

Defining eye enhancement

Part two: the technology

1-DAY ACUVUE® DEFINE® with LACREON® unlocks the potential for a whole new category of contact lenses. In this second article, Mike Mayers, Meredith Jansen and Kathrine Osborn Lorenz describe the design philosophy and technologies behind the lens, its material properties and clinical performance.

We know that the eyes are the facial feature that attracts most attention.¹ We know that appearance and performance are the key reasons for starting to wear contact lenses.² And as we saw in Part one of this article, patients are receptive to the concept of enhancing their eyes with a contact lens, provided that lens has a natural-looking appearance and meets the primary needs of contact lenses for comfort, health, vision and handling.³

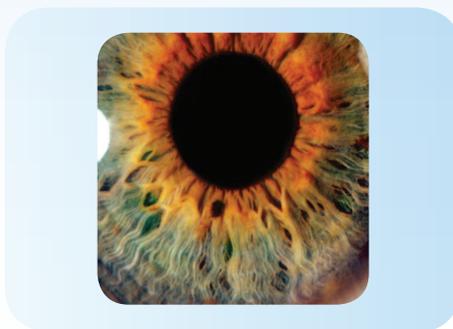
For eye care practitioners as well as potential wearers, such a lens would also need to overcome the limitations of traditional coloured lenses.⁴ Having more daily disposable options, minimal effects on ocular physiology, excellent surface properties and ease of fitting are just some of the needs that are currently unmet, in addition to the desire for more natural-looking designs.

In Part two we review the design philosophy and features of a new type of contact lens that enhances the natural appearance of the eye without changing eye colour: 1-DAY ACUVUE® DEFINE® with LACREON®. We describe novel techniques that have been developed to explore material and surface properties of the new lens, and present results of studies into its clinical performance. We also hear about eye care practitioners' experiences of using the lens in practice.

Lens features

The parameters, design and material properties of 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® are listed in Table 1.

The lenses are manufactured from the proven etafilcon A material used in 1-DAY ACUVUE® MOIST®. LACREON® technology permanently embeds a water-holding ingredient (polyvinyl pyrrolidone – PVP) which does not blink away.⁵ Class 2 UV blocking helps to protect against the transmission of harmful UV rays.



The daily disposable modality provides the convenience, compliance and health benefits of a fresh new lens every day. Recent research has demonstrated the exceptionally low adverse response rate with etafilcon A daily disposable lenses; over the equivalent of 471 years of patient

Table 1 Parameters and design details

Power range	-0.25D to -6.00D (0.25D steps), -6.50D to -9.00D (0.50D steps) +0.50D and +1.00D
Base curve	8.5mm
Total diameter	14.2mm
Centre thickness	0.084mm (for -3.00D)
Material	etafilcon A
Internal wetting agent	Polyvinyl pyrrolidone (PVP) using LACREON® Technology
Water content (%)	58
Oxygen permeability* (Dk)	21.4 x 10 ⁻¹¹
Technologies used	Beauty-Wrapped-in-Comfort™ and LACREON®
Recommended replacement schedule	Single use / daily wear

*Dk value: Fatt units at 35°C, determined via polarographic method (boundary and edge corrected)

wear, users of 1-DAY ACUVUE® MOIST® reported only three non-significant contact lens-related events and no serious or symptomatic infiltrative events.⁶

Design philosophy

1-DAY ACUVUE® DEFINE® lenses have been developed using a combination of design elements and artistic principles to produce the natural-looking effect that patients are looking for. These elements have been further developed based on experience with the lens in Asia over the past decade and on consumer feedback.

Research among women in the US aged 18-25 years, with a mix of eye colours and ethnicities, showed that those interested in enhancing their eyes with contact lenses wanted the eyes to be noticed but were looking for a subtle change to their appearance rather than completely changing the colour of their eyes.⁷ The desire for natural-looking eye enhancement has been confirmed in recent market research in the UK.⁸

The design of 1-DAY ACUVUE® DEFINE® incorporates:

- Colour and contrast – a combination of opacity and translucency to create blending and definition, and colour contrast within the patterns and against the natural iris
- A defined, clear edge – defined iris with clear definition and contrast against the white sclera, and a solid limbal edge for crisp and natural definition
- Iris-inspired patterns – shapes and patterns that appear in and seamlessly blend with the natural iris by highlights and shading
- Light and dark elements – to imply depth and form

The resulting effect on the eye is to enhance the beauty of the wearer's natural iris without completely changing its colour (Figure 2), as traditional coloured lenses do. The design blends both colour and effect with the natural iris colour, again unlike coloured lenses which use opaque pigments that

mask the wearer's natural eye colour. The limbal ring design defines the eye with a clean line rather than a rough edge created by dots, thus forming a natural-looking, defined iris.

1-DAY ACUVUE® DEFINE® lenses also incorporate a technology known as Beauty-Wrapped-in-Comfort™, which completely encloses the pigment within the lens matrix to ensure no contact between pigment and the ocular surface.

Etafilcon A enclosing the pigment is designed to provide a smooth, wettable surface and comfortable lens wear. The print design does not cover the central part of the lens, to minimise the effect on vision. As we will see from clinical studies, the result is a lens that has overall performance comparable to a clear lens.

Material properties

The material properties of 1-DAY ACUVUE® DEFINE® are summarised and compared with 1-DAY ACUVUE® MOIST® in Table 2. New techniques have been developed or applied to determine some of these properties.

Coefficient of friction

Coefficient of friction (CoF) is expressed as the force required to move a known load across a surface at a given speed, after accounting for deformation of the lens surface by the load and any hydrodynamic forces relating to fluid interfaces and lens dehydration. Lubricious materials have low CoF values.

In contact lenses, surface lubricity relates most closely to the ability of the eyelid to travel smoothly across the front surface of the contact lens without irritation. Possible clinical implications of high CoF values include tarsal abnormalities, contact lens papillary

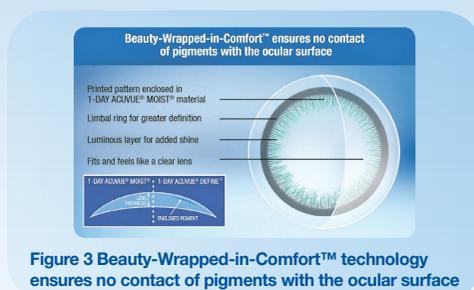


Figure 3 Beauty-Wrapped-in-Comfort™ technology ensures no contact of pigments with the ocular surface

conjunctivitis (CLPC) and upper lid margin staining, which have been linked to comfort.¹⁰

Some studies have shown a direct association between CoF and end-of-day comfort.^{11,12} The recent report from the Tear Film and Ocular Surface Society (TFOS) concluded that this lens attribute was more likely than other bulk and surface properties to be directly associated with contact lens comfort.¹³

Johnson & Johnson Vision Care contracted with SURface SOLUTIONS (SuSoS) of Switzerland, and their world-renowned

Table 2 Comparison of material properties

	1-DAY ACUVUE® DEFINE®	1-DAY ACUVUE® MOIST®
Coefficient of friction	0.024	0.024
Oxygen Dk/t*	25.5 x 10 ⁻⁹	25.5 x 10 ⁻⁹
Flux	88%	88%
Modulus (MPa)	0.25	99%
UV blocking** UVB	99%	99%
Class 2 UVA	85%	85%

*Dk value: Fatt units at 35°C, determined via polarographic method (boundary and edge corrected); -3.00D lens

** Tested at -1.00D

experts in the field of tribology, to develop a CoF testing method designed to resemble on-eye conditions as closely as possible in an in vitro testing situation.¹⁴

Dynamic CoF was measured on the clear central portion and the pigmented peripheral portion of 1-DAY ACUVUE® DEFINE®.

1-DAY ACUVUE® DEFINE® showed minimal differences between the four positions (front centre, front periphery, back centre, back periphery) providing a consistently lubricious lens surface.¹⁴ When compared to 1-DAY ACUVUE® MOIST® tested under the same conditions, the dynamic CoF of 1-DAY ACUVUE® DEFINE® was the same as the non-pigmented 1-DAY ACUVUE® MOIST® lens, at 0.024 for both (front-centre, based on 100 cycle values).

Oxygen delivery

Contemporary, thin hydrogels such as 1-DAY ACUVUE® MOIST® meet the published criteria for central corneal oxygen requirement for maintenance of oedema-free and acidosis-free daily wear.^{15,16} Additionally, in the open eye state, the etafilcon A daily disposable lens provides 88 per cent of available oxygen to the cornea (flux), which determines the proportion of oxygen available to the anterior cornea compared to a no lens situation.

The pigmented portion of a typical coloured contact lens is located in a region of the lens which does not allow for accurate measurement of Dk. Traditionally measurements have been taken through both the clear and coloured portions of the lens and the results averaged.

A novel technique was developed to allow for a Dk measurement of coloured lenses by applying colorant to the centre of the lens in a location where Dk measurements are typically performed.¹⁷

This technique showed that colour pigment does not impact the oxygen permeability (Dk) of the etafilcon A material. 1-DAY ACUVUE® DEFINE® and 1-DAY ACUVUE® MOIST® were found to have the same Dk/t and oxygen flux values (Table 2) and hence both lenses exceed published criteria for oxygen requirement for daily wear.^{15,16}

A further study using the same methodology has since confirmed that neither the colorant nor the PVP moisturising agent affect the edge-corrected Dk of the 1-DAY ACUVUE® DEFINE® lens in comparison with that of its



Figure 2 DEFINE® lenses enhance the beauty of the natural iris (left hand images) and add depth and definition without completely changing iris colour

non-tinted marketed equivalent and lenses which do not contain PVP in the packing solution.¹⁸

Additionally, a clinical study has shown minimal hypoxic effects on corneal physiology with the lens.¹⁹ Corneal swelling after eight hours of daily wear was clinically equivalent with 1-DAY ACUVUE® DEFINE® and 1-DAY ACUVUE® MOIST®, and comparable to no lens wear for central and peripheral corneal swelling, demonstrating that the pigments enclosed in the lens matrix have no impact on corneal swelling.

No endothelial blebs were recorded and there were no distinguishable differences between lenses for limbal or bulbar hyperaemia. Both lens types can therefore be used in open-eye, daily wear with no predicted differences in these key areas of physiological performance or from no lens wear.

Modulus

Modulus relates most closely to the ability of a contact lens material to drape or contour to the eye's surface. The lower the value, the more elasticity or flexibility the material has. Modulus can affect comfort, particularly initially, as well as fit flexibility and mechanical complications such as SEALs (superior epithelial arcuate lesions), CLPC and mucin ball production in the post-lens tear film.²⁰

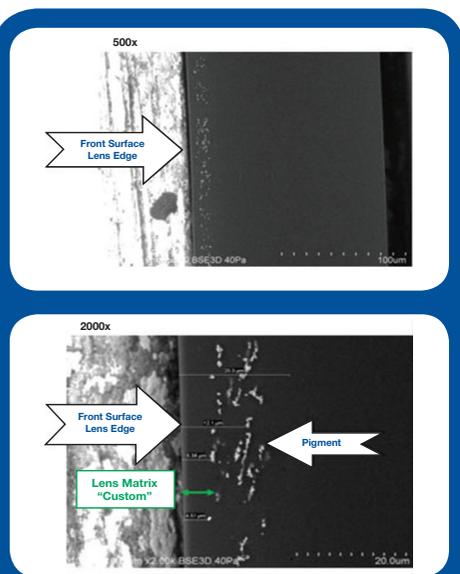


Figure 4 SEM images of 1-DAY ACUVUE® DEFINE® in cross-section (500X and 2000X) show the pigment particles below the front surface of the lens

The modulus value of 1-DAY ACUVUE® DEFINE® (Table 2) is comparable to that for 1-DAY ACUVUE® MOIST®.²¹ These measures show that the pigments enclosed within the lens matrix for 1-DAY ACUVUE® DEFINE® do not impact the material modulus.

UV blocking

1-DAY ACUVUE® DEFINE® incorporates Class 2 UV blocking (as per ANSI Z80.2 2010 and ISO standard 18369), similar to 1-DAY ACUVUE® MOIST®, helping to protect against the transmission of harmful UV rays. Both lenses block 99 per cent of UVB (280-315nm) rays and 85 per cent of UVA (316-380) rays.²¹

Surface properties

Two techniques have recently been used to analyse the pigment location and surface roughness of coloured and eye enhancing lenses: Scanning Electron Microscopy (SEM) and Atomic Force Microscopy (AFM).²²

Scanning Electron Microscopy

SEM uses electrons instead of light or laser beams to form an image. This instrument has a large depth of field and high resolution, which allows more of a specimen to be in focus at one time and at much higher magnification levels than other techniques.

SEM analysis was performed on several brands of coloured and eye enhancement lenses using a variable pressure Hitachi S3400N instrument to discern the placement of lens pigments.²² The SEM magnifies cross-sectioned lenses at 500X and 2000X magnification and confirmed that, for 1-DAY ACUVUE® DEFINE®, the location of pigment was completely enclosed within the lens matrix and not in contact with the ocular surface (Figure 4). The mean depth of pigment was 10.5 microns below the surface of the lens.

Figure 4 SEM images of 1-DAY ACUVUE® DEFINE® in cross-section (500X and 2000X) show the pigment particles below the front surface of the lens.

Atomic Force Microscopy

AFM is a very high-resolution type of scanning probe microscopy, which can image and measure a materials' surface on the nanoscale level. Measures include RMS (Root Mean Square) Roughness, which

assesses the average roughness of a given area, and Peak-to-Peak, the difference in height of the tallest peak to the lowest valley of a given area. The lower the value of RMS Roughness, the smoother the surface of the material.

Results of the AFM analysis (using the Dimension Icon AFM from Bruker Nano) showed that 1-DAY ACUVUE® DEFINE®

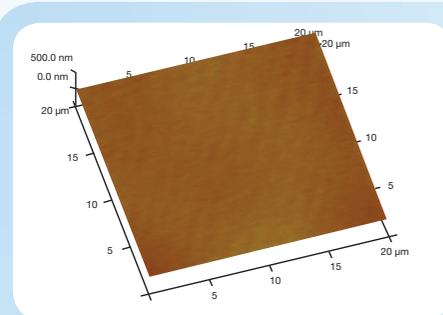


Figure 5 Figure Atomic Force Microscopy shows that 1-DAY ACUVUE® DEFINE® has low Root Mean Square (RMS) and Peak-to-Peak values on the pigmented surfaces and roughness values with low variability

lenses had significantly lower RMS roughness values in the pigmented area of the lens than the other cosmetic lens types tested (Figure 5).^{22,23} With 1-DAY ACUVUE® DEFINE®, the level of surface smoothness in areas of enclosed pigment was comparable to surface smoothness in non-pigmented areas.

To summarise, 1-DAY ACUVUE® DEFINE® has material properties similar to 1-DAY ACUVUE® MOIST®. Lens modulus, CoF, Dk/t and UV blocking are similar for the two lenses. CoF testing shows similar levels of lubricity between both the pigmented and non-pigmented areas. SEM images of the lens in cross-section show the pigment particles completely enclosed below the front surface of the lens. And AFM measurements show similar levels of roughness between the pigmented and non-pigmented areas.

Clinical performance

To investigate the clinical performance of 1-DAY ACUVUE® DEFINE® a four-visit, bilateral cross-over, randomised, one-week evaluation was conducted at 15 sites in the US.²⁴ Subjects were required to be female, existing daily wear soft contact lens wearers and aged between 18-34 years. Inclusion criteria were contact lens sphere powers from -1.00D to -4.50D and astigmatism ≤0.75D in both eyes.

Subjects were randomly assigned to be fitted with either 1-DAY ACUVUE® DEFINE® or 1-DAY ACUVUE® MOIST® lenses which they wore for 7-9 days before the follow-up visit. After a 1-3 day wash-out period they were fitted with the other lens type and again returned for a follow-up 7-9 days later. Subjects wore their lenses for at least six consecutive hours before their follow-up visits.

A total of 252 subjects completed the study (mean age 25 years). Main outcomes were logMAR visual acuity, lens fit acceptance and ocular physiology, along with overall satisfaction with quality of vision, comfort and handling.

Lens fit acceptance

No lenses were deemed to have an unacceptable fit for either lens type at the fitting or dispensing visits, showing the ease of transition from one lens to the other. An acceptable lens fit was defined as having complete corneal coverage in all directions of gaze (ie no limbal exposure), no edge lift or lens fluting, and acceptable lens movement (minimal, optimal, moderate) in at least one of three categories (primary gaze, upgaze, and lens tightness [push-up test] in primary gaze).

Importantly for an eye enhancement lens, where good centration is crucial to the cosmetic effect, all lenses were either centred or de-centred by <500 microns when viewed under 10X magnification by slit lamp biomicroscopy.

Ocular physiology

Almost all eyes wearing 1-DAY ACUVUE® DEFINE® displayed Grade 0 or 1 corneal staining (99.6 per cent), and all showed Grade 0 or 1 conjunctival injection or tarsal abnormalities at the follow-up visit. 1-DAY ACUVUE® DEFINE® met the primary hypothesis of non-inferior for corneal staining, with similar conjunctival injection and tarsal abnormalities compared to 1-DAY ACUVUE® MOIST®.

Comfort

Overall comfort was rated excellent/very good/good by 89 per cent of subjects when wearing 1-DAY ACUVUE® DEFINE® compared to 87 per cent when wearing 1-DAY ACUVUE® MOIST® (Figure 6).

Visual acuity for all eyes at the dispensing visit showed that monocular VA with 1-DAY ACUVUE® DEFINE® was similar to that of 1-DAY ACUVUE® MOIST® (mean logMAR acuity -0.045 vs -0.055 respectively). The difference of -0.010 represents half a Snellen letter difference.

Vision Performance

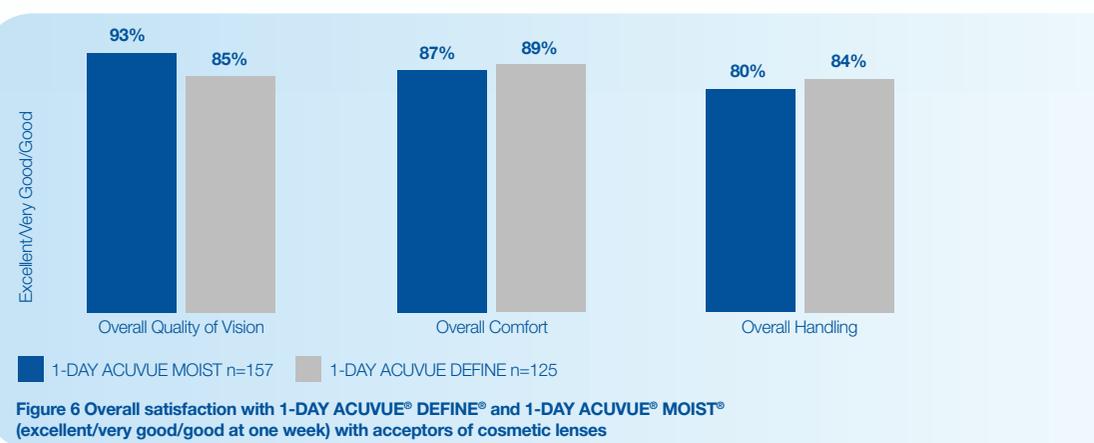
Overall quality of vision was rated subjectively as excellent/very good/good by 85 per cent of subjects when wearing 1-DAY ACUVUE® DEFINE® compared to 93 per cent when wearing 1-DAY ACUVUE® MOIST® (Figure 6). Although some patients may notice a small difference in subjective vision performance compared to 1-DAY

High proportions of subjects rated the lens excellent/very good for a wide range of cosmetic attributes, including 'enhance the appearance of their eyes' (82 per cent), 'create effect of shine and sparkle/luminosity' (77 per cent), 'look natural on eyes' (84 per cent), 'able to give their eyes greater definition' (74 per cent) and 'colour blends well with eyes' (79 per cent).

Product trial led to a high purchase interest; two thirds of consumers were interested in buying 1-DAY ACUVUE® DEFINE® after trying the lens.

Practitioner acceptance

During an in-market assessment in 20



ACUVUE® MOIST® (from peripheral awareness due to the lens' iris pattern), visual acuity is clinically equivalent with the two lens types.

Overall satisfaction

1-DAY ACUVUE® DEFINE® achieved similar subjective ratings for overall handling, as well as for overall quality of vision and overall comfort, as 1-DAY ACUVUE® MOIST® (Figure 6). More than eight in 10 subjects rated both lenses as excellent/very good/good for each of these attributes.

Cosmetic acceptance

To test the cosmetic acceptance of 1-DAY ACUVUE® DEFINE®, a non-dispensing evaluation was conducted among 141 existing soft contact lens wearers.²⁵

practices across the UK (10 multiples and 10 independents), eye care practitioners completed a follow-up questionnaire on their experiences with 1-DAY ACUVUE® DEFINE®.⁸

Most were satisfied (very satisfied/quite satisfied) with the overall performance of the lens (92 per cent). All rated the patient experience of comfort with the lens as excellent/very good/good and all rated lens fit in these categories too. In addition, 92 per cent rated the patient experience of vision in these top three ratings.

On cosmetic appearance, 83 per cent of practitioners rated their overall opinion of the cosmetic effect with 1-DAY ACUVUE® DEFINE® as very good/good and a similarly high proportion (85 per cent) said the lens met or exceeded their expectations and they would actively recommend it to their patient.

In summary, 1-DAY ACUVUE® DEFINE® shows a similar performance to 1-DAY ACUVUE® MOIST® at one week for lens fit, ocular physiology, subjective comfort, handling and visual acuity. The addition of pigment enclosed beneath the front surface of 1-DAY ACUVUE® DEFINE® does not impact these features when compared to the clear, equivalent etafilcon A daily disposable lens.²⁴

Patients show high acceptance of the cosmetic effect of 1-DAY ACUVUE® DEFINE®, high satisfaction with the lens and are highly likely to purchase after trial. As we saw in Part one, potential buyers are likely to be females aged 18-30 who invest in their appearance through the use of makeup and eye-enhancing skincare/beauty products and keep up with trends in these products.⁹ Practitioners are also very receptive to the new lens and rate its performance highly.

Conclusions

1-DAY ACUVUE® DEFINE® with LACREON® from Johnson & Johnson Vision care is a new concept in contact lenses.

The lens not only enhances the natural beauty of the patient's eyes and adds definition by using a new design philosophy and novel lens technologies; it also overcomes many of the limitations of traditional coloured lenses and delivers excellent clinical performance, along with the benefits of the daily disposable modality. With just two pattern designs, the lens is simple to fit and takes little chair time.

By addressing the unmet needs of patients and practitioners, 1-DAY ACUVUE® DEFINE® has the potential to open up new opportunities for your practice, with appearance that your patients will appreciate and performance that you can trust.

A simple fitting procedure

With a high fit acceptance rate, lens selection is simple and quick. During an in-market assessment of the lens in 20 UK practices, practitioners were satisfied with the chair time it took to fit the lenses.⁸

Let patients see the effect on the eye rather than how it appears in the blister. Try both variants, since some patients may make an unexpected choice based on their eye colour, and agree which one to trial first so the appearance can be compared with their natural eye.

Have a mirror handy for the patient to take a look at each step. Good lighting or natural daylight can help them see the effect more easily.

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