As Sauflon launches the Clariti 1 Day silicone hydrogel daily disposable lens, Howard Griffiths reviews the development and performance of this new product

The first generation silicone hydrogel lenses were designed for monthly continuous wear and when this modality did not take off they were then adapted for daily wear. Although these lenses provided high levels of oxygen, the materials tended to be stiffer, not as wettable and attracted more deposits than conventional hydrogel lenses.

Since their introduction a decade ago silicone hydrogel lenses have evolved, with the latest generation of materials providing more comfortable contact lens wear. Additionally, improvements in materials and manufacturing techniques have resulted in the launch of daily disposable modalities of these healthier materials.

From the beginning of Sauflon’s research and development programme into silicone hydrogel materials over five years ago the objective had been to produce a silicone hydrogel lens that provided maximum ocular health using a material that is less stiff, less prone to deposits and with a more wettable surface. This approach would clearly improve wearer comfort by allowing Sauflon to include lower levels of silicone monomers in the Clariti formulation.

The level of silicone was optimised to provide a lens with excellent oxygen performance but keeping it low enough so that it did not negatively impact modulus, wettability, water content and therefore comfort of the lens.

In September 2008 after five years of research and development, Sauflon launched Clariti, a monthly disposable, daily wear silicone hydrogel lens with a high water content and low modulus which is sold exclusively to eye care professionals.

Clariti 1 Day

Having developed the monthly silicone hydrogel lens Clariti, the next step for Sauflon was to develop a daily disposable silicone hydrogel lens. It is considered that silicone hydrogel contact lenses are likely to dominate the contact lens market in the years ahead. In some markets, they already account for up to 70 per cent of new spherical (non-daily disposable) contact lens fits however, until recent times, this type of contact lens material has not been available in a daily disposable product. Exceptional oxygen transmissibility, coupled with the improved hygiene expected with a single use product offers distinct advantages over most existing daily disposable contact lens products available.

Major factors in achieving a daily disposable silicone hydrogel lens included the need for a dramatic improvement in yield and of course the development of a high volume process. The base chemistry used for the Clariti lens provided an excellent starting point. For the daily product Sauflon opted for the development of a more rapid curing process, a more efficient extraction and hydration process, with the resultant high yield which is an absolute requirement for daily disposable manufacture.

Utilising the base chemistry of the Clariti lens allowed Sauflon to optimise lens properties that have the greatest influence on comfort such as water content, stiffness and wettability. The changes made to the silicone monomer and the cure cycle yielded a lens with slightly lower water content than the Clariti monthly lens.

Oxygen performance

For over 30 years the best known methods for measuring oxygen performance of contact lenses have been:

● Oxygen permeability (Dk) of the lens materials
● Oxygen transmissibility (Dk/t) of the finished, manufactured lens which takes lens thickness into consideration.

However, the important factor to consider is how much oxygen the cornea requires to maintain normal

![Figure 1 Corneal oxygen consumption vs lens oxygen transmissibility](image-url)
corneal physiology. Holden and Mertz (1984) presented the best known value, suggesting that a lens with a Dk/t of 24.1 would not induce corneal swelling during daily wear. Harvitt and Bonanno (1999) subsequently proposed a value of 35 units to avoid hypoxia through the cornea.

Clearly for overnight wear more oxygen is required and Holden and Mertz found that a lens with Dk/t of 87 would limit overnight corneal swelling to 4 per cent, a value considered equivalent to a non-lens wearer. They also suggested a compromise threshold of 34 units which might induce some additional swelling after overnight wear but would allow the cornea to return to normal thickness soon after waking.

The guru of contact lens oxygen measurement Irving Fatt considered that the Dk/t measure failed to inform how much oxygen actually gets to the cornea. Consequently over the years alternative methods of describing corneal oxygenation have evolved including oxygen flux (oxygen volume reaching cornea during lens wear) and corneal oxygen consumption. Fatt himself advocated using flux as a better measure of corneal oxygenation. More recently, however, corneal oxygen consumption has been considered as a more important factor by researchers such as Professor Noel Brennan. It is considered to be a better index of corneal physiology because it reflects how much oxygen the cornea metabolises.

It can be seen in Figure 1 below that there is a marked flattening off of corneal oxygen consumption as Dk/t increases. In other words we have a situation of diminishing return between increasing Dk/t and the amount of oxygen used by the cornea. In turn this suggests that the difference in percentage oxygen consumption between an eye wearing a lens with Dk/t of 56 and another wearing a lens with a Dk/t of 300 is surprisingly modest.

This relationship does explain why Dk/t was appropriate in the era of low Dk lenses. If we only consider values of Dk/t up to 30 units then the near-linear relationship between oxygenation and Dk/t would mean that doubling transmissibility would account for approximately twice as much oxygen consumed by the cornea. No such relationship exists for lenses of higher oxygen transmissibility.

Although mathematical diffusion models such as those discussed above provide a helpful indicator of the theoretical situation at the cornea during contact lens wear, it is also important to relate this to clinical observations. A good way to achieve this is to consider the presence or absence of hypoxia related clinical signs across a range of lenses, one example here is limbal hyperemia which is known to be an indicator of corneal hypoxia.

In 2004 researchers at Eurolens Research at the University of Manchester performed a masked, controlled study of neophyte subjects in which they evaluated changes in limbal redness during daily wear of contact lenses. They found that limbal redness increased during daily wear of Acuvue 2 lenses by about half a clinical grade compared to baseline whereas there was no change in limbal redness observed in patients wearing Acuvue Advance or Focus Night & Day lenses (Figure 2).

It is important to note that the four-fold difference in peripheral Dk/t between the two silicone hydrogel lenses in this study did not result in a difference in limbal redness. This is presumably because both lenses fall on the flat part of the blue curve in Figure 1. The Clariti 1 Day lens has a Dk of 60 and a Dk/t of 86 (Figure 3). Therefore taking into account that Holden and Mertz (1984) suggested a Dk/t value of 24.1 and the other estimates of oxygen transmissibility to maintain normal corneal physiology during daily (open eye) wear, it is evident that the Clariti 1 Day lens comfortably provides enough oxygen for optimum corneal health.

**Comfort**

One of the most important attributes that patients demand from their contact lenses today is comfort. By making their objective a lens for daily wear Sauflon was able to keep silicone levels in its formulation lower. This in turn allowed for the optimisation of lens properties that have the greatest influence on comfort such as surface wettability, water content and stiffness.

**Surface wettability** – Inclusion of silicone in a lens formulation makes the surface extremely hydrophobic. The first generation silicone hydrogel lenses therefore required some form of surface modification to overcome the hydrophobicity. Bausch & Lomb’s PureVision lenses rely on plasma oxidation to render the surface more hydrophilic. CIBA Vision’s Air Optix Night & Day Aqua and Air Optix Aqua also utilise plasma treatment to yield a continuous hydrophilic surface for their lenses.

J&J was the first company to move away from surface treatment with its
Acuvue Advance and Oasys lenses which rely on an internal wetting agent, Polyvinyl pyrrolidone (PVP).

Sauflon’s Clariti lens does not use any form of surface treatment or wetting agents. Instead a patented process, AquaGen, is used which produces a unique silicone hydrogel lens material with enhanced oxygen permeability and superior levels of wettability and biocompatibility. This is achieved by controlling how the novel silicone and hydrophilic materials are combined at the molecular level to produce a surface with unparalleled biocompatibility and wettability without the need for surface modification, while retaining excellent clarity and low modulus to achieve the uncompromised visual and comfort standards required by the latest generation of SiH lens products.

**Water content** – Patients often cite lens dryness and irritation as reasons for removing lenses earlier in the day and for dropping out of contact lens wear altogether. The Clariti 1 Day lens has a water content of 56 per cent which is comparable to the mid water conventional hydrogel lenses that have been popular and preferred for their comfort for many years prior to the advent of silicone hydrogel lenses. This higher water content provides excellent biocompatibility with the ocular surface.

**Modulus** – Incorporation of silicone makes silicone hydrogel lenses ‘stiffer’ than conventional hydrogel lenses and this rigidity has been implicated in poorer comfort, papillary conjunctivitis and in continuous lens wear superior epithelial arcuate lesions (SEALs). Higher modulus values can also make switching to these lenses from conventional hydrogels more difficult. Clariti 1 Day has one of the lowest modulus values for a silicone hydrogel lens, measuring 0.5 MPa.

**Clinical performance**

To assess the Clariti 1 Day lens clinically it was decided to evaluate its performance against the only other marketed silicone hydrogel daily disposable contact lens (1-Day Acuvue TruEye) and two other market leading daily disposable contact lenses. These were the conventional hydrogel Proclear 1-Day lens and Focus Dailies All Day Comfort lens. The study was conducted by an independent clinical research group as a dispensing, randomised, crossover clinical study where the clinical performance and subjective acceptance of the four lens types were compared at a single study site.

Thirty existing contact lens wearers were recruited and each subject was required to wear all lens types (as pairs) for a one-week study period. Lenses were worn on a daily wear, daily disposable basis; that is, the lenses were worn during the day and discarded at night. Lenses were worn for a minimum of eight hours a day, six days a week. The lenses were also worn for a minimum of two hours before attending for clinical assessment. Subjects were examined for a dispensing visit and a follow-up visit for all four lens types.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TruEye</th>
<th>Proclear 1-Day</th>
<th>Focus Dailies ADC</th>
<th>Clariti 1 Day</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort after insertion</td>
<td>81.7 ± 17.6</td>
<td>82.0 ± 14.8</td>
<td>83.8 ± 15.1</td>
<td>89.6 ± 9.6</td>
<td>0.17</td>
</tr>
<tr>
<td>Comfort before removal</td>
<td>78.0 ± 18.8</td>
<td>73.1 ± 17.5</td>
<td>71.4 ± 20.9</td>
<td>77.4 ± 17.9</td>
<td>0.35</td>
</tr>
<tr>
<td>Ease of insertion</td>
<td>82.3 ± 16.5</td>
<td>81.0 ± 14.3</td>
<td>78.4 ± 15.4</td>
<td>82.9 ± 15.7</td>
<td>0.34</td>
</tr>
<tr>
<td>Ease of removal</td>
<td>90.9 ± 9.5</td>
<td>81.8 ± 16.7</td>
<td>86.2 ± 13.8</td>
<td>93.4 ± 7.8</td>
<td>0.003</td>
</tr>
<tr>
<td>Overall score</td>
<td>81.7 ± 16.8</td>
<td>80.0 ± 12.9</td>
<td>78.3 ± 15.2</td>
<td>81.6 ± 10.6</td>
<td>0.18</td>
</tr>
</tbody>
</table>

**Figure 5** Lens fit at follow up

**Figure 4** High contrast visual acuity

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**Table 2** Lens parameters for a clinical assessment of Clariti 1 Day

<table>
<thead>
<tr>
<th></th>
<th>Lens 1</th>
<th>Lens 2</th>
<th>Lens 3</th>
<th>Lens 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>Clariti 1 day</td>
<td>1-Day Acuvue</td>
<td>Proclear 1-Day</td>
<td>Focus Dailies</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Sauflon</td>
<td>TruEye</td>
<td>1-Day</td>
<td>All Day</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Filcon II 3</td>
<td>Narafilcon A</td>
<td>Omafilcon A</td>
<td>Nelfilcon A</td>
</tr>
<tr>
<td><strong>EWC (%)</strong></td>
<td>56</td>
<td>46</td>
<td>60</td>
<td>69</td>
</tr>
<tr>
<td><strong>BOZR (mm)</strong></td>
<td>8.6</td>
<td>8.5</td>
<td>8.7</td>
<td>8.6</td>
</tr>
<tr>
<td><strong>Diameter (mm)</strong></td>
<td>14.1</td>
<td>14.2</td>
<td>14.2</td>
<td>13.8</td>
</tr>
</tbody>
</table>
Visual acuity
There were no differences between the lenses for visual acuity (Figure 4) at both the dispensing visit (high contrast p = 0.20; low contrast p = 0.62) or the follow-up visit (high contrast p = 0.81; low contrast p = 0.09).

Lens fit
There was no difference between lenses for proportion of optimum fits at the dispensing visit. All four lenses fitted all eyes acceptably at follow up (Figure 5). There were more optimum fits with Clariti 1 Day than with the other three lenses although this difference was not statistically significant.

Subjective scores at dispensing
Differences between the subjective scores at dispensing (Figure 6) were not statistically significant for comfort (p = 0.91), vision (p = 0.75) or overall score (p = 0.86).

Subjective scores at follow-up
At follow-up, subjective scores (Figure 7 and Table 3) were similar for the four lens types except for lens handling evaluations. For lens insertion (Figure 8 and Table 3), scores were significantly higher with the Clariti lens than with the Proclear 1-Day lens and the Focus All Day Comfort lens.

Summary
In terms of ‘days per week’ of wear and ‘hours per day’ and ‘comfortable hours per day’ of wear, there were no differences in wearing patterns between the study lenses.

Visual acuity was good for all lens types and no differences were established between the lenses. Over-refraction and dispensed lens powers were similar for all the study lenses.

All lenses fitted to at least an acceptable level and there were no differences between the lenses in this regard.

Subjective scores were generally high. No differences were established at dispensing. At follow up, lens handling was generally better with the Clariti lens and the 1 Day Acuvue TruEye lens.

Conclusion
With the benefits of exceptional oxygen transmissibility, high levels of patient comfort, added to the improved hygiene expected with a single use product, the Clariti 1 Day lens clearly offers distinct advantages over most existing daily disposable contact lenses available. Due to its performance and market positioning Clariti 1 Day is set to be a very popular lens for the optical practitioner.

References
7 Data on file Sauflon.
8 Howard Griffiths is technical director of Sauflon Pharmaceuticals