, 1-Day Acuvue TruEye contact lenses. After 4, 8, 12, and 16 hours of wear, lenses were removed and immediately weighed (wet weight). The lenses were then completely dried and reweighed (dry weight). The percent water loss was then calculated for each lens from the wet and dry weights.

6 Results of in vitro study in which Biotrue ONEday, 1-Day Acuvue Moist, Ciba AquaComfort Plus, and 1-Day Acuvue TruEye lenses were allowed to dehydrate under the same ambient conditions of approximately 72°F with a relative humidity of 36%.

Gravimetric weight measurement gathered immediately post removal
Dehydration and desiccation staining: Controlled environment

4 hour trials
Humidity range 5-8%

<table>
<thead>
<tr>
<th></th>
<th>Test Lens</th>
<th>Test Lens Max</th>
<th>1-Acuvue Moist</th>
<th>1-Acuvue Moist Max</th>
<th>TruEye (nara B)</th>
<th>TruEye (nara B) Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>% water loss</td>
<td>1.49</td>
<td>3.1</td>
<td>5.47</td>
<td>11.35</td>
<td>8.47</td>
<td>16.4</td>
</tr>
</tbody>
</table>
Inspired by the biology of the eye...

- The next generation of daily disposable material – HyperGel™
  - Outer surface of the lens is designed to mimic the lipid layer of tear film to prevent dehydration and maintain consistent optics
  - Features the same water content as the cornea, 78%,\(^1\) to support incredible comfort
  - Delivers oxygen level the open eye needs\(^2\) to maintain healthy, white eyes

\(^1\) Bergmanson, Jan, Clinical Ocular Anatomy and Physiology, 14th edition, 2007.
OXYGEN TRANSMISSIBILITY TO THE OPEN EYE

% OXYGEN AVAILABLE TO CORNEA

0 10 20 30 40 50 60 70 80 90 100

Dk/t

26 33 42 65

Ciba Aqua Comfort Plus 1-Day ACUVUE Moist Biotrue ONEday 1-Day ACUVUE TruEye
The Next Generation Material

The Answer: HyperGel™ (nesofilcon A)

- The best features of hydrogel lenses (high water & comfort)
- The best features of silicone hydrogel lenses (oxygen the eye needs for healthy daily lens wear)

Bio-inspired lens that goes beyond hydrogel and silicone hydrogel
Revolutionary Material – HyperGel™
Symptoms and lens dehydration throughout the day

Symptoms vs. lens dehydration throughout wearing time

<table>
<thead>
<tr>
<th>TIME</th>
<th>Symptoms Frequency (%)</th>
<th>Water Loss (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>beginning of wear</td>
<td>Baseline</td>
<td></td>
</tr>
<tr>
<td>in the morning</td>
<td>4 hours</td>
<td></td>
</tr>
<tr>
<td>at noon</td>
<td>8 hours</td>
<td></td>
</tr>
<tr>
<td>in the afternoon</td>
<td>12 hours</td>
<td></td>
</tr>
<tr>
<td>in the evening</td>
<td>16 hours</td>
<td></td>
</tr>
</tbody>
</table>

- **ACUVUE 1-Day Moist**
- **ACUVUE 1-Day TruEye**

Legend:
- | blur | tired eye | dryness |
Biotrue® ONEday…designed to work like the eye to prevent comfort and blurriness issues caused by lens dehydration

Percentage water loss versus Time of Day

- Beginning of wear
- Baseline
- In the morning
- 4 hours
- At noon
- 8 hours
- In the afternoon
- 12 hours
- In the evening
- 16 hours

Water Loss (%)
Twenty-two subjects participated in a randomized, double-masked, contra lateral eye study to evaluate water loss of Biotrue ONEday, 1-Day Acuvue Moist, 1-Day Acuvue TruEye contact lenses. After 4, 8, 12, and 16 hours of wear, lenses were removed and immediately weighed (wet weight). The lenses were then completely dried and reweighed (dry weight). The percent water loss was then calculated for each lens from the wet and dry weights. Gravimetric weight measurement gathered immediately post removal.

Maximum Moisture on the Eye – even after 16 hours

CLINICAL DEHYDRATION COMPARISON AFTER 16 HOURS OF WEAR

<table>
<thead>
<tr>
<th>Lens Type</th>
<th>Water Content (%)</th>
<th>Water Content after 16 hours of wear</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Day ACUVUE Moist</td>
<td>53.1%</td>
<td></td>
</tr>
<tr>
<td>1-Day ACUVUE TruEye</td>
<td>44.6%</td>
<td></td>
</tr>
<tr>
<td>Biotrue ONEday</td>
<td>76.4%</td>
<td></td>
</tr>
</tbody>
</table>

4. Twenty-two subjects participated in a randomized, double-masked, contra lateral eye study to evaluate water loss of Biotrue ONEday, 1-Day Acuvue Moist, 1-Day Acuvue TruEye contact lenses. After 4, 8, 12, and 16 hours of wear, lenses were removed and immediately weighed (wet weight). The lenses were then completely dried and reweighed (dry weight). The percent water loss was then calculated for each lens from the wet and dry weights. Gravimetric weight measurement gathered immediately post removal.
Revolutionary Material – HyperGel™
Thank you