

From bottles to blisters

This year marks the 20th anniversary of the introduction of the first disposable soft contact lens to the UK. Contact lens historian and practitioner **Andrew Gasson** reviews innovations in disposable lenses to the present day, and charts the role of Johnson & Johnson Vision Care in their development

In the last 20 years there have arguably been more developments in the field of contact lenses than in the whole of the preceding century. In 1988, almost exactly 100 years after the first scleral contact lens was recorded in the late 1880s, the first disposable lens was introduced into the UK.

A look back at the history of contact lenses shows that a number of key events followed the introduction of the original glass shells: the application of PMMA in 1937; the corneal lens in 1947; the soft lens by Wichterle in 1961; the fully-fledged, mass-produced, disposable lens by Johnson & Johnson Vision Care in 1988; and the first silicone hydrogels in 1999. Of these events, the arrival of disposable lenses has almost certainly had the greatest effect on practitioners, the public and contact lens manufacturing.

With remarkable prescience, the concept of disposability was predicted by Wichterle himself during the 1960s;¹ and in a 1980s interview when, speaking of lens deposits, he said: 'Discard the coated lenses and replace them with new ones. What we need is an inexpensive, absolutely reproducible lens so the [replacement lens] will not require another fitting.'²

The original concept of disposability, developed by Johnson & Johnson and endorsed by the Food and Drug Administration (FDA) in the US, was that no lens should ever be reused. It should either be for single use and thrown away daily or worn for a prescribed period of extended wear and similarly discarded on removal. This, of course, only became possible in 1988 with the arrival in the UK of the original Acuvue lens (Figure 1), which introduced several ideas new to contact lens practice.

Practitioners had to familiarise themselves with single-use blister packs instead of glass vials which required crimp sealing and autoclaving. There were now diagnostic lenses to replace reusable trial lenses – if a lens was unsuitable on the eye, it was immediately discarded. Practitioners were initially required to purchase

Figure 1
The original Acuvue lens in its plastics container and, 20 years on, the latest addition 1-Day Acuvue TruEye



a comprehensive fitting stock from which to dispense lenses immediately to patients and suddenly they had to come to terms with stock control and a system of packaging to accommodate three or six months' supply of lenses. Johnson & Johnson also led the way in encouraging the use of standing orders and direct debits.

The introduction of the Acuvue lens more or less reinvented extended wear, which had fallen out of favour. There was a two-tier pricing structure to correlate with weekly use for extended wear and fortnightly replacement for daily wear. There was also comprehensive support from a UK professional services team with advice on fitting and any clinical problems. In fact Johnson & Johnson has always employed key professional personnel to assist practitioners, maintain their ongoing educational programmes, and promote research and development. This culminated in 2006 with the opening of its first Vision Care Institute in Europe.

New frontiers

The continuing success of Acuvue lenses has been based in part on the ground-breaking material, etafilcon A, a group IV polymer. This had originally been developed in Jacksonville, Florida, by Seymour Marco of Frontier Contact Lenses, a relatively small US manufacturer. The material had received FDA approval in the US during 1978 and the company was bought by Johnson & Johnson in 1981, subsequently to be renamed Vistakon. In 1984 it acquired the rights to the 'stabilised soft moulding' process developed by Michael Bay of Copenhagen for the rudimentary disposable

Danalens. That, however, is where the similarity ended. The expertise of a major pharmaceutical company prepared to make the large financial investment necessary brought disposable lenses to the next stage. Vistakon spent several years developing the final product, employed the more stable and reproducible etafilcon A material, refined the previously labour-intensive manufacturing process and originated truly airtight and sterile packaging in the form of the now-ubiquitous blister packs. The disposable lens as we know it today had arrived.

The contact lens world was already becoming accustomed to the notion of frequent replacement on a three-monthly basis,³ for example with the Freshlens system from Bausch & Lomb. But it fell to Johnson & Johnson to set the scene for the explosion in disposable lenses to come. These included monthly lenses such as SeeQuence by Bausch & Lomb, soon to be followed by Precision UV from Pilkington and Surevue by Johnson & Johnson as a less expensive alternative to Acuvue with easier handling properties (Figure 2). The disposable route has subsequently been followed by all major contact lens manufacturers to the almost complete exclusion of conventional lenses.

Most practitioners, however, not overly enthusiastic about extended wear, subverted the single-use concept and changed daily-wear frequent replacement – three monthly – into daily-wear 'very frequent replacement' – fortnightly or monthly. Disposable lenses became the accepted term for lenses replaced at intervals of one month or less.

The many advantages of disposability ►

Contact lenses

were soon recognised. There were, understandably, some potential disadvantages, many of which have since been overcome. Table 1 summarises the advantages and disadvantages of the original disposable lenses, along with the additional advantages 20 years on and how the potential drawbacks with these lenses have changed during that time.

Over the years, there have been significant developments since the first disposable lens was introduced. In 1997 Johnson & Johnson responded to concerns about ocular damage from ultraviolet (UV) radiation⁴ and, although not the first to do so, began to include such protection as a standard feature in all subsequent lenses. The following year, it relaunched the original lens as the Acuvue 2 with a new edge design, easier handling and improved comfort. Johnson & Johnson also acknowledged environmental issues and by this time the original plastics containers had been replaced by much smaller and recyclable cardboard boxes. The Acuvue 2 range was later supplemented by Acuvue 2 Colours opaque and enhancer lenses.

Specialist lenses

By the late 1990s disposables had frequently become the lenses of first choice.⁵ Practitioners were impatient for specialist lenses such as bifocals and torics on which various laboratories were known to be working. 1995 saw the introduction of the first monthly disposable lenses for astigmatism, Focus Toric by CIBA Vision and FreshLook Toric by Wesley-Jessen, the former company absorbing the latter in 2000. The new century saw Johnson & Johnson bring its own toric to the market. The company followed its established policy of developing a new lens for the purpose rather than adapting an existing design. In this case dual thin zones were employed to give both good comfort and stability.

In 1996, Bausch & Lomb introduced a monthly disposable multifocal in the form of the Occasions lens, based on its earlier conventional PA1 design. Johnson & Johnson launched during 1998 its Acuvue Bifocal, an innovative

TABLE 1 Advantages and disadvantages of disposable contact lenses

1988	2008
Advantages of original disposable contact lenses	Additional advantages of more recent disposable contact lenses
Fewer complications (inflammatory, allergic or toxic)	Improved performance for comfort, handling, lens design
Spare lenses always available	Improved oxygen performance of silicone hydrogel materials
Minimal deposition	Wider range of fittings and powers
Improved reproducibility	Range of options for astigmats or presbyopes
Minimal replacement cost for loss or damage	Further improvements in manufacturing (reproducibility, quality)
Minimal or no time needed for lens cleaning	Innovative packaging
Cost savings on solutions	UV protection
Easier to fit	
Disadvantages of original disposable CLs	Disadvantages of current disposable CLs
Harder to handle	Mail order and internet supply reduces practitioner control
Restricted range of fittings and powers	Limited range for specialist and high prescriptions
No torics or bifocals	
Increased cost on an annual basis	
Uncertain management of patient compliance	
With clinical problems, patients may replace lenses rather than seek professional advice	

design described as 'pupil intelligent' – a four-zone bifocal with a full range of reading additions. Once again there was a complete system of storage, display and practitioner support. These were followed by other multifocals, such as Rhythmic 1 from Essilor, Progressives from CIBA Vision and Frequency from CooperVision.

Daily disposables

Having been shown the advantages of disposability, practitioners were eager for the next major development, daily disposable lenses. By 1995, these had duly appeared in the UK.

With 1-Day Acuvue (Figure 3), Johnson & Johnson was able to return to the original concept of disposability that no lens should be reused. Once again the company waited until it had

evolved a complete system for the practitioner, utilising the proven etafilcon A material, a comprehensive range of powers and newly designed lens storage and packaging. It was followed in early 1996 by Bausch & Lomb, which had acquired the Award lens manufactured in Scotland, and by CIBA Vision with its Focus Dailies in 1997.

Daily disposables have provided almost as much of a revolution in contact lens practice as disposables in general. They are the ideal lenses for patients who want an irregular wearing schedule for sports or social events. They eliminate altogether the need for cleaning and solutions – ideal for the atopic and indolent patient alike. Emergency visits are less common and they are also an excellent way to rehabilitate patients following contact

TABLE 2 Time line for disposable lens developments in the UK

Acuvue weekly disposable soft contact lens. B&L SeeQUENCE monthly disposable	1-Day Acuvue and Award 1-Day disposable. CIBA Vision Focus Toric monthly	B&L Occasions Multifocal	UV protection added to Acuvue range	Acuvue Bifocal	Acuvue 2 with new edge design and better handling. B&L PureVision and Focus Night & Day silicone hydrogels
1988	1995	1996	1997	1998	1999



lens-associated papillary conjunctivitis, infection or other interruption to their wearing schedule. These advantages had immediate appeal to both the UK profession and public and by 2007 daily disposables accounted for 40 per cent of new contact lens fittings in the UK,⁶ a higher proportion than in the US, the home of disposability.

Since 2001, new designs have emerged including the first multifocal and toric daily disposables, Focus Dailies Progressives and Focus Dailies Toric, and the first daily disposable coloured lens, 1-Day Acuvue Colours. More recently, a second generation of daily disposables has been introduced in which various additives are incorporated within the lens or packaging solution to enhance wearer comfort. Launched in the UK in 2006, 1-Day Acuvue Moist with Lacreon Technology was a recent addition to the Acuvue daily disposable range.

Silicone hydrogels

The next major contact lens development occurred in 1999 with the launch of silicone hydrogels for extended wear,⁷ by Bausch & Lomb (PureVision) and CIBA Vision (Focus Night & Day). Disposables had in a way come full circle. The original Acuvue was thought to be a safer route for extended wear than conventional, non-disposable lenses due to their more frequent replacement and fewer nights of consecutive wear. While extended wear with disposable lenses reduced many inflammatory events associated with overnight wear, disappointingly it did not result in a major reduction in the incidence of microbial keratitis. Silicone hydrogels offer significantly greater oxygen supply to the cornea compared to hydrogel materials, easily fulfilling the Holden-Mertz oxygen criterion for closed-eye conditions.⁸ It was therefore considered that the

lenses launched in 1999 would be safer for extended wear. With the benefit of hindsight, we now know that with overnight wear the incidence of corneal infection with silicone hydrogel lenses is similar to that for traditional hydrogels but the severity is less.⁹

Disposable lenses had returned to the original concept of single use. They now offered what might be termed the two poles of convenience: daily disposables with nothing for the patient to do but insert, remove and discard; or extended wear in which lenses were inserted with no action required by the patient until replacement up to 30 days later. Silicone hydrogel was the first material to be introduced solely in disposable form – the opposite of hydrogel lens development – and it is ironic that in the past year or so, non-disposable lenses such as CIBA Vision's custom-made lens, Air Optix Individual, have appeared in this material.

Silicone hydrogels were immediately welcomed by practitioners for their excellent physiological properties but, partly because of the higher price and recommendation for 30 nights' extended wear, their uptake began fairly slowly and had only achieved 1 per cent of new fittings by 2001.¹⁰ Not all practitioners were comfortable with extended wear and indeed many were very soon requesting lenses in the new material for purely daily use without the premium attached for overnight wear.

Johnson & Johnson was able to satisfy this demand with the launch in the UK during 2004 of Acuvue Advance with HydraClear. This was the first of what has been described as the second generation of silicone hydrogels. The key difference was a much lower modulus of elasticity. This created a more flexible material (galyfilcon A) which, for many

patients, gave better initial comfort and a lower incidence of arcuate staining. In addition, the galyfilcon A material includes within the polymer a wetting agent (PVP) which helps make the lens wettable throughout. The galyfilcon A material also eliminates the need for surface treatment and produces a lens with better wettability and improved comfort at the end of the day. Acuvue Advance was immediately available with two fittings and a full range of powers. Its ready acceptance allowed Johnson & Johnson to use it as the basis for the toric version, Acuvue Advance for Astigmatism, introduced the following year. This employed the new Accelerated Stabilisation Design, which has subsequently been used in its daily disposable hydrogel toric.

In 2005, Acuvue Advance was complemented by Acuvue Oasys (senofilcon A) using related technology called HydraClear Plus. The improved Dk and wettability of these and other silicone hydrogels, such as Air Optix (CIBA Vision), meant that lenses began to be used for either daily or weekly extended wear. With these advances, prescribing of silicone hydrogels for new patients had risen to 15 per cent of new fits by 2005.¹¹ There have since been several other second-generation silicone hydrogels including Biofinity (CooperVision), Premio (Menicon) and a new version of the original PureVision (Bausch & Lomb) which is reported to have a reduced modulus.

More than a million

Since the introduction of the first disposable lenses some 20 years ago, new contact lens designs and materials have appeared with almost exponential regularity. In the UK, soft lenses represented 97 per cent of new fits in 2007, with disposables accounting for 98 per cent of these.⁶ Silicone hydrogels, originally slow starters, accounted for a rapidly increasing 28 per cent of new fittings in 2007 and for more than half of all soft lens refits (52 per cent).⁶ With daily disposables, we can safely say that well over a million new lenses are now opened and used every day in the UK.

Contact lens practitioners and

Figure 2
Acuvue was followed by the Surevue lens, with easier handling properties

Figure 3
The 1-Day Acuvue lens was introduced in the UK in 1995



Acuvue Toric	CIBA Vision Focus Dailies Progressives	CIBA Vision Focus Dailies Toric	Acuvue Advance with HydraClear	Acuvue Oasys with HydraClear Plus. Acuvue Advance for Astigmatism	1-Day Acuvue Moist	1-Day Acuvue for Astigmatism	1-Day Acuvue TruEye silicone hydrogel
2000	2001	2002	2004	2005	2006	2007	2008

manufacturers have embraced disposable lenses for clinical, financial and logistical reasons. In addition, some patients now decline professional advice to have conventionally replaced soft or gas permeable lenses, even when these lenses may be more appropriate, because of the lure of disposability.

Another concern is the universal availability of lenses from non-professional sources – mail order and the internet – which reduces an essential element of practitioner control. Such considerations have led many practitioners to change their professional fee structure and charge more realistically for their time. Patients, on the other hand, demand comfort and convenience, but at the same time have readily assimilated the advantages in hygiene, oxygen performance and UV protection that disposable lenses can provide.

Looking at the time line in Table 2 we can see that Johnson & Johnson has been at the forefront of disposable lens innovation. It has not necessarily always been the first but has consistently decided on a clinical objective, developed the material, manufacturing process and lens for that specific purpose, and set this within a complete system of practitioner support, supply and information.

Present and future

But what would we practitioners ideally like now? The gradual introduction of custom-made silicone hydrogels by various companies is a welcome step but we need a wider range of powers in all disposable lenses, up to perhaps $\pm 20D$. This would accommodate the high prescriptions that used to be available in the conventional lenses which have steadily been discontinued. Johnson & Johnson currently offers a wide range from $-12.00D$ to $+8.00D$ but an extension by all manufacturers would solve many clinical problems.

Next, we would like the greater availability of specialist lenses such as multifocals and torics in daily disposable form. Finally, the current philosopher's stone of contact lens practice is a silicone hydrogel daily disposable that would combine the best physiological characteristics with the ultimate in disposability. Twenty years after the first disposables appeared in the UK, such a lens has just been announced. ●

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Two of those closely involved in the launch of the first disposable lenses in the UK describe their recollections of that time

As country manager for Johnson & Johnson's UK contact lens division, Vistakon, **Martin Edwards** was responsible for introducing both Acuvue and 1-Day Acuvue. Vistakon was unknown in the UK in 1986 when Edwards was invited to join the company but a visit to its Jacksonville, Florida facility convinced him to be on board.

The UK was to be the test market for Acuvue but the launch was switched to the US, leaving the team of three people in the UK office with just a conventional toric soft lens, Vistamarc (pictured), to market and distribute. But setting up a supply chain involving a live link to the US and same-day dispatch proved an invaluable experience for the advent of disposable lenses, where one of the key factors was to be continuity of supply.

For Edwards, other key issues in the early days of disposables were reproducibility, patient compliance and pricing. 'Reproducibility was not a problem with Acuvue and real benefits to patients meant that compliance was less of a concern than expected,' he says. To tackle pricing, J&J's approach was to introduce a standing order system to help practitioners set a fee pattern.

Edwards says there was enthusiasm for disposables but also an understandable fear. 'At the launch meetings we gave practitioners samples to handle and then told them to throw the lenses away – they had real difficulty with that.' The fear factor was even greater when 1-Day Acuvue was introduced in 1995. 'To go from fortnightly disposal to throwing them away every day – that's a lot of lenses.'

Yet disposables very soon came to dominate the market and although growth in the overall number of contact lens wearers was more elusive, practitioners saw an increase in revenue

that Edwards describes as 'massive'. Now retired from the industry, he says J&J was lucky to be first in the market and to establish itself before others came in. 'It was the most phenomenal time in contact lenses and great to be part of it.'

Twenty years ago, Glasgow optometrist **Peter Ivins** was among the first in the UK to fit disposable lenses, as one of six practitioners involved in pre-marketing trials for Acuvue. Now commercial director for Black & Lizards, Ivins presented at launch events around the country and found many of his colleagues were initially sceptical. 'The big issues for practitioners were reproducibility and extended wear, since the lens was approved for overnight use,' he recalls.

But the commercial potential for disposable lenses and the advantages of regular payments soon became clear. 'Bausch & Lomb's Freshlens programme was introduced at about the same time and the concept of paying by standing order, or later by direct debit, quickly became closely associated with disposables.'

The new modality also generated interest outside the profession and Ivins was interviewed widely on TV and radio. 'For the media it was huge – they really liked the idea. It was so alien to be throwing lenses away.'

Despite the success of the first disposables, the daily disposable – worn once and thrown away – seemed unachievable. 'It was unimaginable. You couldn't make enough lenses in a million years,' says Ivins. But by 1995, the daily disposable had become a reality in the UK.

For Ivins, there have been few developments that have moved contact lenses forward from a consumer point of view but the advent of disposable lenses has been among the most important. 'Without a doubt, it was one of the key milestones,' he observes.



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