

Comparative clinical evaluation of two silicone hydrogel lenses for daily wear

Guy Whittaker, Karl Aberdeen and John Rogers provide an overview of a comparative evaluation between silicone hydrogel lens performance and older materials and designs

The properties and performance of one of the latest silicone hydrogel (SiH) lenses, Biofinity (CooperVision), was reviewed last month.¹ This highlighted how, as SiH lenses continue to evolve with newer materials and designs, Biofinity offers a new approach with improvements in comfort, wettability and overall performance relative to some older lens materials and designs.

Until recently, few studies have evaluated Biofinity's clinical performance in daily wear. Therefore, the purpose of this most recent study was to evaluate the lens' daily wear performance in existing soft CL wearers, in addition to comparing its clinical performance against another SiH, Air Optix (CIBA Vision).

Method

This was a two-month, single-masked, randomised, bilateral, cross over daily wear evaluation with subjects wearing Biofinity and Air Optix for one month each. The multi-centre study was conducted at seven sites in the UK. Lens details are summarised in Table 1. To prevent bias, subjects were masked to lens type and sponsor and investigators masked to sponsor, although not necessarily lens type since Air Optix incorporates distinctive markings.

Subjects were current CL wearers, although not using either study lens. Spherical refraction was between -0.50D and -6.00D, with astigmatic correction 1.00D or less. Visual acuity (VA) 6/9 or better was required in each eye. They had normal eyes, with no evidence of abnormality or disease. Subjects needed a mobile phone to receive and send text messages during the study.

Subjects were assessed at baseline when details were taken of habitual lens wear (Table 2). They were fitted with a pair of SiHs, with power closest to vertex-corrected spherical spectacle prescription. Lens performance was assessed after 10-15 minutes; a success-

TABLE 1
Lens parameters

	Biofinity	Air Optix
Manufacturer	CooperVision	CIBA Vision
Material, water content	comfilcon A, 48%	lotrafilcon B, 33%
Dk/t (@-3.00D)	160	138
Surface treatment	None	Plasma coating
Modulus (MPa)	0.75	1.00
Wetting angle (sessile drop)	30°	60°
Diameter/base curve (mm)	8.60 / 14.0	8.60 / 14.2
Centre thickness (mm)	0.08	0.08
Study sphere powers (D)	-0.50 to -6.00D (-0.25D steps)	
Recommended replacement period	Monthly	Monthly (UK)

TABLE 2
Summary of clinical assessments

	Grading	Fitting and dispense	Follow-ups
Monoc. HCDVA with best vision sphere	Snellen to nearest letter	X	X
Subjective visual quality	0-100 scale	X	X
Subjective comfort	0-10 scale	X	X
Comfort by SMS text message to subjects mobile phone during 1 month wear	0-10 scale	4 time-points (8am, 12pm, 4pm & 8pm) on 4 days (3, 7, 13 & 27)	
Symptoms (dryness, discomfort, foreign body sensation)	0 - 3 scale (0=none, 3 = severe)		X
Preference	Study vs habitual lens; study 1 vs study 2		X
Lens handling	0-10 scale		X
Deposits: White spot deposits Film deposits	Yes/no 0-4 scale		X
PLTF assessment (Keeler Tearscope Plus): Lipid layer Non-invasive tear break-up time	0-4 scale Seconds		X
Lens fit: Lens Centration Tightness on push-up Overall fit acceptance Post-blink movement	Centred, slightly or substantially decentered % 0-4 scale 0-4	X	X
Slit-lamp examination: Limbal & bulbar hyperaemia Corneal fluorescein staining Conjunctival lissamine green staining Conjunctival lens indentation	0-4 CCLRU scale NEI grading 0-4 CCLRU scale 0-4 scale	-	X

Contact Lens Monthly

ful fit was greater than Grade 2 overall fit acceptance and VA 6/9 or better. Subjects were issued with Opti-Free Express (Alcon) MPDS, along with instructions on text messaging and recording lens comfort. Lenses were worn daily until the next follow-up appointment, and for a minimum of four hours prior to any appointments, which were two and four weeks after dispensing. The second pair of lenses was issued at the one-month follow-up and the process repeated. Lenses were changed when subjects came in for their follow-up visit; if other replacements were required, only the relevant lens was replaced.

Subjects were sent an SMS text message on four separate days after each dispensing at four time-points throughout the day (Table 2), asking them to grade comfort (0-10 scale). The first SMS of each day asked for lens insertion time; the last asked when lenses became uncomfortable. From insertion time and when lenses became uncomfortable, comfortable wearing time was calculated. Comfort responses returned within 1.5 hours of being sent were included in the analysis.

Results

A total of 51 subjects were enrolled; mean age was 33.5 years and 88 per cent were female. Mean high contrast VA with spectacles was -0.02 logMAR (=6/6); mean spherical refraction was -3.02DS and cylinder -0.35DC. Two subjects were discontinued; one with Air Optix after dispensing due to unacceptable comfort and one after two weeks with Biofinity due to lens intolerance.

Habitual contact lenses

A majority of subjects (60 per cent) were existing wearers of mid or high-water hydrogels; the remainder wore SiHs. The most common previous lens types were Proclear (18 per cent), PureVision and Acuvue Advance (both 16 per cent). All lenses were frequently replaced, with the most popular being monthly (59 per cent), followed by daily (24 per cent). Mean habitual lens power was -2.91D.

Wearing time

Mean wearing times (WTs) were 13.7 and 13.6 hours for Biofinity and Air Optix respectively, compared to 12.7 hours with habitual lenses. Mean comfortable WTs were within 1.5 hours of mean WT (12.4 hours with Biofinity and 11.9 hours with Air Optix, at one month); these differences were not statistically significant.

Figure 1
Summary of comfort via SMS text messaging

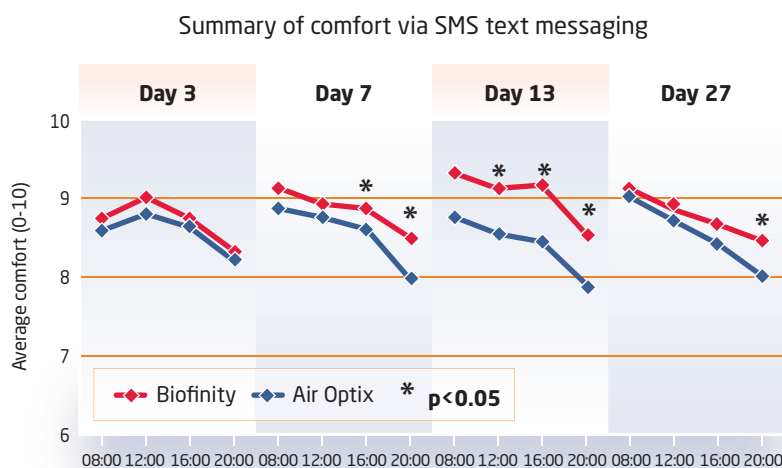
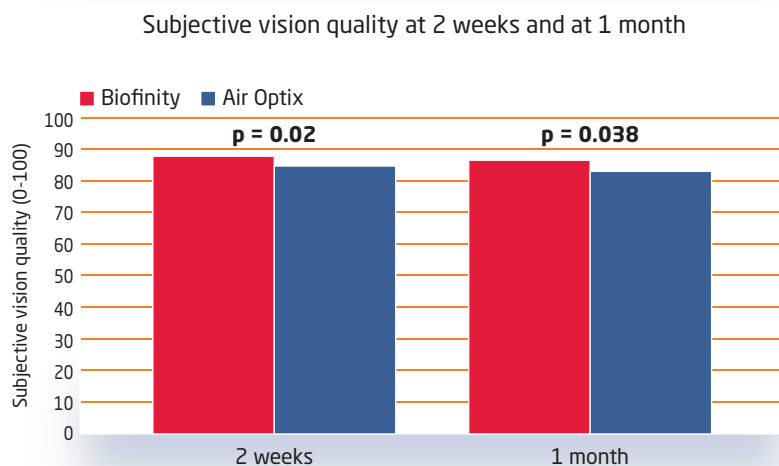


Figure 2
Subjective vision quality at 2 weeks and 1 month



However, when comfortable WT was assessed using SMS results, it was longer for Biofinity on day seven (11.0 vs 8.9 hours, $P=0.01$).

Comfort

Biofinity was rated more comfortable than Air Optix at five of the 16 time points graded with SMS (Figure 1), with differences between lens types ($P<0.0001$) and time of day ($P<0.0001$). End-of-day comfort assessment showed most differences, in particular on days seven, 13 and 27. On day seven, mean comfort scores at 8pm were 8.5 and 8.0 for Biofinity and Air Optix respectively ($P=0.04$). Comfortable WT was also longer with Biofinity on this day (11.0 vs 8.9, $P=0.01$). Mean comfort scores at both follow-up visits were also higher with Biofinity (8.7 vs 8.4 at one month), although this was not statistically significant.

For SMS comfort data, responses were received from 74 per cent of the 1,584 text messages, although the proportion of subjects responding varied depending on time of day and stage of the study. On Day three, response rate was 63 per cent with Biofinity subjects and

73 per cent with Air Optix subjects at 8am; this increased at 8pm to 80 per cent and 78 per cent respectively. On Day 27, response rates at 8am were 69 per cent and 66 per cent for Biofinity and Air Optix respectively, and 73 per cent and 72 per cent at 8pm.

Subjective symptoms

After one month there was more 'discomfort', 'redness' and 'blurred vision' with Air Optix. Discomfort was reported with 15 per cent of Air Optix eyes compared with 8 per cent for Biofinity ($P=0.01$); mild redness affected 7 per cent Air Optix eyes compared with 1 per cent Biofinity ($P=0.03$); blurred vision affected 16 per cent Air Optix eyes compared with 8 per cent Biofinity ($P=0.05$).

Vision performance

Visual performance was similar with the two lenses. Mean VA with Biofinity was significantly higher than with Air Optix; at the one-month visit, there was a difference of two letters in mean logMAR VAs (0.00 and +0.04 for Biofinity and Air Optix respectively). However, there was a significant differ-

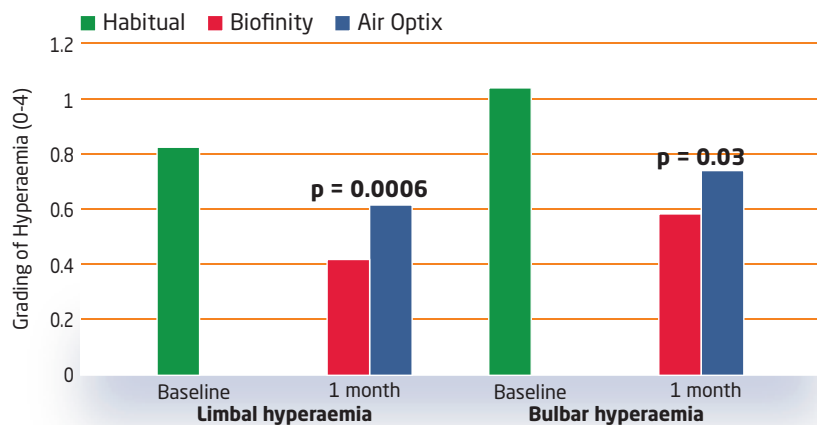


Figure 3 Limbal and bulbar hyperaemia at baseline and 1 month

ence in over-refraction between lenses, where Air Optix wearers needed more minus (mean over-refraction -0.12D vs 0.0D with Biofinity). With the over-refraction in place, there were no differences in VA and normalised VA was within one letter of baseline for both SiHs. Subjective vision quality was graded significantly better with Biofinity at both follow-up visits (Figure 2).

Lens fit and handling

With both lenses, all fits were judged acceptable at the first trial fit and with no significant differences between them. One subject showed excessive, superior decentration with Air Optix at both follow-up visits. The only difference in fit between lenses was noted at two weeks; Air Optix showed less post-blink movement than Biofinity (2.1 v. 2.3, where 2=optimum, $P=0.01$), although clinically this difference is minimal. There were no significant differences in subjects' assessment of handleability.

Tear film assessment and deposition

There were no significant differences in pre-lens tear film assessment with Biofinity and Air Optix (non-invasive break-up time or lipid layer) at either follow-up visit. Mean break-up times were close to 10 seconds, which is relatively long compared with the normal inter-blink period. After two weeks, 15 per cent of both lens types showed some white spot deposits. The mean number of spot deposits was small (0.36 for Biofinity and 0.45 for Air Optix). The proportion of Biofinity lenses with spot deposits did not increase after one month (Air Optix increased to 19 per cent) and means were still small (0.43 and 0.97 respectively). Around a third of the lenses showed film deposits, although

means were again small (0.45 and 0.62 respectively on a 0-4 scale at one month). This lipid film, which tends to be more prevalent in SiH materials, can be helped by ensuring a simple rub and rinse step is implemented.

Ocular physiology

After one month, reductions in limbal and bulbar hyperaemia and vascularisation were noted with both lenses compared with habitual lenses. There was also a reduction in palpebral hyperaemia with Biofinity. At the one-month visit, limbal and bulbar hyperaemia were significantly greater with Air Optix than Biofinity (Figure 3); limbal hyperaemia was noted in 53 Air Optix lens wearing eyes compared with 40 Biofinity eyes. After one month there was a reduction in total corneal staining with both SiHs compared with habitual lenses, in particular, inferior corneal staining.

There were two significant differences in slit-lamp findings at the two-week visit. Central corneal staining was greater with Air Optix, where six eyes (five subjects) showed staining compared to none with Biofinity (0.07 vs 0.00, $P=0.02$). Conjunctival lens edge indentation was also greater with Air Optix (0.43 vs 0.25, $P=0.02$); 34 Air Optix eyes showed some conjunctival indentation compared with 21 Biofinity eyes.

Lens preference

Subjects expressed a preference for Biofinity compared to their habitual lenses (57 per cent at two weeks, $P=0.002$, with 19 per cent no preference). There was no preference for Air Optix compared to habitual lenses (50 per cent vs 42 per cent). At the final visit, more subjects expressed a preference for Biofinity compared to Air Optix (50 per cent vs 35 per cent), although this was not statistically significant.

Discussion

The study demonstrated that Biofinity performed well with existing contact lens wearers for daily wear, and there were significant differences in performance between the two lenses, favouring Biofinity, in particular for comfort, symptoms and ocular physiology.

Biofinity tended to give better comfort, especially end of day. Although differences were not evident at follow-up visits, it was convincingly shown from text message results, illustrating the value of this method of data collection. The apparent contradictory findings in comfort between visit and SMS results could be explained by the fact that differences in comfort were not evident until later in the day, whereas follow-up visits were typically conducted after less than six hours wear.

Differences in comfort were mirrored with symptoms; with Air Optix, more subjects reported discomfort at one month and there was a greater tendency for end-of-day comfort reduction. The reason for comfort differences is not obvious. Possible clues may lie in greater levels of conjunctival indentation and central corneal staining with Air Optix, which may in part be due to lotrafilcon B's higher modulus. Several studies have also noted superior comfort with Biofinity compared with lotrafilcon A lenses, however, only one study to date has compared the comfort between Biofinity and lotrafilcon B lenses.² In this parallel group study, Brennan noted higher average comfort with Biofinity, although this was not statistically significant.

Text messaging was a useful addition to normal comfort data collection at follow-up visits with responses to three quarters of the SMS sent. It provided insights into the decline in comfort during the day, and demonstrated a significant difference in comfort performance that was only evident



with this method of assessments. Not surprisingly, SMS response rates varied depending on time of day and stage of the study, being higher in evenings and earlier on in the study. Other methods have been used to assess CL comfort between visits, such as using handwritten diaries and emails using a BlackBerry device. Paper diaries have caused concerns with accuracy since it is not known if assessments are rated at the correct times, whereas compliance with electronic diaries has been shown to be high.³ A recent study⁴ evaluated text messaging for collecting subjective responses, where subjects found reporting comfort via SMS easier than with paper diaries, in particular when recording data at a specific time period. Three quarters of subjects responded within 10 minutes and there was a reduction in retrospective data completion ('cheating'). Text messaging and email means subjects can only answer once prompted, and response time is recorded, although texting has additional advantages over email. A higher response rate (97 per cent) than in the current study was reported with BlackBerrys, although the method of calculation has not yet been published, so a direct comparison is not possible.⁵

Although Biofinity showed better visual performance than Air Optix, this appears to be back-vertex power-related rather than optical quality since differences were not evident with spherical over-refraction. This suggests Air Optix may incorporate less minus power than Biofinity, and since VA differences were present at dispensing it cannot be due to a CL-induced refraction change.

Both single base curve lenses proved versatile since they all successfully fitted a wide range of eyes with similar fitting characteristics between lenses. This contrasts with one of the first generation silicone hydrogel, Night

& Day, which with its relatively high modulus requires two base curves for optimal fitting.⁶

Slit lamp findings were consistently graded lower (in other words, better) at the final visit compared to baseline. Most of these can be explained by being refitted with high oxygen transmissibility lenses. The few differences between lenses were in favour of Biofinity, although these should be regarded with caution since they were not consistent between two follow-up visits. The reduction in limbal and bulbar hyperaemia was in no doubt due to the increase, for most, in lens' oxygen transmissibility. This effect has been noted by many studies evaluating the effect of refitting with SiHs.⁷

Reductions in corneal staining were most commonly seen inferiorly and temporally. One likely explanation with former conventional hydrogel wearers is a reduction in desiccation staining with the SiH. For those existing SiH wearers, it is possible that refitting with a lower modulus, highly wettable materials such as comfilcon A combines to reduce corneal insult. The greater levels of hyperaemia seen with Air Optix were unexpected; the two lenses have similar oxygen transmissibilities but the differences could be related to other significant differences, that is central corneal staining and conjunctival indentation. Taken with the reduced comfort levels noted earlier, lotrafilcon B's greater modulus could lead to greater mechanical pressure and subsequent ocular insult and discomfort in some wearers, although this explanation would be more convincing if differences in slit lamp findings had been consistent between visits.

Conclusions

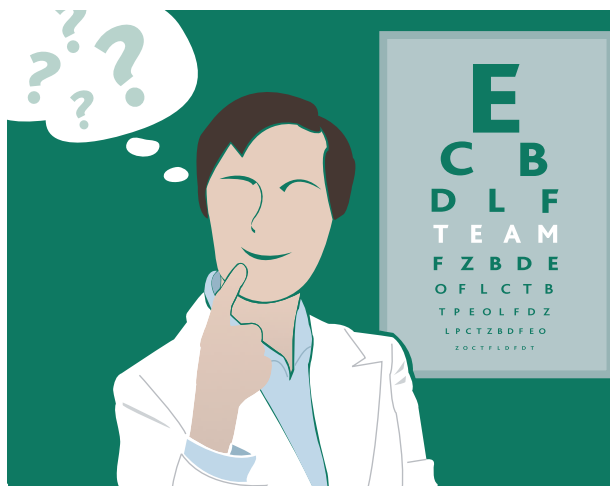
This study shows that Biofinity lenses performed well with regards to clinical

performance when refitting existing CL wearers for DW. When comparing the lens with another SiH, both performed well, although Biofinity gave better comfort performance than Air Optix, particularly later in the day, along with fewer symptoms of discomfort and blurred vision. The study also demonstrated the benefit of SMS text messaging as a way of assessing lens comfort performance. Biofinity led to fewer slit lamp findings than habitual lenses for limbal hyperaemia, bulbar hyperaemia and corneal staining during the month, in addition to less limbal and bulbar hyperaemia than with Air Optix. ●

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