



**F**ollowing five years of research and development, in September 2008 Sauflon launched Clariti, a monthly disposable, daily wear silicone hydrogel (SiH) lens. As well as offering the higher oxygen transmissibility achieved by the inclusion of silicone monomers the lens also had a high water content and low modulus. Sauflon's objective during the development process had been to produce a daily wear SiH lens that provided maximum ocular health using a material that was less stiff, less prone to deposits and with a more wetttable surface. This approach would provide improved 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.

Having developed the monthly SiH lens Clariti, the next step for Sauflon was to develop a daily disposable SiH lens. Sauflon recognised that SiH contact lenses were likely to dominate the global contact lens market in the years ahead. In some markets in 2011, SiH lenses already account for up to 97 per cent of new spherical (non-daily disposable) contact lens fits.<sup>1</sup> However, until the last couple of years this type of contact lens material has not been available in a daily disposable product. The exceptional oxygen transmissibility of SiH coupled with the improved hygiene expected with a single use product offers distinct advantages over most existing daily disposable contact lens products, the majority of which still rely on conventional hydrogel materials.

Recognising this, Sauflon launched Clariti 1 Day in autumn 2009. Utilising the base chemistry of the Clariti lens allowed Sauflon to optimise those lens properties that have the greatest influence on comfort such as water content, stiffness and wettability. From this excellent starting point it was able to overcome the challenges of dramatically improving manufacturing yields and of course the development of a high volume process. For the daily product Sauflon opted for more rapid curing and a more efficient extraction and hydration process, with the resultant high yield which is an absolute requirement for daily disposable manufacture.

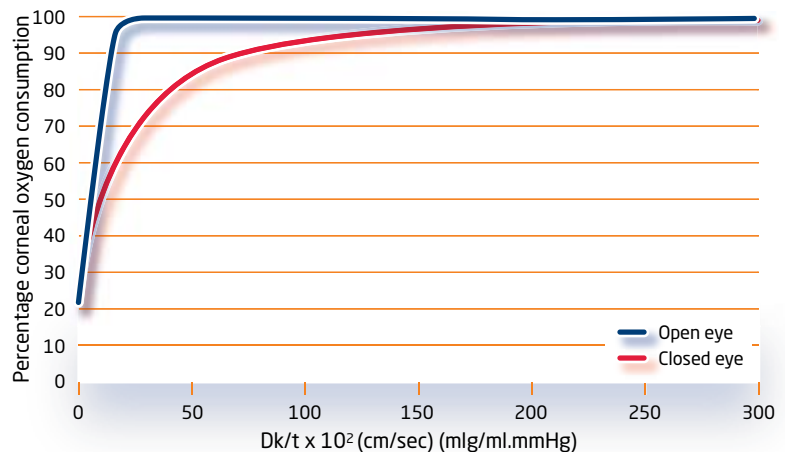
The specifications of the resultant

# World's first SiH daily disposable toric lens

As Sauflon launches the Clariti 1 Day Toric silicone hydrogel daily disposable lens, **Sue Cockayne** and **Howard Griffiths** review the development and clinical performance of this new product

**TABLE 1**  
Specifications for Clariti 1 Day

Material	Filcon II 3 (FDA group II)
Water content	56 per cent
Manufacturing method	Advanced Edge Technology (AET) <sup>®</sup>
Base curve	8.6mm
Diameter	14.1mm
Power range	+8.00 to -10.00 (0.25 & 0.50DS steps)
Modulus	0.5MPa
Centre thickness	0.07mm
Dk/t (at -3.00)	86



**Figure 1** Corneal oxygen consumption vs oxygen transmissibility

lens are detailed in Table 1.

The development, properties and clinical performance of the Clariti 1 Day lens have been discussed previously.<sup>2</sup> This paper reviews the properties, design and clinical performance of the latest introduction to Sauflon's Clariti lens material family – the recently launched Clariti 1 Day Toric lens.

### Oxygen performance

The benefits of the improved oxygen performance of SiH lenses are well understood, with corneal oxygen

consumption now considered as a more important factor by researchers such as Professor Noel Brennan.<sup>3</sup> This parameter is considered to be a better index of corneal physiology because it reflects how much oxygen the cornea metabolises.

This is illustrated in Figure 1 where a marked flattening off of corneal oxygen consumption can be seen as Dk/t increases. In other words, we have a situation of diminishing returns 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 daily wear lens with Dk/t of 56 and another wearing a lens with a Dk/t of 300 is minimal. 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 SiH lenses because they have higher oxygen transmissibility.

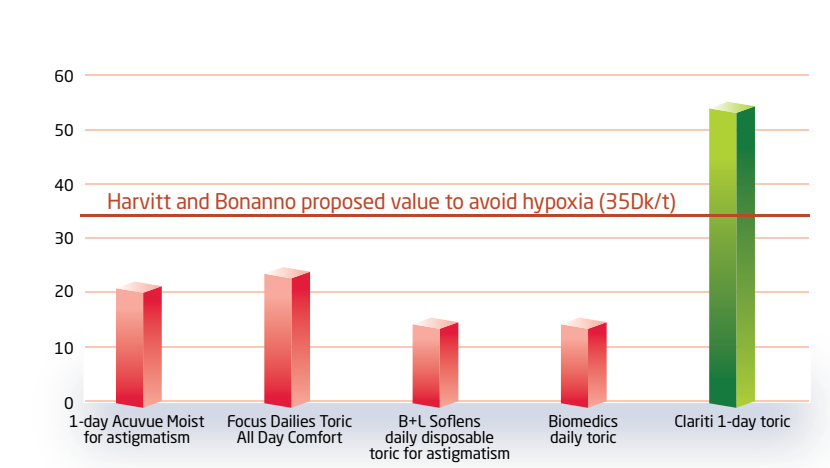
Over the past 30 years there have been several attempts to estimate how much oxygen the cornea requires to maintain normal corneal physiology during daily (open eye) wear. In 1984 Holden and Mertz<sup>4</sup> suggested that a lens with a Dk/t of 24.1 would not induce corneal swelling during daily wear. Later in 1999 Harvitt and Bonanno<sup>5</sup> proposed a value of 35 units to avoid hypoxia through the cornea. The Clariti 1 Day Toric lens has a Dk of 60 and a Dk/t of 57. Comparing these attributes to the required values reported in the literature, it is evident that the Clariti 1 Day Toric lens comfortably provides enough oxygen for optimum corneal health.

## Comfort

One of the most important attributes that patients demand from their contact lenses 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

Sauflon's Clariti family of lenses does not use any form of surface treatment or wetting agents. Instead a patented process, AquaGen, is used which produces a unique SiH material with enhanced oxygen permeability and excellent levels of wettability and biocompatibility. This has been achieved by controlling how the novel silicone and hydrophilic materials are combined at the molecular level. A surface is produced with exceptional 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.



**Figure 2** Dk/t values for a range of daily disposable toric lenses

## 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. Clariti 1 Day Toric 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 SiH lenses. This higher water content provides excellent biocompatibility with the ocular surface.

## Modulus

Incorporation of silicone makes SiH 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 Toric has a low modulus value for a SiH lens, measuring 0.5 MPa.

## Lens design

This new lens benefits from all of the well established Clariti material properties

and the proven toric design first used for Sauflon's Bioclear Toric lens and more recently in the Clariti Toric monthly replacement lens.

The Clariti 1 Day Toric lens utilises a patented manufacturing process. The design was developed by experienced in-house lens designers working with a clinical research group who benchmarked the performance of market leading lenses to ensure the Sauflon lens achieved excellent stability and rotation performance. The final design has the following benefits:

- Back surface toric
- Prismatic front surface featuring a thickness equalising comfort curve
- Comfort chamfer
- Aspheric optics to minimise aberration
- Advanced Edge Technology (AET)
- Blended junctions cut in single pass
- Smooth transition between zones
- Junctionless design
- Constant edge thickness.

## Clinical performance

To assess the Clariti 1 Day Toric lens clinically, its performance was evaluated against two market leading daily disposable toric contact lenses. These

**TABLE 2**

**Lens parameters for a clinical assessment of Clariti 1 Day Toric**

	Lens 1	Lens 2	Lens 3
<b>Name</b>	Clariti 1Day Toric	1-Day Acuvue Moist for Astigmatism	Focus Dailies Toric All Day Comfort
<b>Manufacturer</b>	Sauflon	Johnson & Johnson Vision Care	CIBA Vision
<b>Material</b>	Filcon II 3	Etafilcon A	Nelfilcon A
<b>EWc ( per cent)</b>	56	58	69
<b>BOZR (mm)</b>	8.6	8.5	8.6
<b>Diameter (mm)</b>	14.3	14.5	14.2



were the conventional hydrogel 1-Day Acuvue Moist for Astigmatism and Focus Dailies Toric All Day Comfort lenses (Table 2). The study was conducted by an independent clinical research group<sup>6</sup> as a dispensing, randomised, crossover clinical study where the clinical performance and subjective acceptance of the three 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.

### Wearing patterns

There were no differences between the three lens types in terms of 'days per week' ( $p = 0.72$ ), 'hours per day' of lens use ( $p = 0.11$ ) or 'comfortable hours of wear' ( $p = 0.94$ ).

### Visual acuity

Visual acuity was very good, with the average acuity better than 6/6 for all three lens types. There were no significant differences between the lenses for visual acuity (Figure 3) (high contrast  $p = 0.52$ ; low contrast  $p = 0.15$ ).

### Lens stability – Clariti 1-Day Toric

Lens stability was assessed at 1-minute, 3-minute and 20-minute intervals after application, at 3 minutes all three lenses were within 15° of the ideal settling stability.

**TABLE 3**

#### Clariti 1 Day toric lens specifications

Visual acuity	Toric lens fitting data
Base curve	8.6mm
Diameter	14.3mm
Power range	Plano to -6.00 (0.25D steps) -6.50 to -8.00 (0.50 D steps)
Cylinder options	-0.75, -1.25,
Axis	20°, 70°, 90°, 110°, 160°, 180°
Dk	60
Centre thickness	0.105mm
Dk/t (at -3.00)	57
Water content	56 per cent
Modulus	0.5MPa
UV block	Yes (Class 2 FDA)
Location mark	Single mark at 6 o'clock

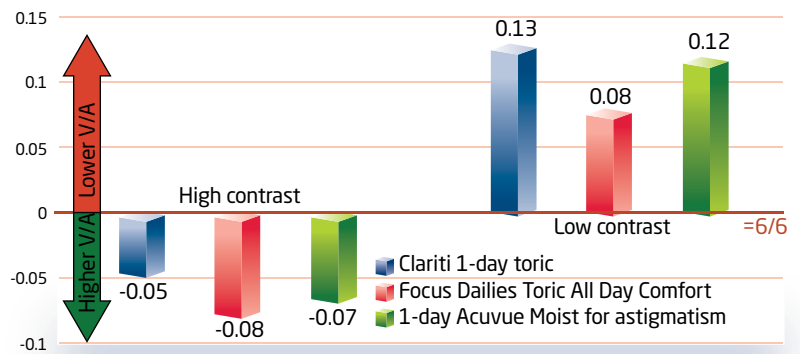
### Lens rotation (toric lens orientation relative to ideal position)

Lens rotation was assessed at 1-minute, 3-minute and 20-minute intervals after application; all lens types showed very good rotation. Clariti 1 Day Toric lenses performed well at each time interval. Twenty minutes after application, all Clariti 1 Day Toric lenses were within 15° of the ideal settling rotation and 84.1 per cent were within 10°. Data is presented in Figures 4 and 5. Clariti 1

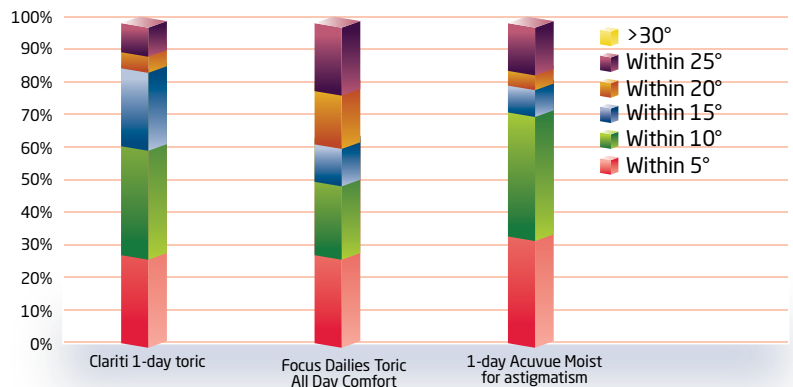
Day Toric also performed best at the one-week follow-up visit with all lenses within 15° of the ideal settling rotation.

### Subjective response

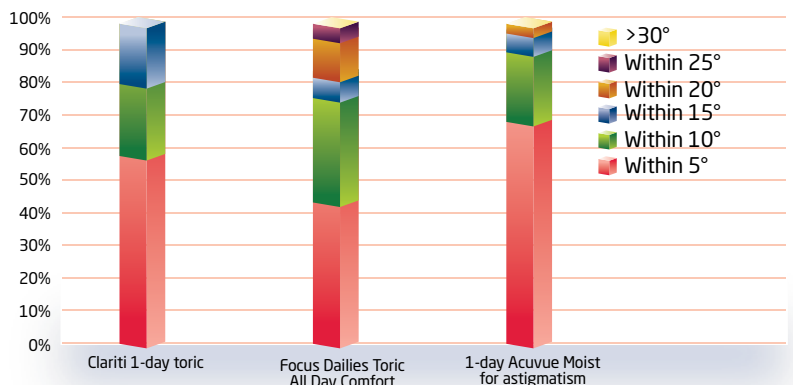
All three lenses scored very high for all subjective responses. The subjective scores for comfort were excellent for the Clariti 1 Day Toric SiH contact lens, particularly when it is taken into consideration that the two comparator lenses are conventional hydrogel lenses. Clariti 1 Day Toric and



**Figure 3** Visual acuity at high and low contrast



**Figure 4** Lens rotation at 1 minute



**Figure 5** Lens rotation at 20 minutes



1-Day Acuvue Moist for Astigmatism performed better than Focus Dailies Toric All Day Comfort lenses for end of day comfort. Overall impression scores were similar for all three lenses. The follow-up subjective scores for comfort are detailed in Figure 6.

## 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.

This toric lens study showed that the toric fitting characteristics were very similar for all three lenses and towards the upper end of performance seen for soft toric lenses. Visual acuity was generally good and better than 6/6 for all lens types and no differences were established between the lenses.

The subjective scores for Comfort were excellent for the Clariti 1 Day Toric

SiH contact lens, particularly when it is taken into consideration that the two comparator lenses are conventional hydrogel lenses.

The Clariti 1 Day Toric lens is available in a power range covering plano to -6.00D in 0.25 dioptre steps and then up to -8.00D in 0.50D steps. There are two cylinder options (-0.75 and -1.25D) and six axes (20°, 70°, 90°, 110°, 160° and 180°). The cylinders and axes being offered for this lens were selected taking into consideration the prevalence of cylinder and axis in astigmatic patients<sup>7</sup> (Figures 7 and 8). It is expected that the range available will cater for a significant proportion of astigmatic refractions. The two lens cylinder powers of 0.75D and 1.25D are considered acceptable for vertex corrected astigmatic refractions within 0.50D, giving coverage for refractions from 0.50 to 1.50D as shown in Figure 7. In terms of the six axes offered, assuming axes are within 10° of spectacle refraction, all but the least prevalent, most oblique are covered.

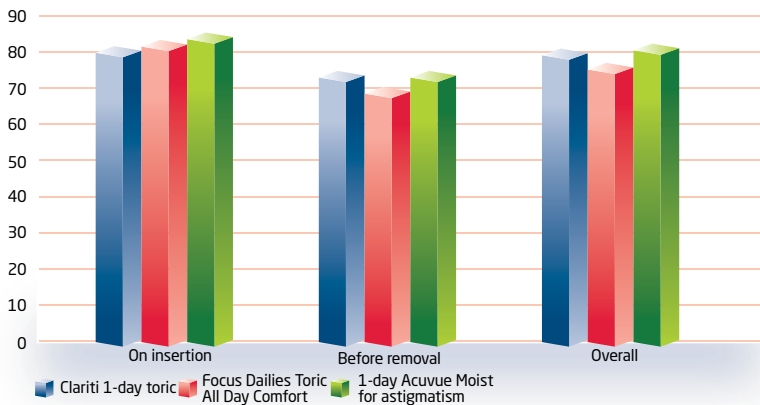


Figure 6 Subjective scores for comfort at follow up

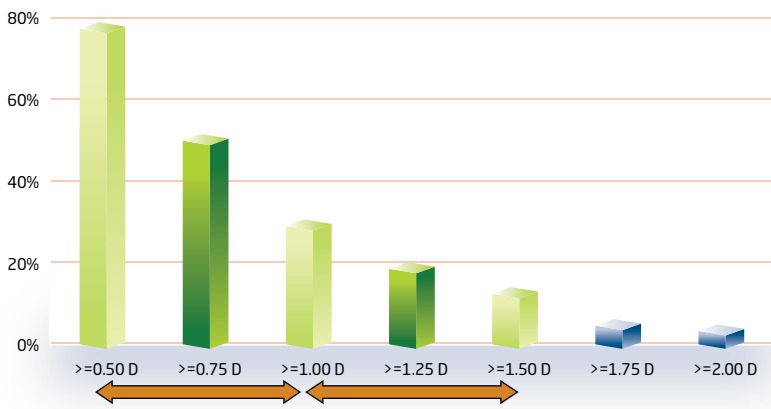


Figure 7 Prevalence of cylinder - proportion of astigmatic patients. Arrows indicate the range of astigmatism correctable by the two Clariti 1-Day Toric cylinder powers shown in darker green

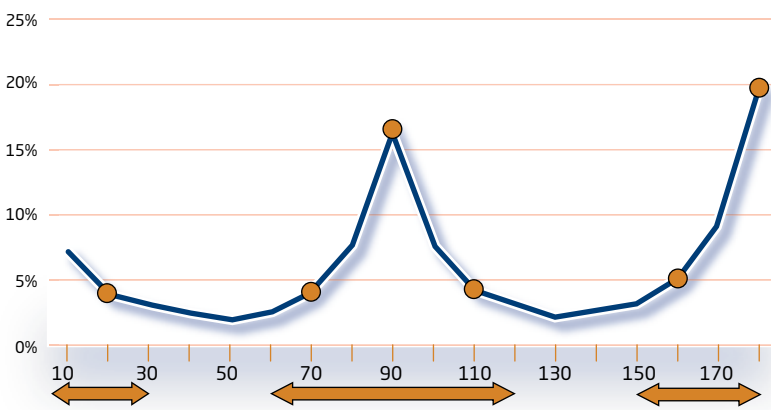


Figure 8 Prevalence of axis - proportion of astigmatic patients. Arrows indicate range of axes correctable by Clariti 1-Day Toric axes (as indicated by the dots)

## 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 Toric lens clearly offers distinct advantages over existing daily disposable toric lenses available. Due to its performance and market positioning Clariti 1 Day Toric is set to be a very popular lens for the eye care professional. ●

## References

- Morgan PB. Personal communication 2011
- Griffiths H. A new silicone hydrogel daily disposable lens. *Optician*, 2009; 238 (6227) 16-19.
- Brennan NA. Beyond flux: total corneal oxygen consumption as an index of corneal oxygenation during contact lens wear. *Optom Vis Sci*, 2005; 82: 467-472.
- Holden B, Mertz G. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. *Invest Ophthalmol Vis Sci*, 1984; 25:1161-1167.
- Harvitt DM, Bonanno JA. Re-evaluation of the oxygen diffusion model for predicting minimum contact lens Dk/t values needed to avoid corneal anoxia. *Optom Vis Sci*, 1999; 76: 712-719.
- Data on file Sauflon.
- Young G. Prevalence of Astigmatism in relation to Soft Contact Lens Fitting. *Eye & Contact Lens*, 2011; 37: (1):20-25.

● Howard Griffiths is technical director and Sue Cockayne professional services manager at Sauflon Pharmaceuticals