

Enhancing contact lens design for complete performance

Dr Gerard Cairns describes the performance of a new daily disposable contact lens designed to give patients the optimum in comfort, vision and ease of handling

A recent survey has shown that daily disposable contact lenses account for approximately one-third of all contact lens fits and re-fits in the UK.¹ This important modality has many benefits for the contact lens patient. Disposing of the lens at the end of the day and opening a new sterile contact lens each morning enhances hygienic practices and reduces compliance issues associated with lens care. Indeed, practitioners may feel compelled to prescribe daily disposables on this basis alone.

Extended, flexi or daily wear of approved hydrogel and silicone hydrogel lenses are a perfectly acceptable means of contact lens correction and a wealth of data is now available which confirms and establishes appropriate prescribing techniques of each. Recent studies on contact lens wear complications have highlighted several items that can be used to screen or advise current and prospective wearers, for example, living far from an ophthalmic or medical practitioner, or smoking.^{2,3} Knowledge of these factors will contribute to successful contact lens practice. Of significant interest is the fact that daily disposable contact lenses are not associated with any increase in risk of infiltrative events or severe keratitis, suggesting the modality is able to accommodate non-compliance.³

Given that there are years of clinical experience to support the health attributes of daily disposable contact lenses, practitioners can confidently prescribe these lenses. From the patient perspective, many take an interest in the health of their eyes, but it is the everyday aspects of contact lens wear that may determine ultimate success. For the daily disposable contact lens modality there are three main aspects of lens wear that drive patients' opinion and accept-

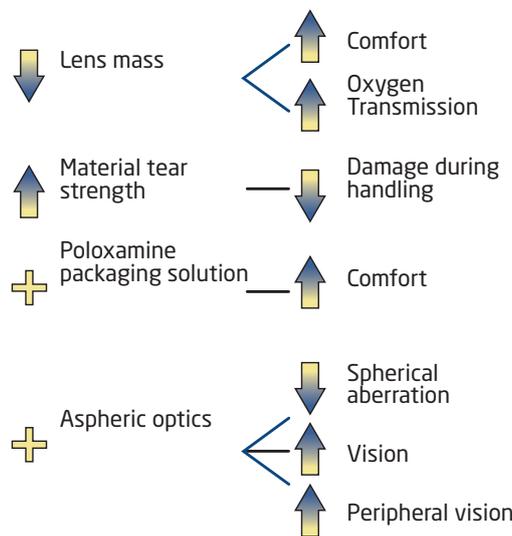


Figure 1 SofLens daily disposable contact lens properties



Figure 2 SofLens daily disposable packaging configuration is designed to nest together, allowing convenient storage

ance: comfort, vision and handling. Each day, these are the factors which the patient will consciously or subconsciously appraise and will be the most important determinants of successful daily disposable contact lens wear. It is important therefore that all of these be specifically addressed in the product design.

The new SofLens daily disposable contact lens, recently launched in the UK by Bausch & Lomb, has been designed on the basis of these three factors. This lens has been made using a hydrophilic polymer, hilafilcon B. The non-ionic properties of this material provide resistance to build up from tear debris, thus providing and maintaining a clean lens surface throughout the day. The lens design has been significantly modified from its predecessor, 'SofLens one day'. The overall reduced lens mass is specifically designed to enhance comfort without compromising handling attributes. A further advantage of a reduced mass lens is improved oxygen transmissibility. It is important to note that the reduced thickness does not indicate a reduction in integrity, as the improved tensile properties of the hilafilcon B material increases tear strength to reduce the incidence of lens damage while handling (Figure 1). Additionally, the lens has been packaged with a solution containing poloxamine which acts as a conditioning agent that attracts moisture to maintain wearing comfort.

To improve further the handling experience, this new lens was combined with an innovative packaging configuration. This blister pack with an easy to grip and smooth tear away label features a tear drop shaped well for ease of lens removal. Furthermore, the unique morphology of the blister is specifically intended to improve compliance as it allows a pair of lenses to nest together, making it easy and convenient to carry

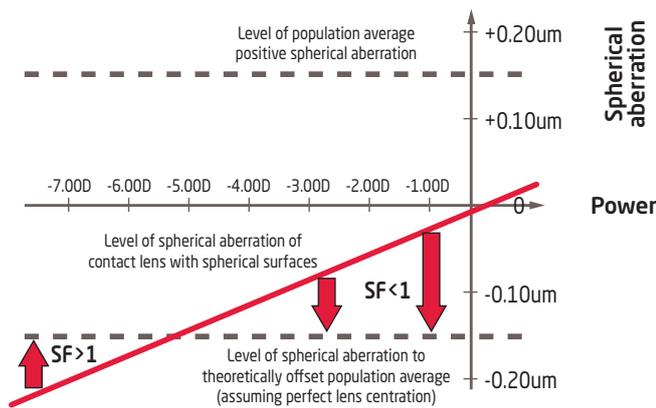


Figure 3 The population average spherical aberration and the level of spherical aberration induced by varying powers of contact lenses with spherical surfaces

a spare set (Figure 2).

Advances in contact lens design have made it possible to introduce aspheric optics into SofLens daily disposable contact lenses. This is an important step as the population average spherical aberration has been reported to be of the order of $+0.15\mu\text{m}$, an amount capable of reducing retinal image quality.⁴ Correcting this aberration is complicated by the fact that the standard spherical optics of contact lenses actually induces an amount of spherical aberration which varies with the power of the lens (Figure 3). The anterior optic zone of the SofLens daily disposable lenses has been designed to adjust the amount of asphericity for each power of contact lens and reduces the population average spherical aberration. When the spherical aberration is reduced, more light reaching the retina is focused at exactly the same point, enabling better resolution. A clinical study of 40 subjects demonstrated the

aspheric optics can provide a significant reduction in spherical aberration when compared to the Acuvue 1-Day lens⁵ (Figure 4). There remain aspects of this lens design which have yet to be fully explored. A recent study examining peripheral visual acuity demonstrated the aspheric optics of SofLens daily disposable to provide a larger field of clear vision when compared to Acuvue 1-day and Focus Dailies,⁶ a feature which could be of tremendous utility in driving or sports.

With design elements targeting the aforementioned three key features (comfort, vision and handling), clinical evaluation was performed assessing their influence on the lens-wearing experience. Several large multicentre

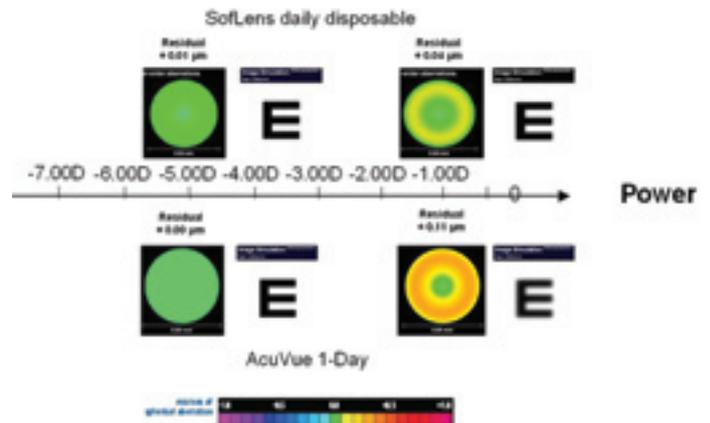


Figure 4 Forty subjects participated in an evaluation of spherical aberration with SofLens daily disposable contact lenses. Subjects were dilated to achieve a minimum of 6mm pupil diameter. Baseline spherical aberration was measured using a Zywave aberrometer. SofLens daily disposable contact lenses and Acuvue 1-day contact lenses (-1.00D and -5.00D) were inserted, and the measurement of spherical aberration was repeated. Wavefront aberration maps and simulated retinal images were generated using Vision Optics Laboratory software. The letter represents a 20/80 letter size viewed through a 6mm pupil and an eye with no other aberration except for spherical aberration

clinical studies have been conducted to test not only the safety of the lenses, but the efficacy in meeting the rigorous demands of patient satisfaction. The first study compared the SofLens daily disposable (test) to its predecessor the SofLens one day (control).⁷ This study was a randomised, crossover study where the 75 subjects who completed the study wore either the test or control lens lenses (-0.25D to -6.00D) for four weeks on a daily disposable schedule. At the end of four weeks, the subjects were examined and rated the lens on a variety of performance-related measures. Subjects were then dispensed the other lens to wear for four weeks again on a daily disposable basis. At the end of the study, subjects were examined, rated the lens and answered a forced choice preference questionnaire.

Throughout the study there were no adverse events and slit lamp findings showed almost no grade 2 or above findings for either lens, demonstrating not only statistical equivalence, but the safety of both contact lenses (Table 1).

In the assessment of lens fit, there was no statistically significant difference in lens centration or movement and the prescribed sphere power was the same for both lenses in all patients (100 per cent) who completed the study. All of these are important considerations when re-fitting existing SofLens one day patients into the new SofLens daily disposable.

Subjects were asked to rate various attributes on a scale from zero to 100, where zero represents the least favour-

TABLE 1

Grade 2 or above slit-lamp findings in a one-month study of SofLens daily disposable compared to SofLens one day

	SofLens daily disposable (occurrence rate %)	SofLens one day (occurrence rate %)
Epithelial oedema	0.0	0.0
Epithelial microcysts	1.3	0.0
Corneal staining	0.0	1.3
Limbal injection	0.0	0.0
Bulbar injection	0.0	0.0
Sup tarsal conjunctival abnormalities	0.0	0.0
Corneal neovascularisation	0.0	0.0
Corneal infiltrates	0.0	0.0

able response and 100 represents the most favourable (Figure 5). The results reveal that the SofLens daily disposable performed significantly better, particularly for 'end of day comfort' and 'absence of dryness' where the difference in scores was 10 and nine respectively. A difference of five is generally regarded as being clinically significant in that a patient is likely to appreciate the difference. Furthermore, 'handling' and 'overall performance' demonstrated a significant advantage for the SofLens daily disposable. The forced choice questionnaire again revealed the SofLens daily disposable to be preferred over the control for comfort, vision and handling attributes by approximately two-to-one (Figure 6).

A second study, almost identical to this first, was conducted, this time employing 106 hyperopic subjects (212 eyes; +0.25D to +6.00D) over a two-week crossover period.⁸ The results mirrored the first study as again there was no difference in slit-lamp findings, centration, movement and sphere power between the SofLens daily disposable and SofLens one day. Additionally, when rating the various attributes of lens performance SofLens daily disposable performed significantly better for most attributes and again 'end of day comfort' and 'absence of dryness' were rated nine points higher than the control lens. Forced choice data showed the same trend with a two-to-one preference for the SofLens daily disposable on comfort and handling attributes; vision achieving nearly a three-to-one preference.

With these large multicentre clinical trials it has become evident that the design attributes of the SofLens daily disposable have indeed created significant improvements in daily disposable contact lens performance and meet the high demands of contact lens wearers. Further assessment of the performance capabilities have been conducted against Focus Dailies disposable lenses. In a one week trial of SofLens daily disposable on 100 subjects who routinely wore Focus Dailies, there were many similarities.⁹ Attributes such as centration and movement were not different ($p > 0.05$ in all cases), again suggesting an easy refit into the SofLens daily disposable. Even when rating comfort throughout the day there was again no difference determined ($p > 0.05$). However, for ratings of 'end of day comfort' and 'absence of dryness', there was a statistically and clinically significant difference in favour of the SofLens daily disposable ($p < 0.05$) (Figure 7).

From this large series of studies

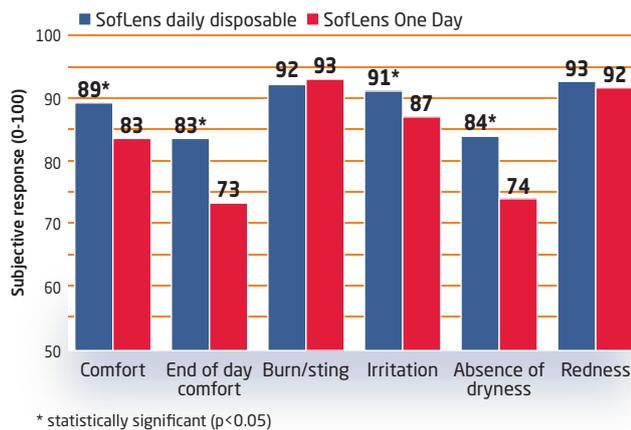


Figure 5 Results from subjective ratings of various performance attributes of SofLens daily disposable and the Control lens. (Subjects were asked to rate these measures on a scale from 0 to 100, where 0 = the least favourable response and 100 = the most favourable response)

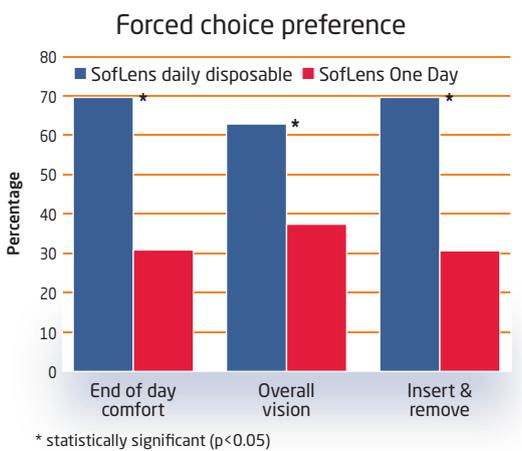


Figure 6 Results from the forced choice preference questionnaire indicating significant preference for the SofLens daily disposable

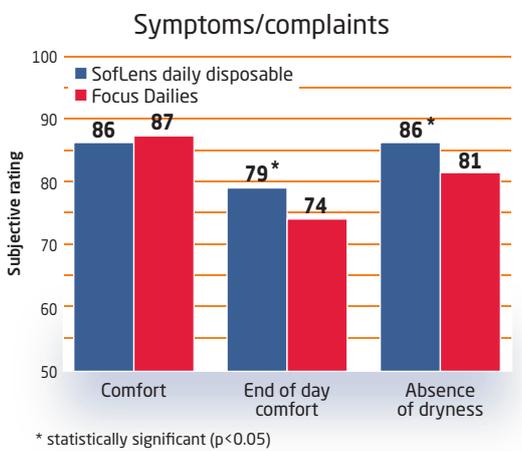


Figure 7 Subjective ratings of comfort related parameters demonstrating better performance with the SofLens daily disposable lens

which were designed to rate performance and efficacy of the lens and determine how well SofLens daily disposable could integrate into contact lens practice, a common theme emerges. The results would indicate that 'end of day comfort' and 'absence of dryness' are distinguishing features of this new lens. The aspheric optics designed into the lens has not only demonstrated reduction of spherical aberration, but excellent visual quality. Lastly, through innovative lens and packaging design, the handling performance of this lens

would appear to be highly rated by contact lens wearers.

The new SofLens daily disposable contact lens is a valuable tool for the contact lens practitioner. Clinically, there is strong evidence for practitioners to seriously consider adopting this lens as a first choice for daily disposable wear. ●

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● **Dr Gerard Cairns** is manager of clinical and scientific affairs for Bausch & Lomb Global Vision Care, Rochester, New York