

In-eye cleaning drops for silicone hydrogel contact lenses

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Various deposits on the contact lens surface are responsible for reduced comfort and increased safety concerns. Preserving a clean contact lens is a major issue for all types of lens materials, especially for silicone hydrogels. Blink'n'Clean is a new in-eye cleaning eye drop which could improve the cleanliness of contact lenses by reducing lens deposition. This article describes a controlled regular study which aimed to evaluate the efficiency of these drops in preserving cleanliness, comfort, tear stability, corneal staining and conjunctival vascular status during in-eye use with silicone hydrogel contact lenses.

Deposits

Minutes after the insertion of contact lenses, debris starts depositing on the surface of the lens. These deposits are comprised of proteins, lipids and mucins from the tear film, as well as substances from the metabolism of micro-organisms which might be present in the ocular environment. The amount of deposits on the contact lens depends on several factors, including contact lens material, age of the lens, water content of the lens, and the wearer's hygiene regime when caring for the contact lenses. Deposits on the lens surface might compromise wearing comfort and induce immunological and inflammatory responses such as papillary conjunctivitis.¹ Lid Parallel Conjunctival Folds (LIPCOF) are a clinical sign of contact lens-induced dry eye. They are subclinical folds in the lateral, lower quadrant of the bulbar conjunctiva, parallel to the lower lid margin.² They are induced by friction during blinking,³ and it has been suggested that the mechanical influence of the lens edge might play a role.⁴ Pult et al.⁴ reported that contact lens wearers

with dryness symptoms exhibit significantly more LIPCOF, making it a good predictor for dry eye symptoms.⁴ It has been hypothesised that tear film deposition may alter the composition and physiology of the normal tear fluid, negatively impacting on tear film structure and function. Effective and full tear-film recovery is believed to depend on the surface-wetting properties of the lens.⁵⁻⁷ Although the newly introduced silicone hydrogel contact lenses accumulate much less protein than conventional hydrogel lens materials and offer very good clinical performance, they attract more lipid deposits.⁸ In a recent report, it was found that silicone hydrogel lenses do not significantly change their surface properties upon soaking in a surfactant-free medium. In fact, the same report showed that some silicone hydrogel lenses exhibited better surface wettability after depletion of surfactants.⁹ Contact lens care products are designed to disinfect, store and clean contact lenses. Several solutions are available on the market, comprising different preservatives and surfactants.

Lens deposit classification	
CLASS	HEAVINESS OF DEPOSIT
I	Clean
II	Visible under oblique light when wet using 7X magnification
III	Visible when dry without special light, unaided eye
IV	Visible when wet or dry with the unaided eye
CLASS	TYPE OF DEPOSIT
C	Crystalline
G	Granular
F	Filmy
P	Plaque
CLASS	EXTENT OF DEPOSIT
a	0-25% of lens
b	25-50% of lens
c	50-75% of lens
d	75-100% of lens

Figure 1
Modified Rudko Scale

The ability of these solutions to remove deposits from silicone hydrogel contact lenses has not been extensively investigated and may be affected by lens materials.⁸ In daily practice, practitioners are still likely to encounter some contact lens wearers who complain of discomfort at the end of the day and throughout the life cycle of the contact lens. Often this discomfort is due to deposits which build up more rapidly in certain contact lens wearers compared with others. Some eye drops on the market are designed as in-eye cleaners, containing surfactants that are able to clean the lens surface without needing to remove the lens from the eye. Although there are only a limited number of such products, one example is Blink'n'Clean (Abbott Medical Optics Inc., Santa Ana, California, USA), which contains the surfactant Tyloxapol and edetate disodium as a chelating agent. This eye drop helps to remove protein deposits on the lens as well as to improve comfort during lens wear. It can be used with both soft and RGP contact lenses. Another example is Clens 100 (Alcon, Fort Worth, Texas, USA), which contains polyethyl glycol-II (PEG-II) lauryl ether carboxylic acid as the surfactant and poloxamine as a wetting agent (note that this is also available as Clerz Plus lens drops for soft lenses only). It is recommended for use two to three times

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per day to improve in-eye lens comfort and to reduce protein build-up on the lens. Murine Contacts refresh and clean (Prestige Brands Inc, New York, USA) is designed to refresh, lubricate and clean contact lenses whilst in the eye. It is a hydrogen peroxide-based eye drop, containing the surfactant Oxyd, and it can be used for all types of contact lenses. These types of eye drops go a step further than traditional re-wetting drops, which contain a lubricating agent only, to help improve lens comfort and to clean the lens at the same time.

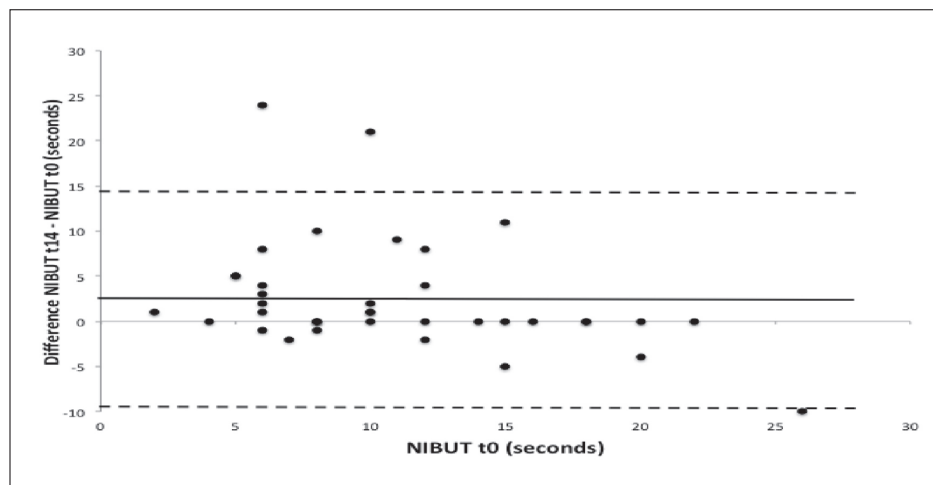


Figure 2

Change in non-invasive tear break up time after 14 days of Blink'n'Clean eye drop use in relation to the baseline measurement

Multi centre registry

The current authors conducted a multi-centre registry to determine the feasibility and clinical usefulness of such in-eye cleaning drops. Accordingly, the authors evaluated the cleaning performance of Blink'n'Clean eye drops in silicone hydrogel contact lenses during wear. This project was performed as a registry. The major difference between registries and studies is that the latter should prove a hypothesis in a well-defined patient cohort, whereas a registry reflects routine treatment of patients. A registry is by definition non-interventional, which can be one of the limitations of this type of clinical investigation. Registries are of high value as they reflect the "real world" of daily patient care and treatment. In contrast, clinical studies, which are essential for new products, prove a product in a very homogenous patient group, due to explicit inclusion and exclusion criteria, and at fixed time points. Both types of programs together deliver the full picture of safety, efficacy and handling of a product. The registry which forms the focus of this study reflects the routine application of in-eye contact lens cleaning drops. Only examinations that would apply to the clinical routine

for the respective pathology were documented, therefore no IRB approval was obtained, or required. Patients were, however, asked to sign an informed consent form so that they knew that their anonymized data will be analysed.

Method

Fifty-one existing contact lens wearers (nine male and 42 female, mean age of 37.2 ± 13.9 years, range 15 to 78 years) who were prone to deposits on silicone hydrogel lenses, based on observations made in clinical records, were instructed to use two drops of

Blink'n'Clean in each eye, twice daily, over a period of two weeks. All of these people were regular patients, wearing their actual pair of lenses at the time of their regular six-monthly appointment, who showed, on average, deposits of grade 2 according to the Rudko scale. Follow-up appointments were made by the same investigator at a similar time of day to avoid systematic, inter-personal bias. Each subject kept the same contact lens brand that they were wearing prior to enrolment in the study and applied Complete Easy Rub multi-purpose solution (MPS)

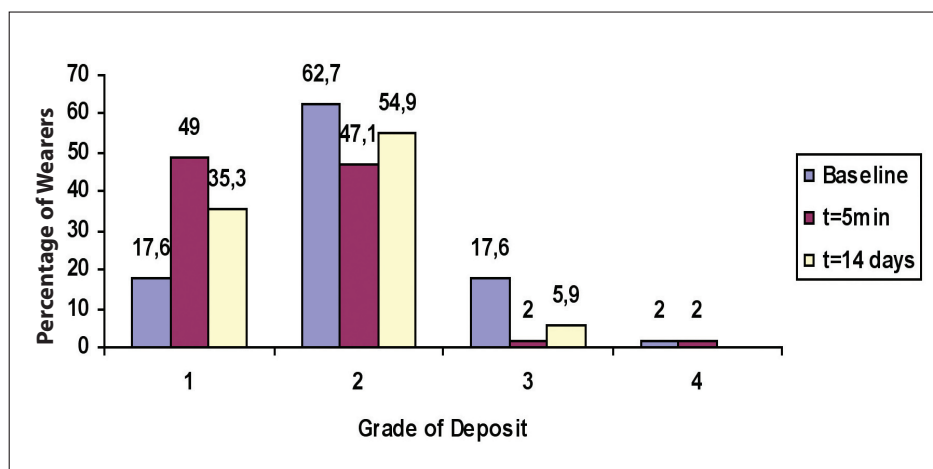


Figure 3

Frequency of deposit heaviness



(Abbott Medical Optics Inc., Santa Ana, California, USA) for the duration of the study. They were instructed to maintain their regular correct cleaning regime (rub and rinse) as well as their normal replacement schedule. Types of contact lenses used in this investigation were Biofinity (CooperVision, Fairport, New York, USA), Acuvue Oasys, Acuvue Oasys for Presbyopia, Acuvue Advance (all Johnson & Johnson Visioncare Inc., Jacksonville, Florida, USA) Air Optix, Air Optix Night & Day (both CIBA Vision, Duluth, Georgia, USA) and PureVision (Bausch & Lomb, Rochester, New York, USA). Subjects were wearing lenses for at least five hours per day and were examined at the following intervals: before administration of Blink'n'Clean eye drops, five minutes after the first instillation of Blink'n'Clean eye drops, and 14 days after first use of Blink'n'Clean eye drops. The authors used the modified Rudko validated scale^{10,11} (Figure 1) for assessment of deposits on contact lenses. Heaviness, extent and type of deposits

were compared before instillation of Blink'n'Clean eye drops, five minutes after the first eye drop instillation, and 14 days after twice daily use. Pre-lens non-invasive tear break-up time (NIBUT) was evaluated without application of fluorescein dye with different types of mires, such as placido disc of the videokeratograph or mires of the keratometer. This allowed calculation of the NIBUT without interfering with tear film stability. Corneal staining, which was analysed with the application of fluorescein dye, and hyperaemia were assessed according to the Cornea and Contact Lens Research Unit (CCLRU) grading scale (School of Optometry and Vision Science, The University of New South Wales, Sydney, Australia). LIPCOF were also counted, vertically below the temporal limbus. A subjective questionnaire (Table 1) was also given to wearers five minutes after first instillation of Blink'n'Clean and again after 14 days of twice daily use. It is necessary to point out that, since the questionnaire has

not been statistically validated at the time of this publication, the results are preliminary but not conclusive.

Analysis and results

Subject's gender is not a parameter to be included in the analysis since the distribution of values is not balanced sufficiently (nine men and 42 women). The age distribution in the sample was normal (Kolmogorov-Smirnov test, $p=0.66$).

The distribution of NIBUT values was normal (Kolmogorov-Smirnov test, $p>0.05$ on all occasions), and therefore parametric tests were applied (ANOVA with post hoc analysis and Pearson's correlation coefficient). The remaining parameters follow categorical scaling and therefore non-parametric tests were applied (Chi-square, Friedman ANOVA, and Wilcoxon matched-pairs signed-ranks tests).

Non-invasive break-up time

Results showed significantly higher NIBUT values after 14 days (13.4 ± 6.7 seconds) of twice-daily use of

1. During a normal day within the last week, how often was the wearing comfort of your contact lenses unpleasant?				
Never	Rarely	Sometimes	Often	Always
2. When exactly did you note this unpleasant wearing comfort?				
Never	Early morning	Noon	Evening	All day
3. If you felt this unpleasant wearing comfort, how unpleasant was this feeling at the end of the contact lens wearing time?				
No problem	Slightly unpleasant	Unpleasant	Annoying	Extremely annoying
4. During a normal day within the last week - how often did you have the feeling that your contact lenses are dirty?				
Never	Rarely	Sometimes	Often	Always
5. How was the wearing comfort after using Blink'n'Clean?				
Much worse	Worse	Same	Better	Much better
6. How was your vision after using Blink'n'Clean?				
Much worse	Worse	Same	Better	Much better

Table 1

Subjective questionnaire used to evaluate the effect of Blink'n'Clean eye drop use on contact lens comfort and vision

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Blink'n'Clean eye drops compared with the baseline NIBUT measurements (10.8 ± 5.4 seconds) ($p=0.02$), with an average increase of 2.5 seconds. NIBUT values at five minutes after instillation (11.8 ± 5.6 seconds) were not significantly different from baseline ($p=0.18$).

The change in distribution of NIBUT as a function of the initial NIBUT (Bland Altman plot) is shown in Figure 2 and reveals that the increase in NIBUT after 14 days of Blink'n'Clean eye drop use occurs mainly for those eyes with lower baseline NIBUT values, although there is variability between individuals. NIBUT values at baseline versus 14 days after instillation are moderately but significantly correlated ($r=0.49$, $p=0.002$).

Lens deposition

Grading of lens deposition using the modified Rudko scale showed significant differences in deposit heaviness between baseline values (mean grade 1.57 ± 0.66) and both the values obtained at five minutes (mean grade 1.67 ± 0.64) after the first instillation of Blink'n'Clean as well as those obtained after 14 days (mean grade 1.67 ± 0.63) of twice daily instillation of these drops (Friedman ANOVA, $p<0.001$). However, grading of deposition was not significantly different at five minutes after instillation of Blink'n'Clean compared with after 14 days of twice-daily use of these drops ($p=0.45$). There was a significant relationship between the initial (baseline) grading of lens deposition and that obtained after 14 days of instillation, towards cleaner contact lenses (Chi-square, $p=0.001$) (Figure 3).

Deposit extension

Since the deposit extension is graded with letters in the modified Rudko scale, the authors converted the scale into a numeric scale for statistical purposes ($a=1$, $b=2$, $c=3$, $d=4$). Deposit extension

Ocular Assessment	Mean Grade	Standard Deviation	Statistical Significance
Hyperaemia at baseline	0.53	0.54	$p=0.157$
Hyperaemia at 14 days	0.47	0.58	
LIPCOF at baseline	0.55	0.79	$p=0.102$
LIPCOF at 14 days	0.47	0.80	
Corneal staining at baseline	0.38	0.53	$p=0.637$
Corneal staining at 14 days	0.36	0.57	

Table 2

Change in conjunctival hyperaemia, LIPCOF and corneal staining from baseline to after 14 days of twice daily use of Blink'n'Clean eye drops

values decreased after the initial five minutes following first instillation of Blink'n'Clean (median \pm interquartile range was 2 ± 1) compared with baseline (median \pm interquartile range was 2 ± 0), but not significantly (Wilcoxon matched-pairs signed-ranks test, $p=0.06$). These values remained low, with no significant difference between the values after 14 days (median \pm interquartile range was 2 ± 1) of eye drop use and those obtained five minutes following the first instillation ($p=0.134$) (Figure 4).

Hyperaemia, LIPCOF and corneal staining

There was no statistically significant difference after 14 days of Blink'n'Clean eye drop use in the measurement of hyperaemia (Wilcoxon matched-pairs signed-ranks tests, $p=0.16$), LIPCOF ($p=0.10$), or corneal staining ($p=0.64$), compared with the baseline measurements (Table 2).

Questionnaire

Statistically significant differences were reported with regards to the frequency of dirty lens sensation (Wilcoxon matched-pairs signed-ranks tests $p=0.012$), and wearing comfort

($p=0.033$) after using Blink'n'Clean eye drops, with improvement reported in both cases. All other items assessed yielded non-significant differences after use of Blink'n'Clean eye drops.

Discussion and conclusion

In vitro studies have shown that wettability of conventional and silicone hydrogel contact lens materials is significantly influenced by the composition of the care regime that they are exposed to.¹² On the other hand, it has also been reported that the quantity and conformation of lysozyme and the quantity of lipid deposited on hydrogel contact lenses is significantly influenced by the composition of the lens material, with higher levels of lysozyme and lower levels of lipid deposition occurring with ionic contact lens materials.¹³ When lysozyme and/or mucin are present, both conventional and silicone hydrogel contact lenses display equivalent wettability performance, and it has been shown that covalent attachment of polyethyleneglycol to the silicone hydrogel contact lens provides complete wetting besides minimizing, or even eliminating, protein adsorption.¹⁴ The use of in-eye cleaning drops during silicone

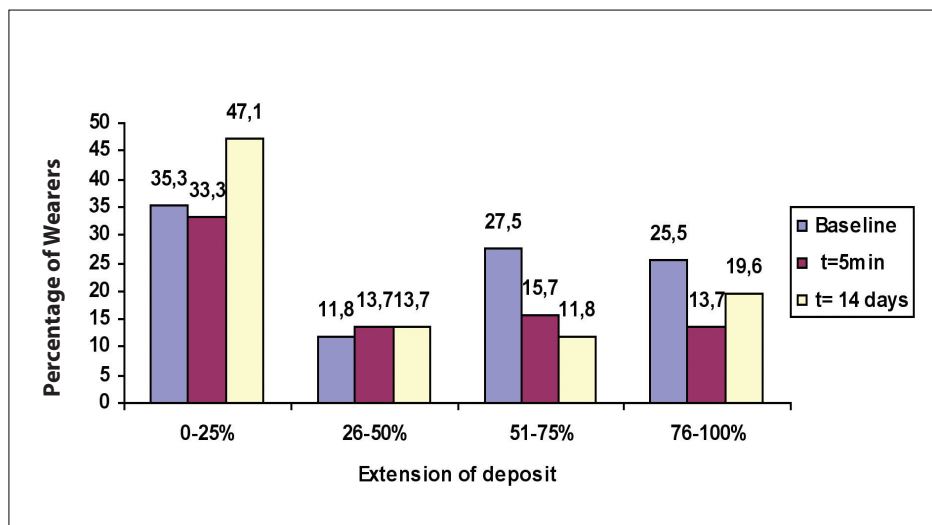


Figure 4

Frequency of deposit extension

hydrogel contact lens wear can decrease the amount of deposits accumulated on the lens surface throughout the day, which might be very beneficial for wearers with increased likelihood of lens deposits and who complain about discomfort before the end of the day.

In this study, Blink'n'Clean eye drops produced a significant reduction in contact lens deposits, in terms of heaviness, from five minutes after instillation and this difference was maintained after two weeks of twice daily use. The extension of deposits also reduced from five minutes after instillation of Blink'n'Clean, although the reduction was not quite significant. The reduction in deposits also translated to improved wettability as suggested from the increased NIBUT. The reduction of deposits and the stabilisation of the tear film translated into a more comfortable wearing experience, as reported by the patients in the questionnaire.

Discomfort and eye dryness are the most common reasons for drop-out from contact lens wear¹⁵⁻¹⁸ and this could be reduced with twice daily use of Blink'n'Clean eye drops, which was found to significantly improve

wearing comfort in the present study. However, the lack of questionnaire validation means that such conclusive statements cannot be drawn as yet. Silicone hydrogel lenses have higher oxygen permeability, reducing hypoxia related to contact lens wear. However, total wearing time achieved and total comfortable wearing time achieved still do not match, with the latter often being shorter for silicone hydrogel wearers.¹⁹ In theory, based on the results of this study, this difference could be reduced by enhancing in-eye cleanliness of contact lenses, but this requires further investigation. Indeed, Subbaraman et al.²⁰ reported a significant improvement in comfort and deposition after instillation of rewetting drops containing surfactants on silicone hydrogel contact lenses, agreeing with the results found in the present study. Improvement in the wetting properties of the lens material after surfactant agent action was suggested as the likely reason for the improvement in subjective comfort.^{21,22}

The use of different devices for NIBUT determination in the present study (videokeratograph vs. keratometer) could be seen as a source of variability

since some inter-instrument difference could be expected. However, the same method was used for each individual participant at each of their follow-up appointments and therefore the interest was in the change in NIBUT rather than the actual value itself. The results reported in this study are for a short duration only (two weeks) and therefore the long-term efficiency of Blink'n'Clean drops needs to be determined. It is also not apparent whether any adverse effects, such as corneal staining, might occur with these drops, although none were observed during the present study. Another limitation is that the lens ages were not consistent for all participants, and this could have a significant bearing on the results since older lenses are more likely to carry heavier and more extensive deposits, which might be more difficult to clean. The study design might also be biased by the lack of a control group (eg, comparison to saline solution) and inter-observer variability. A further study resolving these limitations would be desirable to corroborate the present results, and this should include a validated questionnaire to allow appropriate analysis and conclusive statements to be drawn.

The results of this investigation suggest that the combination of an appropriate MPS cleaning system and in-eye cleaning drops such as Blink'n'Clean could help to reduce deposits on the surface of silicone hydrogel contact lenses and improve wettability, thus increasing NIBUT and improving the contact lens wearing experience without causing a negative impact, such as corneal staining, hyperaemia and LIPCOF, in the short term. The use of drops such as Blink'n'Clean only twice a day should not be too onerous to the patient and therefore, this is a recommendation that

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practitioners could make for patients prone to such deposits and discomfort.

About the authors

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References

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1. The most common reason for contact lens discontinuation (drop-out) is:

- a) Pricing
- b) Hypoxia
- c) Poor vision
- d) Poor comfort and dryness

2. Silicone hydrogel contact lens materials have a tendency towards:

- a) Losing transparency over time
- b) Tearing more easily
- c) Accumulating lipid deposits on the lens surface
- d) Increasing myopia in older people

3. A longer non-invasive tear break up time (NIBUT) in general offers:

- a) Better in-eye contact lens comfort
- b) Less visual fluctuation during contact lens wear
- c) Less lipid deposition on silicone hydrogel materials
- d) All of the above

4. The RUDKO grading scale is created for grading:

- a) Deposits on contact lens surfaces
- b) Visual acuity
- c) Low contrast sensitivity
- d) Tear break-up time

5. In-eye cleaning drops are used to:

- a) Reduce conjunctival hyperaemia
- b) Reduce lipid deposit heaviness on contact lenses
- c) Tighten the fit of a contact lens on the eye
- d) Improve the handling of contact lenses

6. In-eye cleaning drops should:

- a) Be safe and gentle to the ocular surface
- b) Increase the NIBUT and wearing comfort
- c) Be easy to handle for the patient
- d) All of the above



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