# Clinical performance of the Bioclear family of lenses

**Howard Griffiths** looks at the performance of three of Sauflon's Bioclear biomimetic lenses

One of the most important attributes that patients demand from their contact lenses today is comfort during wear. The demands of modern day living means that patients require comfortable wear for at least 12 hours a day. Patients often cite lens dryness and irritation as reasons for removing lenses from their eye earlier in the day than they would like. The most common reason for this is that their contact lenses lose water or 'become dry'. As soft lenses lose water their parameters can change and in some cases lead to steeper base curves, making the lens 'feel tighter on the eye' to the patient.

Sauflon's new biomimetic lens range (Bioclear) which includes a monthly, daily disposable and toric lens was developed to ensure that patients would experience comfortable lens wear all day long. This new lens material contains a biomimetic additive which enhances biocompatibility, ensuring optimal compatibility of the lens with the cornea. The lens material is made up of 45 per cent polymer and 55 per cent water, the presence of water making soft contact lenses soft and flexible. Sauflon's biomimetic lens will hold onto the water and compared to many other contact lenses the material is less prone to 'dry out', so it remains soft and flexible from the time the lens is inserted until the end of the day. This lens is ideal for those patients who experience dryness or discomfort during lens wear.

Bioclear includes an additive in the monomer mix, AquAtract, which when polymerised encourages hydrogen bonding of water to the lens material. When AquAtract is polymerised it forms hydroxyl groups on the lens surface and encourages hydrogen bonding of water to the lens material enabling it to retain water for longer.

Unlike wetting additives used in other contact lenses which are released from the lens and washed away by the tears, AquAtract surface bonding is permanent, lasting for the life of the lens.

AquAtract acts like a magnet to water molecules, bonding them to the whole lens. The water also forms a barrier to deposits on the lens surface, significantly reducing deposition. The Bioclear family of lenses was evaluated in a series of clinical studies by an independent clinical research group.

**TABLE 1**
**Monthly lens parameters**

| Name | Bioclear | Proclear |
|---|---|---|
| Manufacturer | Sauflon Pharmaceuticals | CooperVision |
| Material | Filcon IV 1 + Aquatract | Omafilcon A |
| EWC (%) | 55 | 62 |
| FDA classification | Group IV | Group II |
| BOZR (mm) | 8.6 | 8.6 |
| Diameter (mm) | 14.2 | 14.2 |

**TABLE 2**
**Wearing patterns**

| Lens | Proclear | Bioclear |
|---|---|---|
| Days per week | 5.9 ± 1.0 (n=21) | 6.1 ± 1.0 (n=21) |
| Hours per day | 11.5 ± 2.9 (n=21) | 12.7 ± 2.7 (n=21) |

**TABLE 3**
**Visual acuity scores**

| Visit | Parameter | Proclear | Bioclear |
|---|---|---|---|
| Dispensing | High contrast | -0.10 ± 0.06 (n=22) | -0.12 ± 0.07 (n=21) |
| | Low contrast | 0.19 ± 0.08 (n=22) | 0.20 ± 0.08 (n=21) |
| Follow-up | High contrast | -0.09 ± 0.09 (n=21) | -0.10 ± 0.09 (n=21) |
| | Low contrast | 0.21 ± 0.11 (n=21) | 0.20 ± 0.12 (n=21) |

## Bioclear spherical monthly lens

The Bioclear spherical lens was evaluated in a subject-masked, randomised, crossover study where 22 subjects were recruited to wear the Bioclear lens (Sauflon) and the Proclear lens (CooperVision) with each lens used for two weeks on a daily wear basis (Table 1).

All in One Light (Sauflon) was used as the care regimen by all subjects. For all subjects for all lens types, a dispensing examination was conducted at which the lenses were fitted and evaluations were made of initial subjective scores, lens fit and visual acuity. Subjects were also seen for a follow-up visit after two weeks at which the same assessments and a biomicropscopic evaluation were performed.

- **Wearing patterns.** There was a difference in the number of days per week of lens wear ($p = 0.03$). Post-hoc tests showed that the greater use of the Bioclear lens than the Proclear lens was

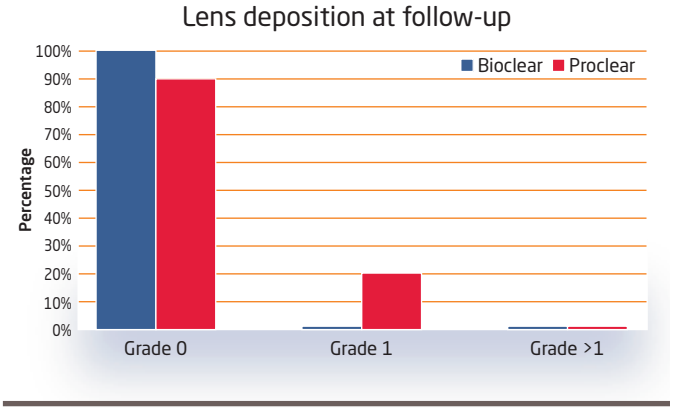


**Figure 1** Lens deposition at follow-up

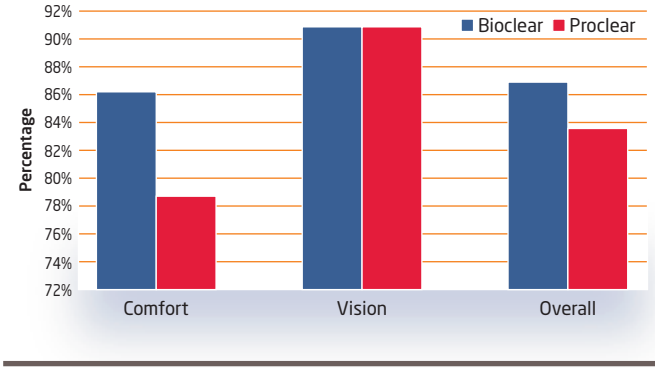


**Figure 2** Initial comfort scores

statistically significant (p = 0.06) (Table 2). The difference in 'hours per day' was not statistically significant (p = 0.09).

- **Visual acuity** was measured using logMAR charts at high and low contrast, and scores were generally good for both lens types. There were no differences between the lenses for visual acuity measured at the follow-up visits (high contrast p=0.19; low contrast p=0.13); or the dispensing visit (p = 0.31). (Table 3).
- **Lens fit**. All lenses were found to fit acceptably in the subject group. The proportion of optimum fitting lenses was between 33 per cent and 48 per cent for the two lens types at each of the two study visits and there were no statistically significant differences between the lenses. This range is typical for contemporary soft lenses. Where lenses were not reported as fitting optimally, this was usually due to temporal and/or superior decentration.
- **Lens surface**. At the follow-up visits, there were no significant differences between the lenses for deposition (Figure 1), post-lens debris or wettability with each lens type performing well in this regard.
- **Biomicroscopy**. Scores for biomicroscopic findings were within clinically acceptable norms and no subjects required clinical management due to any biomicroscopic signs.
- **Subjective scores**. A range of subjective responses were measured in the study. Initial comfort scores were best with the Bioclear lens. (Figure 2). At the follow-up visit, subjective scores were very similar for the Proclear lens and the Bioclear lens (Table 4).
- **Lens preference**. At the final visit patients were asked to select their preferred lens type, 11 subjects selected the Bioclear lens and eight selected the Proclear lens.

## Summary

In the monthly lens study the Bioclear lens was worn for a greater number of days per week compared to the Proclear lens. Visual acuity was good and comparable for both lenses. Lens fits were good with 100 per cent being classed as at least acceptable. Data for lens deposition, debris and wettability were similar for both lenses. Overall in this study, the Bioclear lens performed similarly to the Proclear lens.

## Bioclear Toric

The Bioclear Toric lens (Sauflon) has the following properties:

- Back surface toric
- Prismatic front surface featuring a thickness equalising comfort curve
- Comfort chamfer
- Aspheric optics to minimise aberration
- Advanced edge technology
- Blended junctions cut in single pass
- Smooth transition between zones
- Junctionless design
- Constant edge thickness.

The Bioclear Toric lens was evaluated in 24 astigmatic subjects (with a refractive cylinder of at least 0.75DC in each eye) who were first adapted to the Frequency Xcel Toric lens (CooperVision) (Table 5).

Each subject wore the two lenses as a pair for a two-week period and were examined when the lenses were dispensed and at a follow-up visit.

- **Fitting performance**. Lens fits were acceptable in terms of centration, movement and corneal coverage. Perhaps of more interest was the fitting performance from a toric lens perspective; to ascertain this, lens 'rotation' and 'stability' were measured. The first parameter is an assessment of the position of the lens relative to its desired rotation and is the angular measurement of the lens orientation marking from the vertical. The latter measurement is the maximum change in rotation when the eye is moved from the primary position into left, right, up and down gaze in turn. For both rotation and stability, lower scores represent better clinical performance.

The performance of the lenses for rotation was very good for the two lenses (Figure 3). At dispensing, the Bioclear Toric (92 per cent of fits within 10° of the optimum position) was slightly better than the Frequency Xcel lens (82 per cent of fits within 10° of the optimum position) (p = 0.02); there was no significant difference at follow-up (p = 0.43).

There were no differences between the two lens types for stability measures (p = 0.14 at dispensing and p = 0.94 at follow-up). About 90 per cent of all stability measures were 10° of less, suggesting a high level of stability for both lens types at both visits. There were

**TABLE 4**

**Subjective scores at follow-up**

| Parameter | Proclear | Bioclear | p |
|---|---|---|---|
| Comfort after insertion | 81.7 ± 18.3 (n=21) | 84.4 ± 15.9 (n=21) | 0.002 |
| Comfort before removal | 74.0 ± 21.0 (n=21) | 75.0 ± 18.7 (n=21) | 0.0005 |
| Vision | 89.6 ± 11.0 (n=21) | 90.9 ± 10.8 (n=21) | 0.0002 |
| Vision at night | 88.7 ± 10.9 (n=21) | 89.7 ± 11.5 (n=21) | 0.001 |
| Variable vision | 87.9 ± 15.7 (n=21) | 89.3 ± 12.3 (n=21) | 0.006 |
| Redness | 89.8 ± 14.1 (n=21) | 83.7 ± 19.7 (n=21) | 0.20 |
| Ease of insertion | 87.8 ± 20.6 (n=21) | 87.6 ± 18.0 (n=21) | 0.04 |
| Ease of removal | 87.2 ± 16.6 (n=21) | 87.3 ± 19.0 (n=21) | 0.04 |

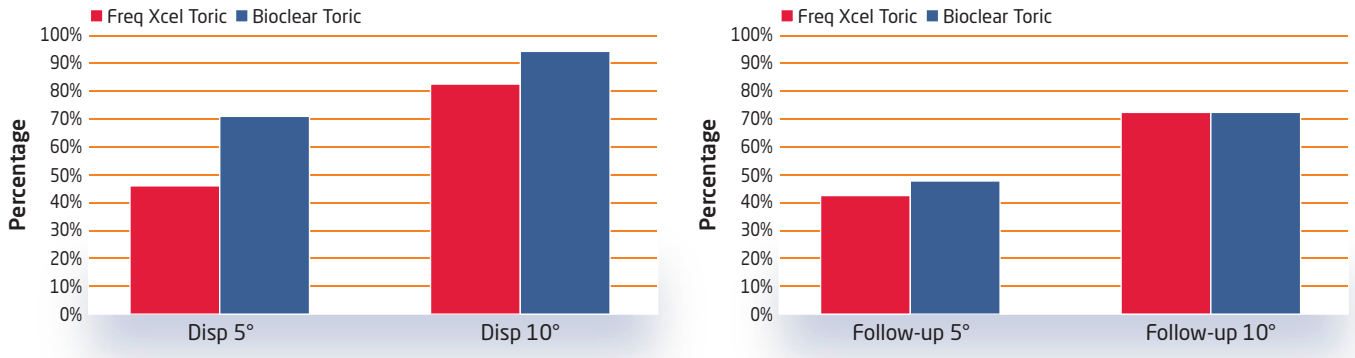


**Figure 3** Rotation performance for Bioclear Toric and Frequency Xcel Toric

very few reports of deposition for the two lens types at the follow-up visits.

- **Visual acuity** was very similar for the two lens types (about 6/6 on average at high contrast) at both the dispensing and the follow-up visits ($p \geq 0.45$ for high and low contrast assessments at both the dispensing and the follow-up visits) (Figure 4).
- **Subjective scores**. Subjectively, there were no differences between the lenses for vision ($p = 0.94$) and for overall score at the dispensing visit ($p = 0.67$). At the follow-up visits, all the subjective scores were similar for the two lens types. None of the differences were statistically significant.
- **Scores for biomicroscopy** were generally unremarkable and typical for soft contact lenses. All recorded signs were within the range of scores typical for current soft lenses.

## Summary

This toric lens study showed that the toric fitting characteristics were very similar for the Sauflon Bioclear Toric lens and the Frequency Xcel Toric lens and towards the upper end of performance seen for soft toric lenses. Visual acuity was good for both lens types. At follow-up, the average acuity was better than 6/6 for both lenses.

In general, the subjective scores seen for the two lenses were good but the forced choice assessment indicated a split within the subject group as to the preferred lens with Sauflon Toric scoring 7 out of 12 and CooperVison Xcel Toric scoring 5 out of 12.

Overall, the data generated by this clinical study suggest very similar performance between the two soft toric lenses examined. Where differences were found between the two lens types they were not at a level considered to be clinically significant.

**TABLE 5**

**Toric lens parameters**

| Name | Bioclear Toric | Frequency Xcel Toric |
|---|---|---|
| Manufacturer | Sauflon Pharmaceuticals | CooperVision |
| Material | Filcon IV 1 + Aquatract | Methafilcon A |
| EWC (%) | 55 | 55 |
| FDA classification | IV | IV |
| BOZR (mm) | 8.7 | 8.7 |
| Diameter (mm) | 14.4 | 14.4 |
| Spherical powers (D) | -2.00 to -4.00 | -2.00 to -4.00 |
| Cylindrical powers (DC) | -1.25 | -1.25 |
| Axes (°) | 180,20,90 & 160 | 180,20,90 & 160 |

**TABLE 6**

**Daily disposable lens parameters**

| Name | Bioclear 1 Day | Focus Dailies ADC |
|---|---|---|
| Manufacturer | Sauflon Pharmaceuticals | CIBA Vision |
| Material | Filcon IV 1 + Aquatract | Nelfilcon A |
| EWC (%) | 56% | 69% |
| FDA classification | Group IV | Group II |
| BOZR (mm) | 8.60 | 8.60 |
| Diameter (mm) | 14.10 | 13.80 |

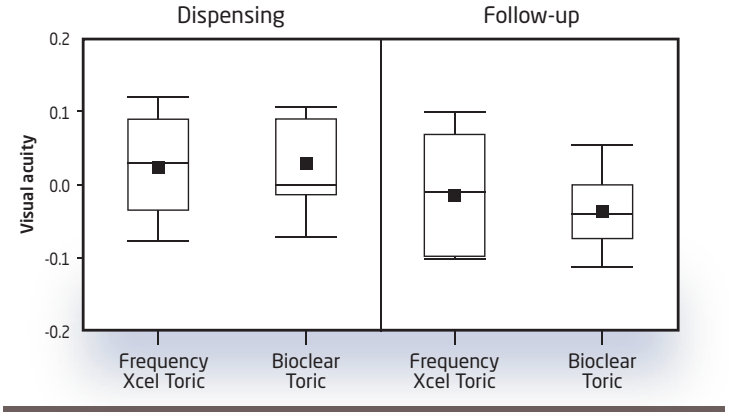


**Figure 4** Bioclear Toric and Frequency Xcel Toric acuity performance

## Bioclear 1 Day

The Bioclear 1 Day lens (Sauflon) was evaluated in wearers adapted to Focus Dailies All Day Comfort lenses (CIBA Vision). This dispensing study was an unmasked and controlled sequential 'switch' study where all subjects were fitted first with the Focus Dailies All Day Comfort lens followed by the Bioclear 1 Day.

To achieve this, 30 existing contact lens wearers were recruited and asked to wear Focus Dailies All Day Comfort lenses in the usual way for two weeks before wearing Bioclear 1 Day lenses for the same period. Lenses were worn on a daily disposable basis. Subjects were examined for a dispensing visit and a follow-up visit for both lens types. All 30 subjects attended all study visits; there were no clinical discontinuations.

- **Visual acuity**. There were no differences between the lenses for visual acuity, with both lenses providing average high contrast visual acuity at about the 6/5 level (Figure 5)
- **Lens fit**. Both lens types fitted all eyes acceptably. In cases where lens fit was not optimum, this was usually due to the Focus Dailies All Day Comfort lens offering some inferior decentration and the Bioclear 1 Day being associated with superior decentration. There were very few reports of lens surface deposition in this daily disposable study
- **Biomicroscopy**. Scores for biomicroscopic findings were similar for the two lens types and comfortably within clinical norms (Figure 6)
- **Subjective scores**. The subjects reported similar levels of subjective acceptance at the dispensing visits for the two lens types.

At follow-up, subjective scores were generally similar for the two lens types; differences were not statistically significant. The only exception here was for ease of lens removal which was better for the Bioclear 1 Day lens (Table 7).

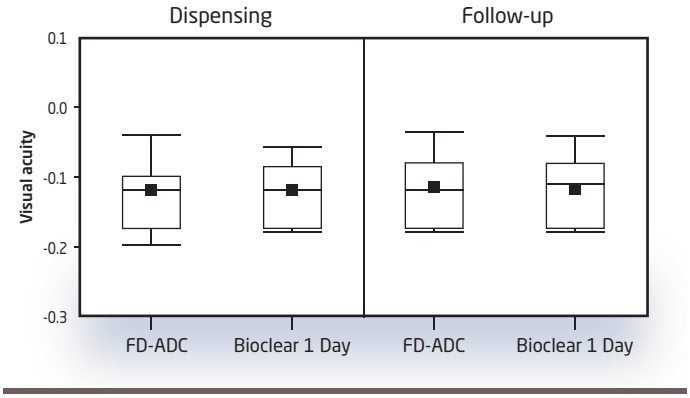


**Figure 5** Acuity performance of Focus Daily All Day Comfort and Bioclear 1 Day

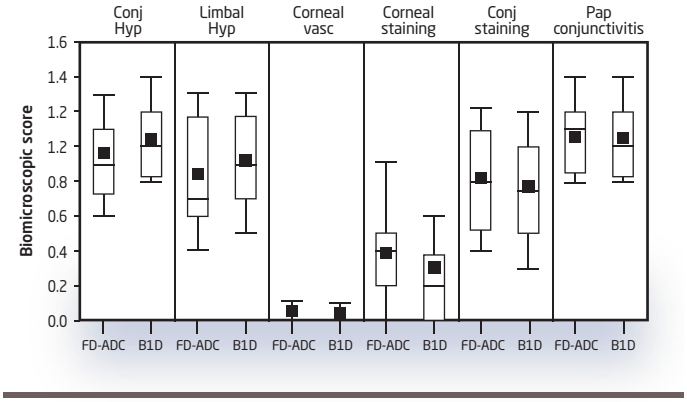


**Figure 6** Biomicroscopy results for Focus Daily All Day Comfort and Bioclear 1 Day

## Summary

In the daily disposable lens study no difference was seen in wear time and on average, both lenses were worn for over six days per week and for over 11 hours per day. Visual acuity with both lenses was similar providing high contrast visual acuity at about 6/5 level. Both lenses achieved 100 per cent acceptable fits.

As far as patient lens preference there were no differences in subject scores at the dispensing visit with high mean values for the three recorded parameters. At the follow-up visits, the only clear difference between the two lens types was that subjects found the Bioclear 1 Day lens easier to remove. This latter finding is supported by the greater number of reports of lens binding with the Focus Dailies All Day Comfort lens.

Overall, the performance of the two lens types was similar and wearers and practitioners wishing to move from one lens type to the other are unlikely to have any significant difficulty doing so.

**TABLE 7**

**Subjective scores at follow-up**

| Parameter | FD-ADC | Bioclear 1 Day | p |
|---|---|---|---|
| Comfort after insertion | 78.1 ± 18.2 | 76.3 ± 22.2 | 0.69 |
| Comfort before removal | 65.8 ± 25.1 | 67.7 ± 19.5 | 0.66 |
| Overall comfort | 73.1 ± 18.5 | 74.9 ± 18.8 | 0.62 |
| Dryness | 73.3 ± 19.4 | 75.4 ± 16.9 | 0.58 |
| Grittiness | 84.2 ± 16.9 | 84.6 ± 19.6 | 0.88 |
| Burning/stinging | 89.3 ± 13.7 | 84.9 ± 19.1 | 0.20 |
| Vision | 87.6 ± 13.7 | 88.0 ± 15.5 | 0.86 |
| Night vision | 86.2 ± 15.3 | 86.1 ± 16.7 | 0.99 |
| Variable vision | 81.5 ± 19.0 | 86.1 ± 16.6 | 0.13 |
| Ocular redness | 86.8 ± 17.6 | 84.8 ± 19.3 | 0.60 |
| Ease of insertion | 80.3 ± 17.7 | 79.3 ± 20.5 | 0.82 |
| Ease of removal | 79.9 ± 20.5 | 87.3 ± 14.6 | 0.05 |
| Overall score | 74.0 ± 18.9 | 74.8 ± 17.5 | 0.82 |

## CONCLUSION

These studies have shown that all three lenses in the Bioclear family performed equally well against market-leading contact lenses in each of their respective categories. Practitioners wishing to recommend a change to Bioclear are unlikely to experience any difficulty in patient acceptance. The Bioclear family of lenses is exclusively available only to the optical profession.

● **Howard Griffiths** is technical director of Sauflon Pharmaceuticals