

The performance of galyfilcon A

Dr Karen French presents a round-up of the various peer-reviewed papers published to date relating to the clinical performance of Acuvue Advance with Hydraclear

In 2004, Johnson & Johnson Vision Care launched its first silicone hydrogel contact lens, Acuvue Advance with Hydraclear, made from galyfilcon A, which is now the leading, branded, reusable SiH in Europe.¹ It was developed to provide a lens that could deliver the key benefit of improved end of day comfort as well as higher oxygen delivery when compared to hydrogel contact lenses.² It was the first SiH designed specifically for daily wear rather than extended or continuous wear, has a wide power range (+8.00DS to -12.00DS) and is available in two base curves.

Galyfilcon A has a Dk/t of $86 \times 10^{-9} \text{cm s}^{-1} \text{mLO}_2 \text{ mL}^{-1} \text{mmHg}^{-1}$ (calculated from measurements obtained using Polarographic method, edge and boundary corrected), which, although lower than first generation SiHs, is significantly higher than conventional hydrogel materials. The lens has a central oxygen flux of 97 per cent in open eye conditions, which means it provides 97 per cent of oxygen that would be available to the central cornea with no lens wear, very similar to higher Dk/t SiH contact lenses. However, galyfilcon A has a water content of 47 per cent and retains a modulus of 0.43Mpa. This is not statistically different from many conventional hydrogels (~0.2-0.3Mpa), and is significantly lower than most other SiHs on the market, especially first generation SiHs. Complications such as loose fitting lenses, contact lens-induced papillary conjunctivitis (CLPC), superior arcuate lesions (SEALs) and post lens debris have been observed with higher modulus materials. There may also be greater lens-awareness on the eye. The flexibility of galyfilcon A aids comfort and adaptation and reduces the mechanical impact of the lens on ocular tissues, giving the fit of a conventional hydrogel material, with a similar feel.²

Where galyfilcon A differs from other SiH materials is in the Hydraclear technology used to render the lens wettable without the need for surface treatment. Surface treatment was the primary technological approach used to create first generation SiHs, like balafilcon A (Pure Vision, Bausch & Lomb) and lotrafilcon A (Air Optix Night & Day, CIBA Vision) and continues to be used today in more recently launched lenses

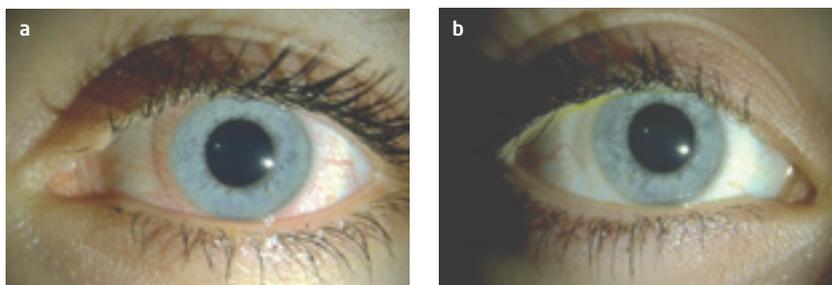


Figure 1
(a) Limbal hyperaemia
(b) White eye with silicone hydrogel
(Images courtesy of David Ruston)

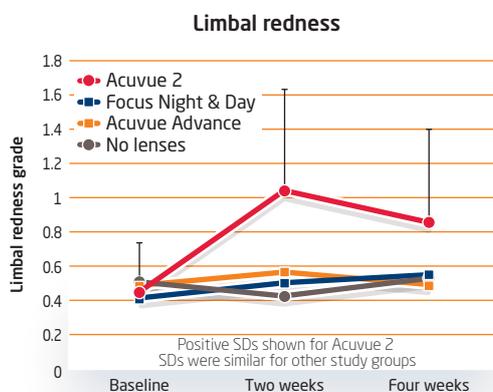


Figure 2 Limbal redness at baseline, two and four weeks with hydrogel and silicone hydrogel contact lenses. Redrawn with permission from *Optom Vis Sci*[®]

such as lotrafilcon B (Air Optix Aqua, CIBA Vision). In contrast, galyfilcon A contains a moisture-rich wetting agent, PVP, throughout the lens, which helps to achieve a highly wettable, low friction lens surface. The wetting agent absorbs moisture and helps to minimise on-eye dehydration during wear while also providing a lubricious lens.³ Lubricity is the property of a wetted material to resist friction. Galyfilcon A has a very low coefficient of friction⁴ which gives the lens a smooth feel when the eyelid travels over the surface during blinking and helps to enhance comfort by minimising any irritation on the upper lid margin.²

In the four years since its launch, there have been several peer-reviewed publications examining the performance of galyfilcon A. These publications provide credible sources of information on lens performance, where study design and results will have demonstrated that they follow good clinical practice guidelines. The results may add weight to the eye care practitioners' own experience of the product performance.

Physiological performance of galyfilcon A

Much research has been carried out examining the clinical benefits of SiH lenses, including numerous observations that they do not induce limbal hyperaemia.⁵⁻⁷ This has been attributed to increased oxygen tension at the limbus, hence limbal redness is taken as an important indicator of an acute hypoxic response (Figure 1). Two studies have looked at galyfilcon A's physiological performance with relation to limbal redness.

Maldonado-Codina *et al*⁸ compared two SiH materials, lotrafilcon A and galyfilcon A and a conventional hydrogel material, etafilcon A (Acuvue 2, Johnson & Johnson Vision Care), evaluating the degree of induced limbal redness in neophyte contact lens wearers (Figure 2). The use of neophyte subjects was particularly interesting because results obtained could not be influenced by any previous contact lens wear. Subjects were randomly assigned to one of the three lens wearing categories or a no lens wear category and wore lenses on a daily wear basis for four weeks. There was a statistically significant increase from baseline limbal redness in subjects wearing conventional hydrogel lenses compared to no significant increase in limbal redness with the SiH lens wearers. There was also no statistically significant difference between the two SiHs.

This finding is supported by Brennan *et al*⁹ where galyfilcon A was again compared with lotrafilcon A. Lenses were worn by successful contact lens wearers for daily wear over two weeks. No signs of physiological compromise were observed with either lens. Limbal injection decreased significantly from baseline with both lenses, the decrease being marginally, but not significantly,



greater for lotrafilcon A than galyfilcon A.

Both studies demonstrate that galyfilcon A worn on a daily wear schedule is not likely to cause any clinical signs of hypoxia including limbal redness and, for the lens parameters worn in the study, there was little if any difference in oxygen performance between galyfilcon A and lotrafilcon A.

If oxygen performance is considered in terms of oxygen flux, in the open eye, galyfilcon A makes available 97 per cent of the maximum possible amount of oxygen to the central cornea, compared to 99 per cent for lotrafilcon A. Despite apparently disparate Dk/t values (lotrafilcon A 175; galyfilcon A 86) there is actually only a 2 per cent difference in oxygen flux between the two materials for daily wear, making it seem more reasonable that there should be very little difference in limbal redness between the two lenses and indeed the no lens wear situation.

Hamano *et al*¹² looked at the oxygen performance of SiH CLs compared with two well-established daily disposable lenses. They studied the impact of dozing or napping in lenses on corneal thickness increase and endothelial bleb development. The number of lens wearers who opt for continuous wear is relatively small; however, many wearers may doze in their lenses for short periods of time. In this study, test lenses were worn for seven hours, one hour of which was spent with closed eyes to simulate napping. After the closed eye period, there was no significant difference in corneal thickness increase after 'napping' in galyfilcon A lenses compared with 'napping' in no lens. Similarly there were no significant differences between the different SiHs, despite any Dk/t differences. However, corneal thickness increases noted with the daily disposable hydrogels were significantly higher than both the control (no lens) and the SiHs.

The same study also looked at endothelial bleb formation. Blebs are an acute endothelial response to hypoxia and can therefore be considered a sensitive index of the oxygen performance of a lens. The results showed that bleb formation with the daily disposable lenses was significantly greater after napping, than with the SiHs, and there was no significant difference in bleb formation in SiH CLs compared with no lens.

These studies highlight the excellent and equivalent oxygen performance of galyfilcon A compared with other SiHs during daily wear and 'napping'. Bearing in mind some material characteristics that can be seen in the hyper-Dk, first

generation SiH materials, such as higher modulus, aiming for oxygen performance at the expense of other material properties can affect lens performance with undesirable effects.

Maldonado-Codina *et al* found that levels of corneal staining were similar for galyfilcon A and lotrafilcon A and were comparable with levels of staining seen in the no lens-wearing group. At all times the staining was less than grade 1 (Efron grading scale) and required no intervention by the practitioner. They found that conjunctival staining for both SiH groups was higher than with no lenses, although again there was no difference between the two lenses. They postulated that this result may be due to lens movement, abrupt changes in the tear film at the lens edge or a thin post lens tear film at the lens edge. They also found significantly less change from baseline in the levels of papillary conjunctivitis for galyfilcon A compared with lotrafilcon A during the one-month study.

Brennan *et al* found that there was more conjunctival staining associated with galyfilcon A than lotrafilcon A, although it remained within clinically accepted limits. They suggested that this may be due to the specific design features such as the edge profile of the lens.

Wettability and deposition

Maldonado-Codina *et al*⁸ and Brennan *et al*⁹ compared the wettability and deposition characteristics of galyfilcon A with lotrafilcon A. They both reported that the *in vivo* wettability of galyfilcon A was significantly better than lotrafilcon A over time, although both materials showed similar *in vivo* wettability at baseline. Maldonado-Codina *et al* also reported that the deposition on galyfilcon A was less than lotrafilcon A after four weeks. It should be noted that the lenses in this study were changed according to the manufacturers' recommendation, ie galyfilcon A was replaced after two weeks and lotrafilcon A was worn for the full four weeks of the study.

Guillon and Maissa¹³ examined the wettability of galyfilcon A in comparison with a conventional hydrogel material, alphafilcon A (SofLens 66, Bausch & Lomb). They used a Tearscope both to examine the *in vivo* wettability of the lens materials, and also to characterise the structure of the pre-lens tear film (PLTF) and measure its stability. Results suggested that galyfilcon A showed superior *in vivo* wettability to alphafilcon A. The galyfilcon A PLTF consisted of thicker aqueous and lipid layers and showed greater overall stability. The difference in performance between the

two materials was present after a two-week time period, suggesting that the results were material specific and not confounded by replacement frequency.

Several authors have examined the deposition characteristics of SiH materials, including galyfilcon A. One of the key studies involving galyfilcon A was carried out by Nichols.¹⁴ In this study he looked at the frequency of deposition and the impact of various care regimes on galyfilcon A. Existing lens wearers wore galyfilcon A lenses for daily wear over two weeks, with wearing times in excess of eight hours a day. Wearers used AMO's Complete MoisturePlus without a rub step in the first phase of the study. Lens front surface deposition was analysed on a five-point scale using a slit lamp where Grade 0 corresponded to no deposition and Grades 3 and 4 were deemed to be significant deposition covering 16-25 per cent and >25 per cent of the lens front surface respectively. Subjective outcomes such as perceived vision and overall comfort were also examined by questionnaire. Results showed that 9.5 per cent of wearers exhibited Grades 3 or 4 deposition, although there were no subjective differences in perceived vision and overall comfort between those wearers with or without significant deposition. In the second phase of this study, the one in 10 wearers who exhibited significant deposition were randomly allocated one of four care regimes: Complete Moisture Plus (AMO) with a rub step, Opti-Free Express (Alcon) with a rub step, Opti-Free Express without a rub step, ASept (CIBA Vision) with a Miraflo (CIBA Vision) rub step. Lenses were again worn for two weeks and were subsequently analysed for front surface deposition. In this deposit prone group, the rub step was responsible for significantly reduced levels of deposition, regardless of the solution. It was concluded that a small number of galyfilcon A wearers may experience significant levels of deposition, although this deposition is likely to have little or no impact on the objective or subjective performance of the lens. The simple compliance measure of introducing a digital rub step with the care regime can significantly reduce heavy deposition and ensure that wearers receive the full comfort and health benefits of their lenses.

Several authors have examined bacterial adhesion or *Acanthamoeba* attachment to SiH materials, including galyfilcon A.¹⁵⁻¹⁹ Results showed that galyfilcon A had the lowest levels of binding of the SiH lenses examined using strains such as *Staphylococcus epidermidis* and *Pseudomonas aeruginosa*,

and in some cases there were no differences between this lens and a conventional hydrogel. When considering the attachment of *Acanthamoeba*, again galyfilcon A showed lower levels of attachment than on the first generation SiHs, with no difference from etafilcon A. It is acknowledged in these studies that the work was carried out *in vitro*; thus far there have been very few cases of microbial or *Acanthamoeba* keratitis associated with any type of SiH lens.

Andrasko and Ryen²⁰ examined the ocular responses associated with certain lens and care solution combinations in the light of reports of high levels of staining associated with SiH materials and multipurpose care solutions.²¹⁻²⁴ Their results would seem to suggest that non surface treated SiH materials such as galyfilcon A exhibit lower levels of corneal staining compared with surface treated lenses, such as lotrafilcon A or lotrafilcon B (Air Optix, CIBA Vision) and balafilcon A (PureVision, Bausch & Lomb), in combination with biguanide-based lens care solutions.

Comfort and clinical performance

Dryness and discomfort are the most common complaints of CL wearers, with anywhere between 37 per cent and 73 per cent of wearers complaining of dryness during their normal lens wearing period.^{25,26} In addition, dryness and discomfort are the most commonly cited reasons for dropping out of CL wear; one study found that 51 per cent of previous lens wearers blamed discomfort as the main reason for giving up lens wear.²⁷ There have been several papers examining patient comfort with galyfilcon A.

Brennan *et al*⁹ compared the performance of galyfilcon A with lotrafilcon A for daily wear over two weeks (Figure 3). The subjective response was overwhelmingly in favour of galyfilcon A, with the lens being rated excellent in terms of overall comfort by nearly four times as many people as lotrafilcon A, even with the study period being only half the recommended wear schedule for lotrafilcon A. The conclusion was that galyfilcon A showed better overall daily wear clinical performance than lotrafilcon A, possibly as a result of the lower silicone and higher water content. When looking for a silicone hydrogel lens for daily wear, choosing a material with the highest Dk/t provides no extra benefits in terms of physiological performance for the vast majority of patients, and indeed may compromise other factors important for comfortable lens wear.

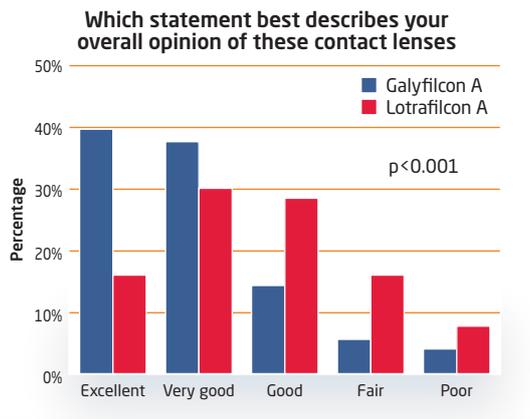


Figure 3 Overall opinion of galyfilcon A vs lotrafilcon A Redrawn with permission from *Clin Exp Optom*⁹

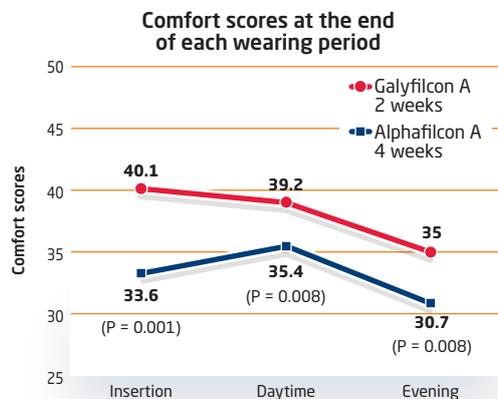


Figure 4 Comfort scores at the end of each wearing period independently for three times of day (insertion, daytime, evening) Redrawn with permission from *Contact Lens and Anterior Eye*¹³

In Guillon's study¹³ comparing the performance of galyfilcon A with hydrogel material alphafilcon A, subjective acceptance was rated on a continuous 0-50 point scale, with added descriptors ranging from 'impossible to wear' up to 'excellent comfort all the time'. Comfort was rated for the first 30 minutes of wear, for daytime wear (up to 8pm) and evening (from 8pm to lens removal) (Figure 4). There was a subjective decrease in comfort in the evening for both lenses. However, there was a distinct preference for galyfilcon A over alphafilcon A at all time points. The improved comfort scores were attributed in part to the superior wettability of galyfilcon A, allowing the tear film to act as a continuous lubricant between the contact lens front surface and the palpebral conjunctiva of the upper lid during blinking.

Young *et al*²⁸ carried out a study looking at the range of challenging environments experienced by hydrogel lens wearers in everyday tasks and comfort in these situations. The study then looked at the effect on comfort of

refitting these lens wearers with one of three next generation SiHs (senofilcon A (Acuvue Oasys with Hydraclear Plus, Johnson & Johnson Vision Care), galyfilcon A and lotrafilcon B (Air Optix, CIBA Vision)). The type of situation leading to discomfort during lens wear includes computer use, demanding task content such as driving at night or reading, environments such as air-conditioning or heating, low humidity, smoky, dusty or polluted environments and napping in lenses. The most common challenging situations reported in the study were driving at night, using a computer and being in a heated or air-conditioned car. Following a refit with the SiHs, many wearers reported some increase in comfort in these challenging situations. Those refitted with galyfilcon A reported a statistically significant improvement in comfort in all of the challenging situations, except for computer use.

UV protection

Ultraviolet (UV) radiation is well known to damage ocular tissue. The large diameter of a soft CL and its position on the cornea mean that it can reduce the level of UV radiation reaching the ocular surface, protecting the cornea and internal eye structures. The amount of UV absorbed and transmitted by a soft CL depends on the brand of lens. Galyfilcon A was the first of the SiH materials to incorporate a UV-blocking agent and meets the strictest standards of Class 1 UV blocking (blocking more than 90 per cent UVA and over 99 per cent UVB). Galyfilcon A was the first lens material to receive the World Council of Optometry's global seal of acceptance for their UV protection.

Moore and Ferreira²⁹ carried out an independent study examining UV attenuating properties of various lenses, including galyfilcon A. Galyfilcon A had a UV transmittance that allowed it to meet the ANSI standard^{30,31} for UV blocking. They also calculated a protection factor for each of the test lenses, which is designed to quantify the UV protection afforded by a CL in a similar manner to the protection factor on a bottle of sunscreen, with higher protection factors indicating superior levels of UV blocking. Galyfilcon A was found to have a UV protection factor (10.02) significantly higher than lenses without a UV blocking agent.

Galyfilcon A and children

Walline *et al*^{32,33} have carried out several studies into the benefits of contact lens wear in children, in particular the younger 8-12 year age group.



These 'Contact Lens in Pediatrics' (CLIP) studies have used lenses based on galyfilcon A (Acuvue Advance or Acuvue Advance for Astigmatism). The conclusions drawn from this research are that children as young as eight years old benefit as much from wearing contact lenses as older children and teens. When using galyfilcon A in this younger age group, fitting was found to be very straightforward with the vast majority of study participants fitted successfully from the available parameters. There was no evidence of hypoxic related complications in any of the study groups ranging from 8-17 years, including no significant increase in bulbar or limbal conjunctival redness from baseline levels. Additionally it was concluded that the younger age group of 8-12 year-olds required no more chair time than the older age groups to fit the lenses. Galyfilcon A is an excellent lens choice for children; they experience significant benefits from lens wear with few complications as demonstrated by these studies.

Summary

Galyfilcon A was the first of the next generation SiH materials launched specifically to improve comfort for daily wear contact lens users. The reduction in the level of silicone and consequent higher water content resulted in a lower Dk/t in comparison to the first generation lenses, but the oxygen delivery is still far in excess of conventional hydrogel materials. The higher water content afforded by the lower level of silicone, as well as the Hydraclear technology, have resulted in a lower modulus material with flexibility similar to that of conventional hydrogel materials and a lens that appears to provide high levels of patient satisfaction in terms of comfort and wearing time.

The peer-reviewed literature discussed in this article supports the idea that when choosing a lens for daily wear, galyfilcon A provides sufficient oxygen performance to eliminate any hypoxic complications, including limbal redness. Furthermore, galyfilcon A has other material benefits important for comfortable lens wear, such as increased flexibility and wettability. Galyfilcon A has good compatibility with multipurpose lens care solutions and the incorporation of a UV blocking agent has resulted in the material receiving Class 1 UV blocking status. The studies reviewed highlight the many benefits of galyfilcon A material for daily wear, and should give the practitioner confidence in prescribing the lens even for younger age groups. ●

References

- 1 Value share sales, Europe, GfK, August 2008.
- 2 Steffen RB, Schnider CM. A next-generation silicone hydrogel lens for daily wear: Part 1 – Material properties. *Optician*, 2004; 227(5954): 23-25.
- 3 Jones L, Subbaraman L, Rogers R, Dumbleton K. Surface treatment, wetting and modulus of silicone hydrogels. *Optician*, 2006; 232(6067):28-34.
- 4 Ross G, Nasso M, Franklin V, Lydon F, Tighe B. Silicone Hydrogels: Trends in Products and Properties. Poster presented at BCLA 29th Clinical conference and exhibition, Brighton, UK; 3-5 June 2005.
- 5 Papas EB, Vajdic CM, Austen R, Holden BA. High-oxygen-transmissibility soft contact lenses do not induce limbal hyperaemia. *Curr Eye Res*, 1997; 16(9):942-8.
- 6 Papas E. On the relationship between soft contact lens oxygen transmissibility and induced limbal hyperaemia. *Exp Eye Res*, 1998; 67(2):125-31.
- 7 Papas EB. The role of hypoxia in the limbal vascular response to soft contact lens wear. *Eye Contact Lens*, 2003; 29(1 Suppl):S72-4; discussion S83-4, S192-4.
- 8 Maldonado-Codina C, Morgan PB, Schnider CM, Efron N. Short-term physiologic response in neophyte subjects fitted with hydrogel and silicone hydrogel contact lenses. *Optom Vis Sci*, 2004; 81(12):911-21.
- 9 Brennan NA, Coles ML, Ang JH. An evaluation of silicone-hydrogel lenses worn on a daily wear basis. *Clin Exp Optom*, 2006; 89(1):18-25.
- 10 Holden BA, Mertz GW. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. *Invest Ophthalmol Vis Sci*, 1984; 25(10):1161-7.
- 11 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(10):712-9.
- 12 Hamano H, Maeda N, Hamano T, Mitsunaga S, Kotani S. Corneal Thickness Change Induced by Dozing While Wearing Hydrogel and Silicone Hydrogel Lenses. *Eye & Contact Lens: Science & Clinical Practice*, 2008; 34(1):56-60.
- 13 Guillon M, Maissa C. Use of silicone hydrogel material for daily wear. *Contact Lens and Anterior Eye*, 2007; 30:5-10.
- 14 Nichols JJ. Deposition rates and lens care influence on galyfilcon A silicone hydrogel lenses. *Optom Vis Sci*, 2006; 83(10):751-57.
- 15 Kodjikian L, Casoli-Bergeron E, et al. Bacterial adhesion to conventional hydrogel and new silicone-hydrogel contact lens materials. *Graefes Arch Clin Exp Ophthalmol*, 2008; 246(2):267-273.
- 16 Beattie TK, Tomlinson A, et al. Enhanced attachment of acanthamoeba to extended-wear silicone hydrogel contact lenses: a new risk factor for infection? *Ophthalmology*, 2003; 110(4):765-771.
- 17 Beattie TK, Tomlinson A, et al. Surface treatment or material characteristic: the reason

for the high level of *Acanthamoeba* attachment to silicone hydrogel contact lenses. *Eye Contact Lens* 2003; 29(1 Suppl):S40-43; discussion S57-49, S192-194.

18 Beattie TK, Tomlinson A, et al. Attachment of *Acanthamoeba* to first- and second-generation silicone hydrogel contact lenses. *Ophthalmology*, 2006; 113(1):117-125.

19 Henriques M, Sousa C, Lira M, et al. Adhesion of *Pseudomonas aeruginosa* and *Staphylococcus epidermidis* to silicone hydrogel contact lenses. *Optom Vis Sci*, 2005 Jun; 82(6):446-50.

20 Andraso G, Ryan K. Corneal staining and comfort observed with traditional and silicone hydrogel lenses and multipurpose solution combinations. *Optometry*, 2008; 79(8):444-454.

21 Jones L, MacDougall N, et al. Asymptomatic corneal staining associated with the use of balafilcon silicone-hydrogel contact lenses disinfecting with a polyaminopropyl biguanide-preserved care regimen. *Optom Vis Sci*, 2002; 79(12):753-761.

22 Epstein A. SPK with daily wear of silicone hydrogel lenses and MPS. *Contact Lens Spectrum*, 2002; 17(11):30.

23 Fonn D. Observations of corneal staining with MPS and silicone hydrogel lenses. *Contact Lens Spectrum*, 2002; 17(11):32.

24 Garofalo RJ, Dassanayake N, et al. Corneal staining and subjective symptoms with multipurpose solutions as a function of time. *Eye Contact Lens*, 2005; 31(4):166-174.

25 Begley CG, Caffery B, Nichols KK, Chalmers R. Responses of contact lens wearers to a dry eye survey. *Optom Vis Sci*, 2000; 77(1):40-6.

26 Vajdic C, Holden BA, Sweeney DF, Cornish RM. The frequency of ocular symptoms during spectacle and daily soft and rigid contact lens wear. *Optom Vis Sci*, 1999; 76(10):705-11.

27 Young G, Veys J, Pritchard N, Coleman S. A multi-centre study of lapsed CL wearers. *Ophthalmic Physiol Opt*, 2002; 22(6):516-27.

28 Young G, Riley CM, Chalmers RL, Hunt C. Hydrogel lens comfort in challenging environments and the effect of refitting with SiH lenses. *Optom Vis Sci*, 2007; 84(4):302-8.

29 Moore L, Ferreira JT. Ultraviolet (UV) transmittance characteristics of daily disposable and silicone hydrogel contact lenses. *Cont Lens Anterior Eye*, 2006; 29(3):115-22.

30 ANSI/Z80.3 - 1996 (R1999) Non-prescription sunglasses and fashion eyewear - requirements.

31 ISO 8599:1994 Optics and optical instruments - contact lenses - Determination of the spectral and luminous transmittance.

32 Walline JJ et al. Contact lenses in Pediatrics (CLIP) study: Chair time and ocular health. *Optom Vis Sci*, 2007; 84(9):896-902.

33 Walline JJ et al. Benefits of contact lens wear for children and teens. *Eye and Contact Lens*, 2007; 33(6):317-21

● **Dr Karen French** is head of optometry at Hinchingsbrooke Hospital. She has previously carried out research in the area of contact lens material properties