



# Effect of Rewetting Drops on Comfort and Protein Deposition of Silicone Hydrogel (Focus Night&Day) Contact Lenses



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## Introduction

- Silicone Hydrogel (SH) contact lenses provide sufficient corneal oxygenation to allow for edema-free overnight wear.<sup>1-4</sup>
- However, symptoms of dryness with SH lenses are still prominent in wearers of these lenses and previous work by our group has demonstrated that their relatively hydrophobic surface can result in an increased percentage of lysozyme being deposited, compared with non silicone-containing materials.<sup>5</sup>

## Purpose

- To investigate the impact of using a rewetting drop (Clerz® Plus; Alcon Laboratories, Inc.) on the comfort and protein deposition that occurs when wearing SH contact lenses in 30-day continuous wear (CW) mode.

## Methods

- A prospective, investigator-blind, randomized, cross-over clinical trial was conducted with 32 subjects.
- Each subject wore Focus Night&Day (FND) SH lenses on a 30-day CW basis for one month, while inserting either 0.9% unpreserved unit-dose saline (S) or multi-dose Clerz Plus (CP) four times per day.
- Follow-up visits were performed at 14 days and at 28 days into each phase. After maximum 30 days, lenses and solutions were collected and a second pair of lenses was dispensed, which was also worn on a 30-day CW basis, but with the second rewetting regimen.
- Subjects completed analogue scales at each visit to evaluate several symptoms and comfort experienced with the study lenses and the rewetting drops.
- The severity of the symptoms was indicated on a scale from 0 to 50, 0 being the best rating or no symptoms, 50 being the worst rating or maximum symptoms.
- Comfort and dryness were graded on insertion of the drops, on waking, at noon, and towards the end of the day. Mucous discharge was rated on waking only. Vision quality was rated at noon and towards the end of the day.
- All lenses were collected aseptically and immediately placed in 1.5 mL of extraction buffer, comprised of 50:50 acetonitrile:0.2% trifluoroacetic acid.

Table 1: Analytical Methods

Variable	Assay
Total Protein (µg/lens)	Amido-black based dot-blot assay
Total Lysozyme (µg/lens)	Western blotting
Denatured Lysozyme (%)	Modified micrococcus lysodeikticus

## Results

- 24 subjects completed the study successfully.

### Subjective Ratings:

- While lens comfort was consistently rated better and symptoms of dryness consistently rated less with the Clerz Plus drops, this difference was not significant (p=NS). Symptoms of dryness and comfort varied across the day regardless of drop-type (p<0.001), with dryness being highest on waking, lowest in the middle of the day and increased towards the evening. Clerz Plus drops provided greater comfort on insertion, visual quality and less mucous discharge on waking than the control product (S).
- Table 2 shows the results for comfort on insertion, ratings of blurry and cloud/filmy vision and of mucous discharge upon waking. Figure 1 shows the subjective ratings of various visual aspects.

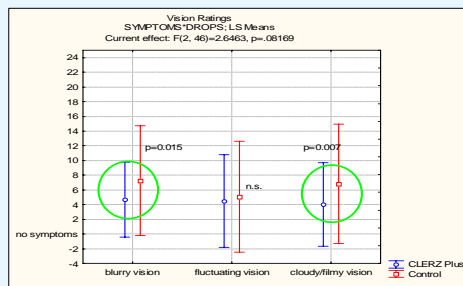


Figure 1: Subjective Vision Ratings

### Laboratory Results:

- Total protein deposition was lower with the Clerz Plus drop, as was lysozyme deposition. The percentage of denatured lysozyme was also reduced when subjects used the Clerz Plus drops compared with the control drops.
- Table 3 shows the results of the assays. Figure 2 shows an example of the Western blotting analysis.

Table 3: Laboratory Results

Variable	Clerz Plus	Control	P value
Total Protein (µg/lens)	1.2 ± 0.7	1.9 ± 0.8	< 0.001
Total Lysozyme (µg/lens)	0.7 ± 0.5	1.1 ± 0.7	< 0.001
Denatured Lysozyme (%)	76 ± 10	85 ± 7	0.002

Table 2: Subjective Ratings Results (0=best 50=worst)

Variable	Clerz Plus	Control	P value
Lens Comfort on Insertion of the Drops	2.5 ± 4.2	5.5 ± 10.5	0.020
Blurry Vision	4.7 ± 7.3	7.3 ± 9.6	0.015
Cloudy/Filmy Vision	4.0 ± 7.5	6.8 ± 10.8	0.007
Mucous Discharge on waking	3.8 ± 7.9	7.8 ± 11.9	0.015

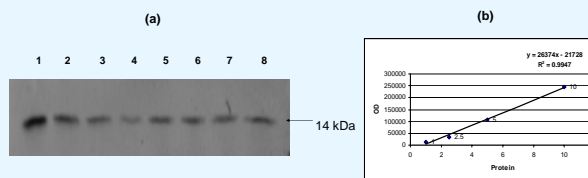


Figure 2: Western Blot and Regression Analysis for Lysozyme Quantification

- (a) An example of a lysozyme Western blot. Lanes 1-4 are purified human neutrophil lysozyme (lane 1 = 0.01, lane 2 = 0.005, lane 3 = 0.0025, lane 4 = 0.001 µg/µl). Lanes 5 - 8 are lens extracts when patients used either S (lanes 5 & 6) or CP drops (lanes 7 & 8).

- (b) A regression curve was created by graphing applied concentration of lysozyme standard against the optical density (OD) of the resulting band immunoreactivity. Total lysozyme concentration was quantified by extrapolation from this curve.

## Summary

- Lens comfort on insertion was rated better while using Clerz Plus drops than while using Saline.
- Vision was rated less blurry and less cloudy/filmy while using Clerz Plus drops than while using Saline.
- Less mucous discharge on waking was reported while using Clerz Plus drops than while using Saline.
- Total protein deposition was lower with Clerz Plus drops than with Saline.
- Lysozyme deposition was lower with Clerz Plus drops than with Saline.
- The percentage of denatured lysozyme was reduced when using Clerz Plus compared with Saline.

## Conclusions

- The use of rewetting drops containing surfactants may prove beneficial in the management of patients using SH lenses on a CW basis.
- The use of Clerz Plus drops provided greater subjective satisfaction, reduced protein deposition and reduced denatured lysozyme than rewetting the lenses with saline alone.

## References

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## Acknowledgements

This work was supported by Alcon Research Ltd, Fort Worth, Texas USA.