World's first daily disposable flat pack contact lens

The Miru 1day Menicon Flat Pack contact lens features a new flat package design, and clinical evaluation shows benefits that may positively influence patients' satisfaction. **Hideji Ichijima** and **Craig Smith** review the package functionality and clinical performance

The most striking characteristic of the Miru 1day Menicon Flat Pack, launched in the domestic market in Japan (under the name Magic) by Menicon in November 2011, is a newly designed flat package approximately 1mm thick (Figure 1). This is the world's thinnest package for disposable and frequent replacement contact lenses without the usual blister-pack shape. However, compact size is not the only thing that was demanded of this product; comfort and safety were also addressed.

Miru 1day is manufactured from poly (HEMA-GMA) (hioxifilcon A) with 57 per cent water content, which is classified by the US Food and Drug Administration as Group II (high water content, nonionic material). GMA (glycerol monomethacrylate) has a molecular structure similar to HEMA (hydroxyethyl methacrylate), but two times more hydroxyl groups (-OH). The structure of the GMA chains found in (HEMA-GMA) is similar to the structure of oligosaccharide which makes up a significant proportion of mucin, the body's own natural wetting substance, found in tears.[1] Therefore, it is expected that the poly (HEMA-GMA) lens' excellent hydrophilic property and water retention capability will lead to better comfort and less dryness.

Menicon established a new contact lens manufacturing plant in Singapore in 2011 to produce the lens. Now in 2013, the company is launching the Miru 1day Menicon Flat Pack in the European market. Table 1 shows the specifications of the lens.

Package functionality

Pack structure

Miru 1day Menicon Flat Pack is packed in a dual-side aluminum-sealed primary package, which is designed to eliminate frustration for wearers. Figure 2 shows how to remove a lens from the flat package. There are three kinds of frustration with lens handling that have been eliminated; the first of which addresses the peeling action used to open the blister pack. Less than 5N of force is required to open the Miru 1day package, compared to a mean opening force of 15 to 20N for usual blister packs. This allows wearers to more easily control and open their lens packaging with freshly washed hands. In addition, the Miru 1day package contains only 0.2mL of shipping solution, in order to allow easier lens handling and reduce solution spillage.

Figure 1 The Miru 1day Menicon Flat Pack showing (left) secondary package containing 30 lenses and (right) side-view of primary package with approximately 1mm thickness including three lenses

The second frustration is the identification of lens orientation. The Miru 1day package stores the lens with the outer (front) surface always facing 'up' using proprietary and novel flat pack technology. This makes the lens easy to pick up in one smooth motion without any confusion about its orientation, and negates the need to look for anti-inversion marks. In addition, by pinching the outer surface, the lens can be removed without any need to touch the inner surface. The structure of the container makes it difficult to touch the inner (back) surface of the lens.

The third is the shape-holding stability of the lens. When a Miru 1day lens is positioned with the inner surface up (concave surface upwards), on the index finger of the dominant hand in readiness for insertion, it maintains a stable form. These factors have combined to greatly reduce frustration during lens handling.

Reduced microbial contamination

The primary contamination risk for daily disposable contact lenses is at the time of lens insertion; that is, there is a risk of microbial contamination through transfer from wearers' fingers. The lens' outer surface always facing 'up' is guaranteed for Miru 1day, and by pinching the outer surface the lens can be easily removed from the package without touching the inner surface. Therefore, the inner surface of the Miru 1day lens is better protected from microbial contamination.

The results of an *in vitro* contamination study conducted by Nomachi *et al*[2] confirmed the adherence of microbial colonies to both the inner and outer surfaces of the usual blister-packed contact lenses tested. In contrast with this, colony adherence was, however, observed only on the outer surface of the Miru 1day lens, and no colony formation was observed on the inner surface. Thus, the authors demonstrated the efficacy of a flat package in reducing microbial contamination of Miru 1day lenses.

Other advantages of the flat pack

With usual blister-packed daily disposable contact lens products, non-compliant wearers could use a blister pack instead of a storage case without throwing away, and reuse their lenses the following day. Boost *et al*[3] reported that such violation would increase the risk of microbial keratitis. As Miru 1day is packed in a flat package with approximately 0.2mL of shipping solution and lacking a blister shape, this practice becomes physically impossible. In addition, the Miru 1day lens package has been designed to emulate a well-known single-use device, the sticking plaster. It is hoped that wearer compliance can be improved by these design and shape inputs.

One primary package strip of Miru 1day containing three lenses has a size of 9.3mm by 4.2mm and is approximately 1mm thick. You can easily store it in your bag, wallet etc, and its portability makes it especially suitable for travel, sports, and other occasions.

One secondary packed-product of Miru 1day contains 30 lenses (10 strips), with a volume approximately two thirds to one half of usual blister-packed daily disposable contact lenses. This eliminates the need for retailers and practitioners at eye clinics to keep large stock areas, and they can show Miru 1day attractively with smaller shelf space.

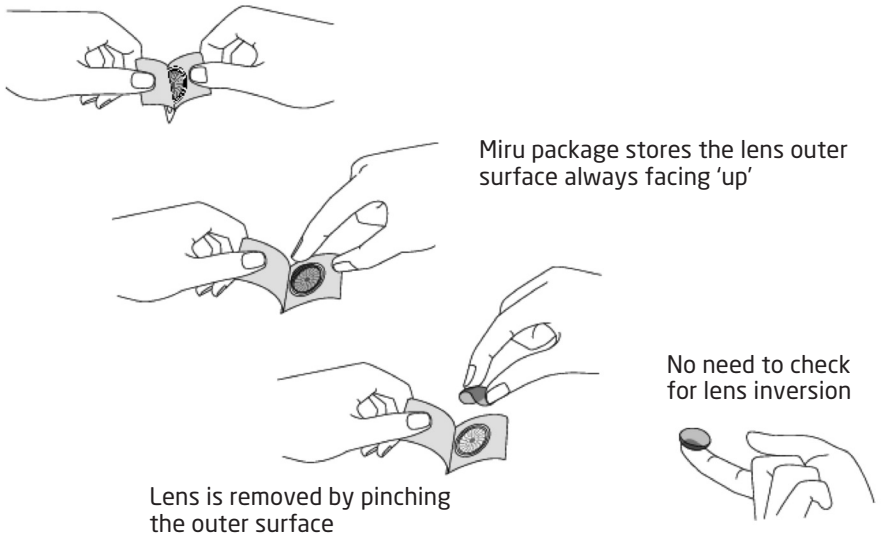

Figure 2 How to remove a Miru 1day lens from the package

Clinical performance

A clinical study was undertaken to investigate the effect of the hydrophilic properties and water-retention characteristics of the poly (HEMA-GMA) material of Miru 1day Menicon Flat Pack on comfort and dryness in contact lens wearers.

Method

A prospective clinical evaluation of Miru 1day was carried out at one eye clinic in Tokyo, Japan from March to May 2012.[4] The study involved 117 subjects (44 male, 73 female, total of 234 eyes, average age 31.8, range 13 to 60 years old, spherical power -0.50D to -6.00D, cylinder power not more than -1.50D, without any ocular abnormalities except for refractive error). Subjects comprised 97 habitual soft lens wearers, eight rigid gas-permeable lens wearers and 12 spectacle users. The brand names of subjects' habitual contact lenses are shown in Figure 3.

After routine eye examination at the initial fitting/dispensing visit and baseline assessments with their existing vision correction, subjects were asked to wear Miru 1day lenses for at least eight hours' daily wear for two weeks, discarding the lenses daily. At the two-week follow-up visit, subjects completed a questionnaire. For previous lens wearers, comfort and dryness were compared between habitual lenses and Miru 1day lenses overall (immediately after insertion, morning, afternoon, evening, and immediately before removing at end of day) using visual analogue scales (VAS: inferior 0 to superior 100). All subjects rated subjective vision on a four-point scale ('good', 'fair', 'somewhat poor' and 'poor') for immediately after insertion, morning, afternoon, and night.

Comparative evaluation for comfort, dryness, vision and handling was performed between habitual lenses and Miru 1day, and all subjects recorded their degree of satisfaction with Miru 1day on a four-point scale ('satisfied', 'mostly satisfied', 'a bit dissatisfied' and 'dissatisfied'). Corneal and bulbar conjunctival staining with sodium fluorescein eye drops was compared between habitual lenses at baseline and Miru 1day worn for two weeks using a slit lamp biomicroscope.

Results

All 117 subjects successfully completed the study and no adverse events were reported.

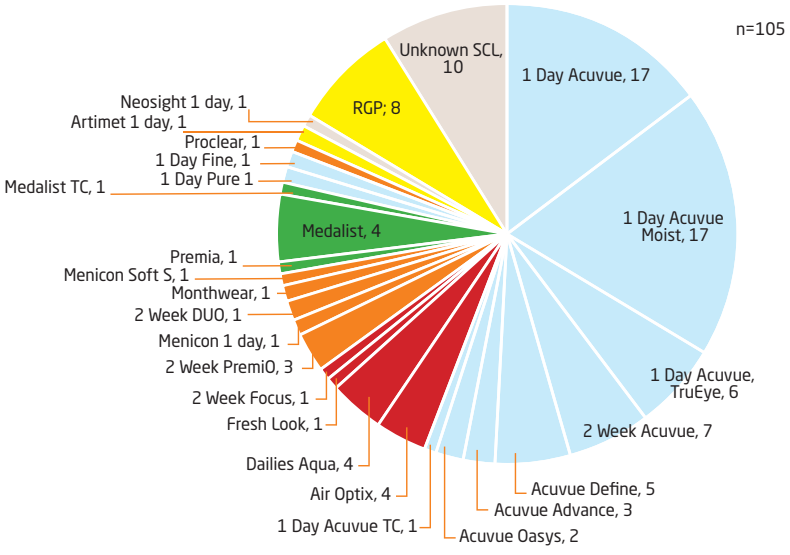

Figure 3 Brand names of habitual contact lenses worn by subjects in clinical evaluation

Comfort
Subjective comfort of Miru 1day was evaluated at five intervals with a four-point scale as described above. Of all subjects, 77.7 per cent rated comfort 'good' or 'fair' overall. As illustrated by the median VAS score for comfort in Figure 4, previous lens wearers scored the Miru 1day lens significantly higher for comfort than their habitual lenses (80.0 vs 75.0, P<0.01, Wilcoxon signed rank test).

Dryness
Subjective dryness with the Miru 1day lens was also evaluated at five intervals with four grades. Of all subjects, 73.3 per cent responded 'good' or 'fair' overall. Figure 5 shows median VAS scores for dryness in previous lens wearers. Miru 1day was associated with significantly less dryness (ie higher score) than habitual lenses (75.0 vs 62.0, P<0.01, Wilcoxon signed rank test).

Vision
The subjective ratings for vision with the Miru 1day lens were excellent, with 86.2 per cent of all responses 'good' or 'fair' overall. The lens was rated highly at all four intervals during the day (Figure 6).

Comparative evaluation
The results of comparative subjective evaluation of comfort, dryness, vision and handling for previous lens wearers (except for RGP wearers) are shown in Figure 7. Overall, the ratio of subjects who answered 'Miru 1day was better' was significantly higher than 'habitual lenses were better' (P<0.05, McNemar test). With regard to handling the lens, this comparative evaluation included ease of opening, removal from package, insertion/taking out, as well as portability. Wearers mentioned 'ease of opening', 'no need to check whether the lens is inside-out' and 'less spilling' among reasons why they preferred Miru 1day.

Satisfaction
Most subjects answered that they were satisfied with and would continue to use Miru 1day. The degrees of satisfaction after wearing Miru 1day for two weeks were 'satisfied' (69.2 per cent), 'mostly satisfied' (21.4 per cent), 'a bit dissatisfied' (6.0 per cent), and 'dissatisfied' (3.4 per cent). Furthermore, results for the question, 'Would you like to continue using Miru 1day?' were 47.0 per cent 'definitely yes', 41.0 per cent 'somewhat yes', 8.5 per cent 'somewhat no', and 3.4 per cent 'definitely no'.

Negative answers for the Miru 1day lens included presbyopia, preferring habitual cosmetic lenses, requiring a higher power (the highest available was -6.00D at the time of the study) and itching.

TABLE 1
Specifications of Miru 1day Menicon Flat Pack

Material	hioxifilcon A (FDA group II)
Water content	57%
Base curve	8.6mm
Diameter	14.2mm
Handling tint	Light blue
Centre thickness	0.10mm (-3.00D)
Power range	-0.50 to -6.00D (-0.25 steps) -6.50 to -10.00D (-0.50 steps)
Dk	19.0×10^{-11} (cm^2/sec).(mLO_2/(mLxmmHg))

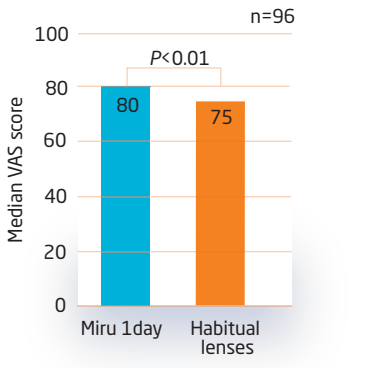

Figure 4 VAS score of comfort, Miru 1day at two weeks vs habitual lenses

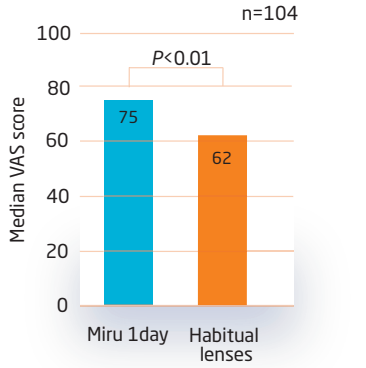

Figure 5 VAS score of dryness, Miru 1day at two weeks vs habitual lenses

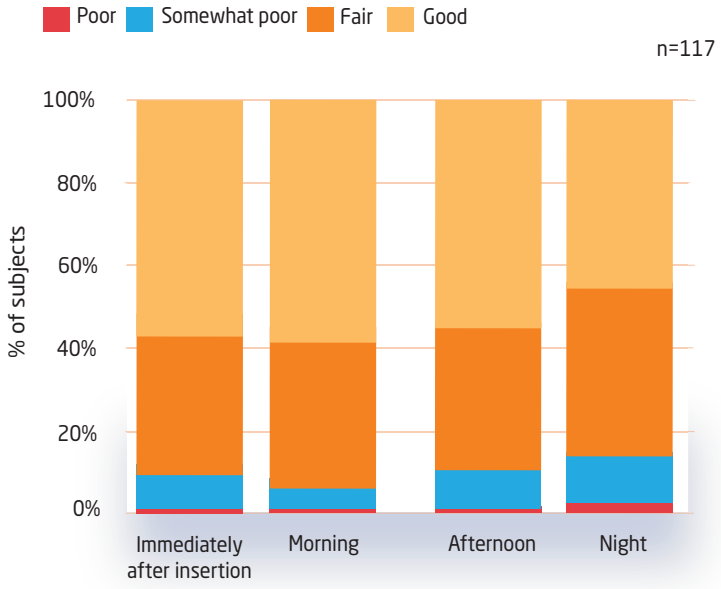

Figure 6 Subjective rating of vision with Miru 1day at two weeks

Slit lamp findings
Corneal and bulbar conjunctival staining was examined by slit lamp biomicroscopy after two weeks' daily wear of the Miru 1day lens, and compared with findings with habitual lenses at baseline (Figure 8). The proportion of subjects showing bulbar conjunctival staining with Miru 1day was significantly less than that with

their habitual lenses (7.0 per cent vs 18.3 per cent, P<0.01, Fisher exact test).

Discussion

The Miru 1day Menicon Flat Pack lens is manufactured from poly (HEMA-GMA) and is expected to have excellent hydrophilic properties and water-retention characteristics, leading to better comfort and less dryness due to its structure being similar to that of oligosaccharide. In this clinical evaluation, it was found that overall comfort and dryness while wearing the Miru 1day lens were significantly better than with subjects' habitual lenses. Vision with the Miru 1day lens was also good with 86.2 per cent satisfaction among subjects. It is thought that this can be attributed to the aberration controlling optical design and constantly changing aspheric optics over the power range in Miru 1day lenses.

Bulbar conjunctival staining with the Miru 1day lens was significantly less than that with habitual lenses. Lakkis and Brennan[5] reported that bulbar conjunctival staining which occurred with mechanical stress at the edge of hydrogel lenses was related to a sensation of dryness. Using ultra-high resolution optical coherence tomography, Shen *et al*[6] observed that bulbar conjunctival buildup and tear film gaps were associated with pressure from the lens edge, and suggested a relation to bulbar conjunctival staining. The edge design of the already thin Miru 1day retains a high-quality surface finish and tapered shape (via Menicon's proprietary Centraforming manufacturing technology). Given the lower sensation of dryness with the lens, it was thought that mechanical stress at the bulbar conjunctiva was reduced, and that these factors lessened bulbar conjunctival staining.

Conclusions

Miru 1day Menicon Flat Pack has a package function which is designed to eliminate lens handling frustrations and to reduce microbial contamination. The Miru 1day lens provides better comfort and less dryness than subjects' habitual contact lenses, and is considered to be a daily disposable soft contact lens with a high degree of satisfaction and less bulbar conjunctival staining.

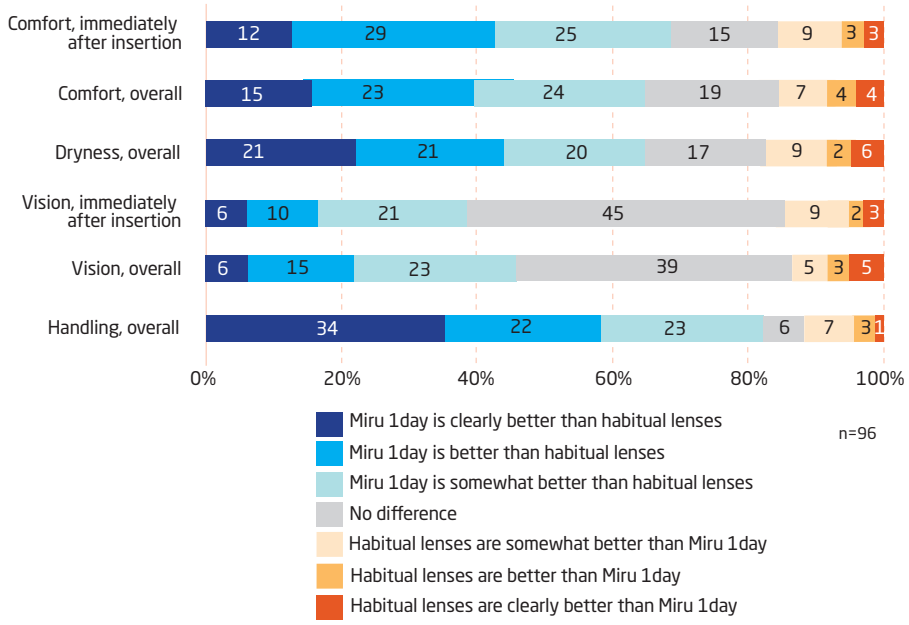

Figure 7 Comparative subjective evaluation of comfort, dryness, vision and handling, Miru 1day at two weeks vs habitual lenses

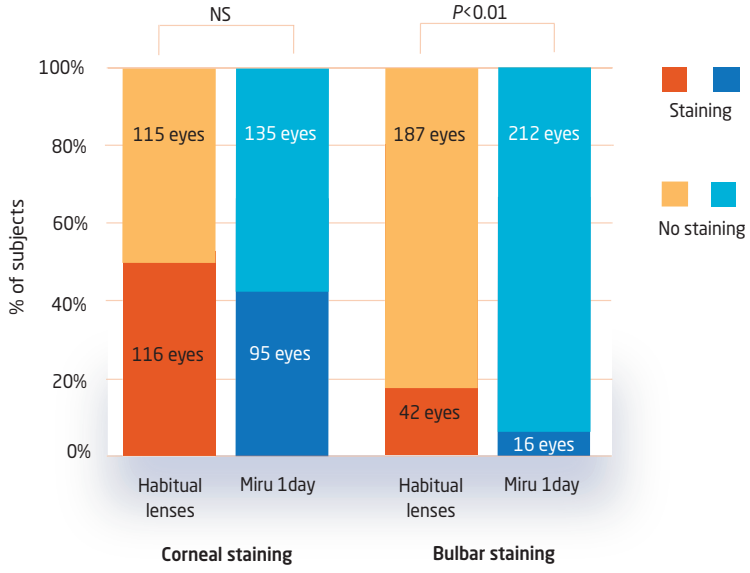

Figure 8 Corneal and bulbar conjunctival staining with Miru 1day at two weeks vs habitual lenses

References

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