



Performance of daily disposable contact lenses with moisturising agents

Dr Tim Giles and Mary Fahmy describe how moisturising agents influence the wear of daily contact lenses

Since daily disposable soft contact lenses were first introduced in Europe in 1996, the simplicity, convenience and clinical benefits of this modality have proven popular with patients and practitioners alike.

Daily disposable contact lenses are a leading mode of vision correction in Japan (56 per cent of fits) and the UK (35 per cent of fits)¹ and in Europe the number of daily disposable fits is growing. Daily disposable lenses are convenient, easy to care for and may provide patients with advantages over their current contact lens regimen. Daily disposable wearers are the most compliant with lens replacement,³ and non-compliance is a major concern for eye care practitioners.

Compared with conventional daily wear, daily disposable contact lens wearers experience improved comfort, better vision, increased wearing time, and fewer unscheduled visits.⁴ Patients who suffer from ocular allergies have also been shown to experience fewer symptoms when wearing daily disposables than with re-usable lenses.^{4,5}

Despite this success, dryness and discomfort with contact lens wearers still remain a concern. The frequency of self-reported dry eye is high, especially in contact lens wearers.⁶ Contact lens-induced discomfort has consistently been reported as the most common cause for discontinuing contact lens wear and is most often or synonymously described by patients as dryness.⁷ Comfort of contact is also a major concern amongst glasses wearers,⁸ creating a possible barrier to trying contact lenses in the first place. Manufacturers have continued to seek improvements in contact lens technology aimed at alleviating patient symptoms of dryness.

In daily disposable lenses, contact lens manufacturers are incorporating moisture additives in their contact lenses to help decrease the symptoms

of dryness and discomfort. Examples include povidone in the 1-Day Acuvue Moist lenses (etafilcon A), polyvinyl-alcohol (PVA) in the Focus Dailies with All Day Comfort (nelfilcon A) and hydroxypropyl-methylcellulose, polyethylene-glycol and PVA in the Dailies AquaComfort Plus lenses (nelfilcon A). In the latter two lenses PVA is released from the lens throughout the course of the day to renew the lens surface of the lens and moisturise the tear film.

This article describes the results of a clinical trial comparing the performance of new Dailies AquaComfort Plus (DACP) with that of 1-Day Acuvue Moist (1DAVM).

Trial objectives/design

The primary purpose of the trial was to compare the subjective performance of Dailies AquaComfort Plus (DACP) to that of 1-Day Acuvue Moist (1DAVM) with regard to comfort. Other variables such as subjective vision and handling, lens fit and comfortable lens wearing time were also evaluated as well as preferences between the two lenses.

Materials and methods

The trial was a prospective, randomised, bilateral crossover design involving 313

patients at 14 investigational sites in Germany. The sponsor of the trial was masked to subjects to minimise potential bias. Each patient wore DACP lenses bilaterally and 1DAVM bilaterally in randomised order for one week each, following a daily wear, daily disposable modality. Patients were seen for a baseline/dispensing visit and a follow-up/crossover visit at one week. The second follow-up/final visit occurred one week after the crossover visit. The test and control lens specifications are summarised in Table 1.

All ratings were based on a scale from 1 to 10, with 1 being poor and 10 being excellent. Mixed effect linear model was fitted to evaluate differences between Test and Control, in subjective ratings, with non-inferiority margin of 0.5. For subjective ratings on a scale of 1 (poor) -10 (excellent), non-inferiority of DACP compared to 1DAVM was assessed with a margin of 0.5 grade (1-sided $\alpha=0.05$).

One-sided 95 per cent confidence limit on the paired difference between DACP and 1DAVM was constructed to determine whether superiority can also be attained once non-inferiority was proven.

All patients enrolled into the study were current daily disposable wearers.

TABLE 1
Test and control lens specifications

	Control	Test
Name	1-Day Acuvue Moist	Dailies AquaComfort Plus
Material	etafilcon A	nelfilcon A with triple action moisturising agents
Water content	58 per cent	69 per cent
Base curve	8.5 mm and 9.0 mm	8.7 mm
Diameter	14.2 mm	14.0 mm
Trial power availability	-0.50 to -6.00 in 0.25D steps	-0.50 to -6.00 in 0.25D steps
Visibility tint	Yes	Yes
Storage solution	Sterile buffered saline	Sterile buffered saline

Contact Lens Monthly

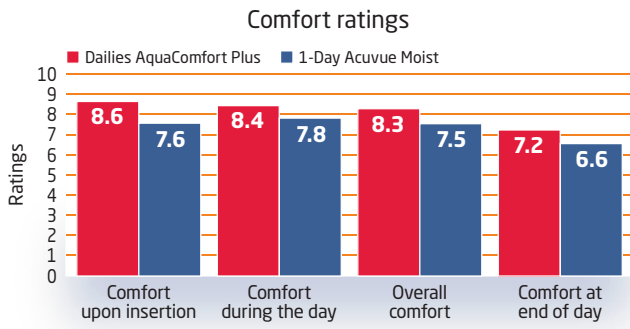


Figure 1 Subjective comfort ratings 1 week data; scale of 1 to 10 with 1 being poor and 10 being excellent, n=313
*Statistically significant (p<0.05, 95 per cent 1-sided lower CI >0)

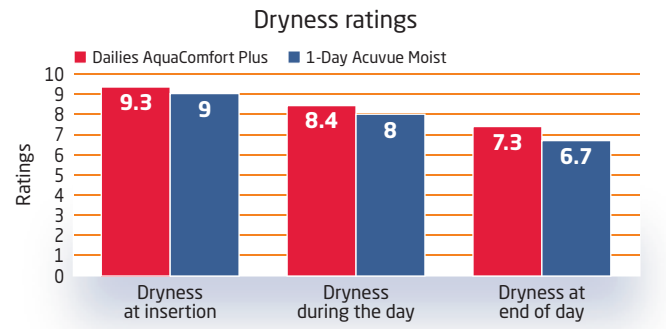


Figure 2 Subjective dryness ratings 1 week data; scale of 1 to 10 with 1 being poor and 10 being excellent, n=313
*Statistically significant (p<0.05, 95 per cent 1-sided lower CI >0)

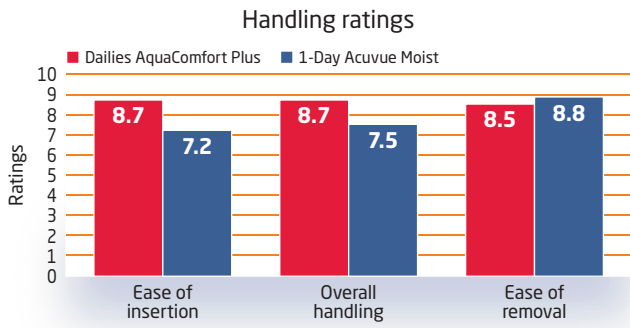


Figure 3 Subjective handling ratings 1 week data; scale of 1 to 10 with 1 being poor and 10 being excellent, n=313 *Statistically significant (p<0.05, 95 per cent 1-sided lower CI >0)

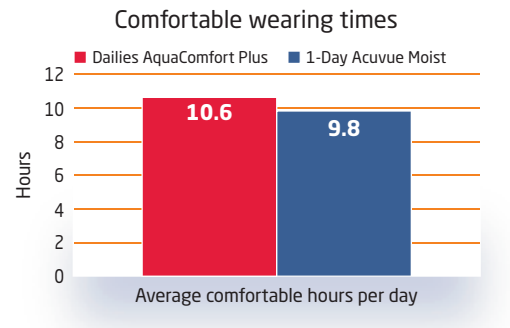


Figure 4 Comfortable wearing times 1-week data, n=313 *Statistically significant (p<0.05)

To reflect the market share in 2007 for Europe and the US, desired distribution of patients was 60 per cent Focus Dailies, 30 per cent 1-Day Acuvue and 10 per cent other daily disposable lenses. The final patient distribution for this study was: 65 per cent Focus Dailies, 27 per cent 1-Day Acuvue; 8 per cent other daily disposable lenses.

Results

Of the 313 patients enrolled and dispensed lenses, 309 completed the trial. Four subjects discontinued the trial, one due to unrelated medical problems while wearing DACP, one due to unacceptable fit while wearing 1DAVM, one was lost to follow-up and one for other reasons, both while wearing 1DAVM. All subjects were habitual soft daily disposable lens wearers.

DACP was rated significantly better than 1DAVM for comfort at insertion, during the day, and at end-of-day, as well as for overall comfort (Figure 1). Dryness ratings at insertion, during the day, and at end-of-day were superior for DACP compared to 1DAVM (Figure 2). Ease of insertion and overall

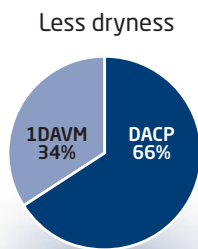


Figure 5 n = 233

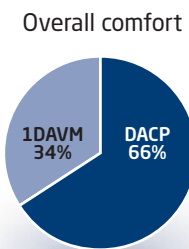


Figure 6 n = 261

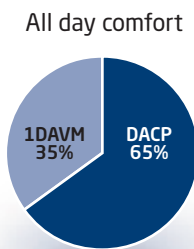


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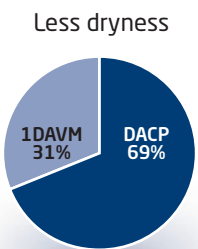


Figure 8 n = 176

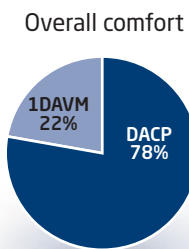


Figure 9 n = 207

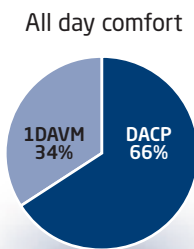


Figure 10 n = 288

Figures 5-10 Patient preference results comparing DACP and 1DAVM
*Statistically significant, p< 0.05, of those with a preference

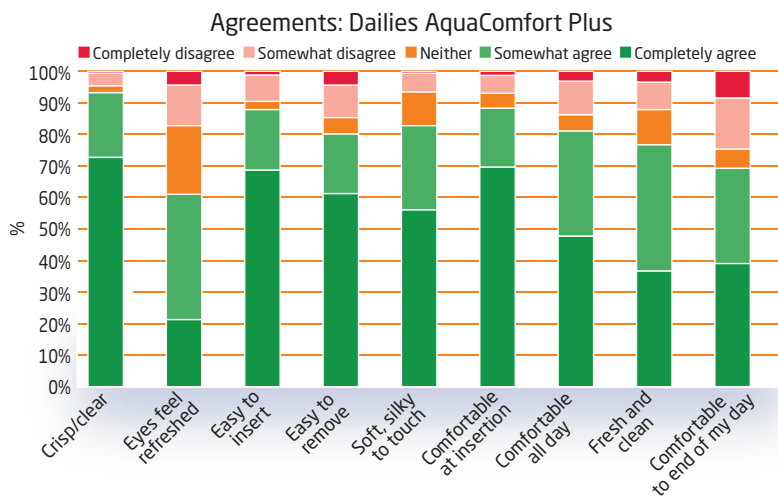


Figure 11 Agreement statements for Dailies AquaComfort Plus

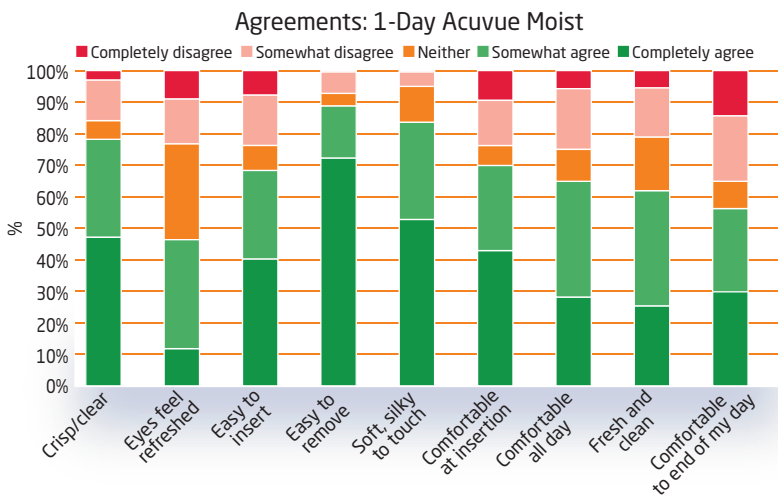


Figure 12 Agreement statements for 1-Day Acuvue Moist

handling were rated superior for DACP compared to 1DAVM at the one-week visit (Figure 3).

In addition, subjects experienced almost one more full hour of comfortable wear with DACP than with 1DAVM (Figure 4).

With the exception of ease of removal, among those patients with a preference (which was at least 55 per cent in all cases), DACP was preferred more often than 1DAVM by a statistically significant margin for all attributes that were tested, including all dryness, comfort, and vision attributes as well as overall preference. Figures 5-10 summarise the preference results.

Patients were asked to indicate their level of agreement with statements describing the attributes of DACP

lenses such as 'provide crisp, clear vision', 'comfortable all day', 'eyes feel refreshed throughout the day', 'comfortable at insertion', 'easy to insert', 'easy to remove', 'feel soft and silky to the touch', 'feel fresh and clean throughout the day', and 'wear comfortably to the end of my day'.

With the exception of 'easy to remove' and 'feel soft and silky to the touch', there was a greater tendency for subjects to 'completely agree' or 'somewhat agree' with the statements for DACP than 1DAVM (Figures 11 and 12).

Visual acuity (VA)

On average, visual acuity was similar for DACP and 1DAVM at both dispensing and follow-up.

Centration/overall fit

Overall, while the majority of both lenses fit optimally, there was a significant difference in fit between DACP lenses and 1DAVM lenses ($p < 0.05$) with 1DAVM lenses fitting looser than DACP. While the majority of both lenses were well-centred or slightly decentred, DACP lenses centered significantly better than 1DAVM lenses ($p < 0.05$).

Biomicroscopy

Bulbar and limbal redness as well as corneal and conjunctival staining were assessed at baseline, follow-up, and exit. Biomicroscopy findings were similar with both DACP and 1DAVM from baseline to exit with no clinically significant differences noted.

Conclusion

As manufacturers continue to address the most important unmet patient need of comfortable contact lens wear, new contact lenses continue to emerge in the market. In this study, for the vast majority of ratings, Dailies AquaComfort Plus performed significantly better than 1-Day Acuvue Moist.

In addition, Dailies AquaComfort Plus was preferred significantly more often for virtually all measures tested, including comfort, vision and handling. Based on these results, the overall performance of Dailies AquaComfort Plus lenses was demonstrated to be superior to that of 1-Day Acuvue Moist. ●

References

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