A made-to-order silicone hydrogel lens

Professor Lyndon Jones, **Kathy Dumbleton** and **Jill Woods** describe Air Optix Individual, a new silicone hydrogel lens with an enhanced parameter range that should allow practitioners to fit a broader spectrum of patients

The development and commercialisation of silicone hydrogel lenses has offered practitioners a tremendous opportunity to fit their patients with lenses that offer substantially greater degrees of oxygen transmissibility to the cornea than those offered by HEMA-based materials.

To date their clinical performance has been exceptional, and hypoxic complications have been virtually eliminated with this new family of materials.[1-11] However, one disadvantage of the currently available materials (Table 1) is that the lenses are only available in a limited number of parameters. While these parameters are adequate for many patients, there are inevitably occasions where patients who would ideally benefit from the oxygen performance of a silicone hydrogel remain unable to be fitted, due to the available lenses either fitting poorly or being unavailable in the required power.

With these difficulties in mind, CIBA Vision recently introduced Air Optix Individual (Figure 1), the first and only made-to-order silicone hydrogel lens from a worldwide manufacturer of silicone hydrogel lenses. Air Optix Individual offers a silicone hydrogel material in a 'custom-design'. It is offered in a wide range of base curves and diameters and an extensive power range of +20D to -20D (Table 2). While initially limited to a single-vision spherical design, it is envisaged this lens material will eventually be available in extended designs, including torics and multifocals. Made-to-order silicone hydrogel lenses will greatly aid practitioners fitting patients with abnormally small or large, flat or steep eyes and with prescriptions outside the available power range.

Table 3 compares the new lens with the other silicone hydrogel lenses available from CIBA Vision. Several important differences can be seen, along with a number of similarities. What remains unchanged is the aspheric design; the plasma surface treatment, which produces a high refractive index; 25nm-thick plasma coating on the lens surface after manufacturing;[12-14] and that the lens can be used with all available care products. What is novel is the fact that making a lens with such parameter flexibility produces some manufacturing dilemmas. Virtually all spherical frequent replacement lenses made since the early 1990s have been moulded. However, to produce a 'custom-design' lens requires that the lens be manufactured via a lathing process. This has been difficult to achieve, since most silicone-containing polymers are too 'rubbery' to lathe.

Figure 1 Air Optix Individual, the world's first custom-manufactured silicone hydrogel lens

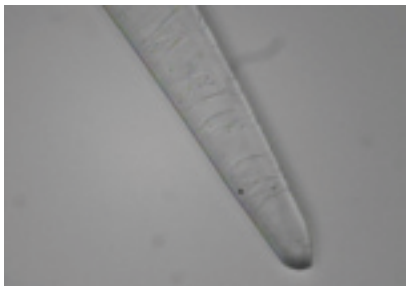

Figure 2 Edge profile for the Air Optix Individual lens, produced by the InnoLathe process

CIBA Vision overcame this problem by developing a unique latheable polymer called sifilcon A, with a water content of 32 per cent and Dk of 82. The lens is manufactured via the InnoLathe process, which produces a rounded edge profile (Figure 2), resulting in very good comfort. The lens has a modulus between that of the existing CIBA Vision silicone hydrogel materials, a light green handling tint and a large font inversion indicator.

Air Optix Individual is initially only available as a daily wear lens, but eventually overnight approval will be sought. Figure 3 compares the central Dk/t for a typical -3.00D lens and Figure 4 compares its water content and modulus with other available silicone hydrogel and conventional HEMA-based materials.

The made-to-order process inevitably results in higher manufacturing costs. The material surface combination for Air Optix Individual has been evaluated for long-term stability and, due to its ability to demonstrate no reduction in surface quality over a three-monthly period, it is replaced on a quarterly basis. It is packaged as either single lenses (for initial fitting purposes) or in packs of two, providing a six-month supply for each eye. In these days of short replacement periods, three months may seem a long time interval for lenses to be worn. However, silicone hydrogels deposit minimal levels of protein[15-17] and acceptable levels of lipid[18] and to date (in trials and following its launch in the US) there are no reports of significant visible lens deposition throughout the three-month lens life.

The fitting process is somewhat different to that used with most modern contact lenses, in that trial fitting sets will not be made available and the lens will be fitted empirically. This may seem daunting to the practitioner who has spent decades using trial lenses before ordering lenses for patients, but there is a fitting guide available to help the decision process. Practitioners are also welcome to call CIBA Vision technical consultancy on 01489 775 533 with the spectacle prescription, horizontal visible iris diameter (HVID) and keratometry readings for fitting advice. The diameter chosen for the trial lens must be at least 2mm larger than the HVID, the back vertex power is ordered as the vertex corrected spectacle lens power and the initial base ▶

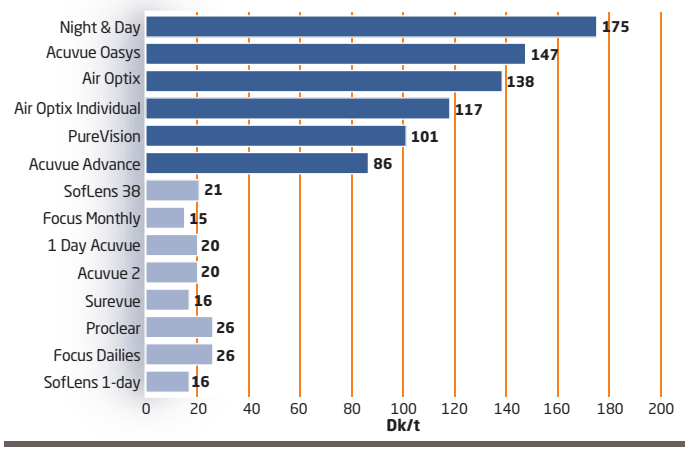

Figure 3 Oxygen transmissibility (Dk/t) for a variety of silicone hydrogel (dark blue bars) and conventional HEMA-based lenses (light blue bars), with values given for the central Dk/t at -3.00D

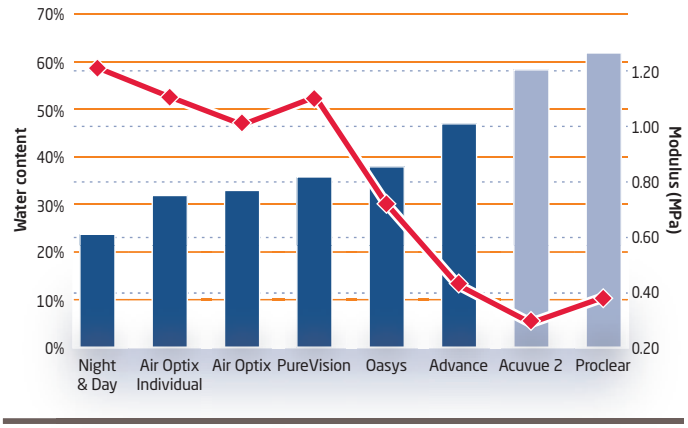

Figure 4 Comparison of water content (dark blue bars for silicone hydrogels and light blue bars for HEMA-based materials) versus water content (red line), showing the relatively tight relationship between increasing water content and reducing modulus

TABLE 1
Available parameters for current silicone hydrogel lenses

Material	No of diameters	No of base curves	Rx range D
PureVision	1	1	+6.00 to -12.00
Acuvue Advance	1	2	+8.00 to -12.00
Air Optix Night & Day	1	2	+6.00 to -10.00
Air Optix	1	1	+6.00 to -10.00
Acuvue Oasys	1	1	+8.00 to -12.00
Biofinity	1	1	-0.75 to -6.00

TABLE 2
Initially available parameters for Air Optix Individual

Diameter	Base curves
13.2	7.4, 7.7, 8.0, 8.3
14.0	7.8, 8.1, 8.4, 8.7, 9.0
14.8	8.0, 8.3, 8.6, 8.9, 9.2

curve selected is decided from a table in the fitting guide provided (Table 4). The rigidity of the lens material/design allows reasonable masking of corneal cylinders and surprisingly good visual acuity has been recorded with corneal cylinders up to 1.25D.

Once the base curve, diameter and power have been decided, a pair of lenses (packaged as single lenses) is ordered from CIBA Vision, and used for the first three months, if fitting is acceptable. On receipt of these first lenses the subject returns for a fitting evaluation. Practitioners can feel confident that the lens fitting characteristics observed within 20 minutes of insertion in the consulting room remain constant throughout the lifespan of the lens. If the first lens fits appropriately and the visual acuity and over-refraction is acceptable then the patient is dispensed with the lens for a period of time. It may be prudent for this extended trial to last two to three weeks, because, as in many instances where patients are refitted into silicone hydrogel lenses, there may be a short period of adaptation before the patient reports equivalent or superior comfort to their previous, low oxygen permeability lenses. This

TABLE 3
Comparison of Air Optix Individual with other CIBA Vision SH lenses

Product Details	Air Optix	Air Optix Night & Day	Air Optix Individual
Material	lotrafilcon B	lotrafilcon A	sifilcon A
Water content	33%	24%	32%
Dk & Dk/t @ -3.00D	110 & 138	140 & 175	82 & 117
Surface treatment	Permanent plasma surface treatment	Permanent plasma surface treatment	Permanent plasma surface treatment
Modulus	1.0 MPa	1.2 MPa	1.1 MPa
Handling tint	Light blue	None	Light green
Wearing schedule	DW and EW up to 6N	DW and CW up to 30N	DW
Replacement schedule	Monthly	Monthly	Quarterly
Packaging	3 pack	3 pack	1 & 2 pack
Design used	Bi-aspheric	Bi-aspheric	Bi-aspheric
Diameters	14.2	13.8	13.2 / 14.0 / 14.8
Base curves	8.6	8.4, 8.6	7.4 to 9.2
Sphere powers	+6.00D to -10.00D	+6.00D to -10.00D	+20.00D to -20.00D
Centre thickness	0.08 @ -3.00D	0.08 @ -3.00D	0.07 @ -3.00D
Manufacturing process	Cast mould	Cast mould	Lathe cut
Recommended lens care	Peroxide or MPS	Peroxide or MPS	Peroxide or MPS

may be due to the increased lens rigidity, change in surface properties from their habitual lens or due to the rapid oxygenation of the cornea, resulting in hypoxic rehabilitation.

Many of the patients fitted with these lenses are likely to have been wearing low oxygen-permeable materials for many years and typically exhibit chronic hypoxic signs, such as neovascularisation, polymegethism and pleomorphism, and chronic oedema. In addition, chronic hypoxia also results in a degree of 'myopic creep', with a corresponding increase in the degree of myopic prescription, which may well reduce once they are refitted into a silicone hydrogel material.[4,19]

Patients can be dispensed with any of the currently available care regimens, but CIBA Vision recommends either AOSept Plus – as first choice – or Focus Aqua.

After the extended trial period, the patient returns for an evaluation of the lens fit and performance. A careful evaluation of the visual acuity and over-refraction must be undertaken to look at whether any prescription changes have occurred and a slit-lamp examination must also be performed. Particular factors to look for include the presence of any microcysts, which may be increased initially when refitting patients into silicone hydrogels as any chronic hypoxia subsides,[11] regression of neovascularisation[2,3] and any epithelial staining due to solution incompatibility.[20,21]

On completion of this visit any minor alterations to the lens parameters can be decided upon. If a large alteration is required then a replacement pair of lenses can be ordered and the fitting process repeated. If only a small change is needed (as occurs in most instances) then a two-pack of lenses for each eye can be ordered, which will provide the patient with lenses for six months. The regular replacement of this lens means that it can easily be incorporated into the regular direct debit payment method, which has become very popular with disposable lens wearers and practitioners alike.

In summary, Air Optix Individual will allow those patients who have previously been excluded from the silicone hydrogel lens market to experience this new generation of contact lenses. It will also provide practitioners with an option to use highly oxygen permeable materials for patients who have abnormal topography, including cases such as piggy-back lenses in keratoconus, irregular corneas due to trauma, juvenile aphakia and as bandage lenses in cases which require long-term bandage lens treatment, such as encountered with trichiasis and bullous keratopathy.

TABLE 4
Initial fitting guide

Measured HVID	Recommended diameter	Flat K		
		<7.50mm	7.50-8.05mm	> 8.05mm
<11.00mm	13.2mm	7.7mm	8.0mm	8.3mm
11.0 - 12.0mm	14.0mm	8.1mm	8.4mm	8.7mm
>12.00mm	14.8mm	8.3mm	8.6mm	8.9mm

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