Clinical Study of Individual Make to Order SIFILCON A Silicone Hydrogel Contact Lenses

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1 Purpose

Primary objective of this clinical study was the evaluation of the clinical performance of a custom made silicone hydrogel contact lens (sifilcon A) over a three months wearing period in a daily wear mode.

2 Material and Methods

Subject population

35 trial subjects out of the contact lens wearer pool at the investigational site of JENVIS Research at the University of Applied Sciences in Jena, Germany could be included in this trial. Trial lenses were fitted to 32 subjects. One subject discontinued and data of three subjects were not evaluated due to control visits out of the time frame of the study protocol. For 28 evaluated subjects, 20 females and 8 males ranged in age from 18 to 56 years with an average of 29.5 ± 5.1 years.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Sign written Informed Consent
- Legal age
- Habitual soft contact lens wearer
- VA distance of 20/40 or better in each eye
- Ametropia of min. Sphere ± 6 D and max. ± 20 D or
- K-Readings < 7.4mm or K-Readings > 8.2 or
- HVID < 11.3mm or HVID > 12.5mm
- Astigmatism < 1/5 of sphere power
- Willing to use AO Sept Plus (Clear Care) for trial period

Exclusion Criteria

- Requires concurrent ocular medication
- Eye injury or surgery within twelve weeks immediately prior to enrolment for this trial
- Pre-existing ocular irritation that would preclude contact lens fitting
- Currently enrolled in an Ophthalmic Clinical Trial
- Evidence of systemic or ocular abnormality, infection or disease likely to affect successful wear of contact lenses or use of their accessory solutions
- Monovision or Monocular subjects
- Currently silicone hydrogel lens wearers
- Continuous contact lens wear in the last 30 days
- Pregnant or nursing

Material

Table 1 Overview Trial Lens Specifications

lens properties	sifilcon A
Water Content	32%
Dk & Dk/t @ -3.00D	82 & 117
Surface Treatment	permanent plasma surface treatment
Modulus	1.1 MPa
Handling Tint	Light green
Wearing Schedule	DW
Replacement Schedule	Quarterly
Sphere Powers	+20.00 D to -20.00D
Center Thickness	0.07 @ -3.00D
Manufacturing Process	Lathe Cut

Table 2 Lens Parameter Combinations

Lens Diameter	Available Base curves (mm) depending on the Lens Diameter										
	7.4	7.7	7.8	8.0	8.1	8.3	8.4	8.6	8.7	8.9	9.2
13.2 mm	x	x		x		x					
14.0 mm			x		x		x		x		x
14.8 mm				x		x		x		x	

Fitting Instructions of Sifilcon A make to order Contact Lenses

The fitting procedure of an aspherical custom made sifilcon A lens differs from the fitting rule of a conventional soft hydrogel custom made lens. Due to the design and the new material, the lenses would be too loose on the eye if this lens type will be fitted using standard fitting rules.
The following procedure was used in this study. As a first step, the lens diameter was selected by table #4. After the selection of the diameter, the base curve was chosen by table #5.

Table 4 Selection of Lens Diameter

HVID (mm)	Lens Diameter (mm)
< 11.40	13.20
11.40 – 12.20	14.00
> 12.20	14.80

Table 5 Selection of BC

Lens Diameter (mm)	Average of Central K-Readings (mm)		
	>8.10	8.10 – 7.30	< 7.30
13.20	8.30	8.00	7.70 or 7.40
14.00	9.00 or 8.70	8.40 or 8.10	7.80
14.80	9.20 or 8.90	8.60 or 8.30	8.00

Study Design

The study was open and prospective and with approval of an IEC. Fit, VA, comfort, slit lamp findings, wearing time and wettability were assessed at baseline with the habitual lenses. The same parameters were assessed at dispensing visit respectively at the follow up visits after one week, one month and three months.

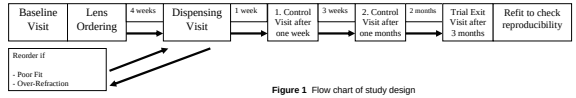
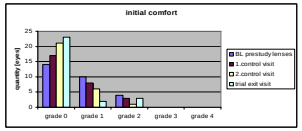


Figure 1 Flow chart of study design

3 Results

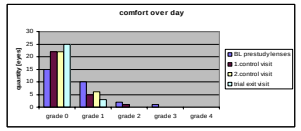
Comfort

Figure 2 Initial Comfort



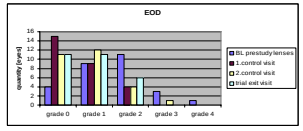
No statistically significant difference (**p=0.38**) between the initial comfort of the habitual lenses and the sifilcon A lenses were found at first control visit. At the second control visit the initial comfort was rated better (**p=0.058**) but not significantly different compared to habitual lens data. At 3 months 23/28 subjects (82%) reported excellent initial comfort with the sifilcon A lens vs 14/28 (50%) with habitual lenses. There is a statistical difference when comparing the initial comfort with habitual lenses and the trial lenses at trial exit visit (**p=0.032**). Wilcoxon matched pairs signed rank test

Figure 3 Comfort over Day



At the first control visit the comfort with the trial lenses was evaluated as more comfortable than with habitual lenses. There is a statistically significant difference (**p=0.014**) when compared with the habitual lenses and the trial lenses at first control visit. At the 3 months trial exit visit 25/28 subjects (89%) reported excellent comfort throughout the day with sifilcon A lenses vs 15/28 (53%) with habitual lenses which is a statistically significant difference (**p=0.009**). Wilcoxon matched pairs signed rank test

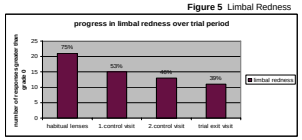
Figure 4 End of Day Comfort



At the first control visit the EOD with the trial lenses was evaluated as more comfortable than with habitual lenses. There is a statistically significant difference (**p<0.001**) when compared with the habitual lenses and the trial lenses at first control visit. At the second control visit the EOD was graded worse than at first control visit but in comparison with BL EOD better (**p<0.001**). At 3 months trial exit visit, 11/28 subjects (39%) reported excellent end of day comfort with sifilcon A lenses vs 4/18 (14%) with habitual lenses (**p=0.002**). Wilcoxon matched pairs signed rank test

Redness

Figure 5 Limbal Redness



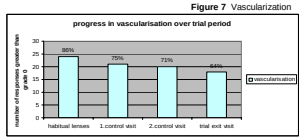
The reduction of limbal redness over the trial period shown in figure 5 (subgroup: grade 1 to 4) is statistically significant **p*<0.001**. Cochran´s Q Test

Figure 6 Progress of ocular redness

Subject # 32 OD

1.CV after one week | 2. CV after one month | Trial Exit Visit after 3 months

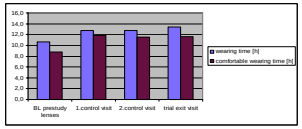
Figure 7 Vascularization



The reduction of vascularisation over the trial period shown in figure 7 (subgroup: grade 1 to 4) is statistically significant **p*=0.004**. Cochran´s Q Test

Further Results

Figure 8 Wearing Time



An increased wearing time was seen in the majority of the study participants. There is a statistically significant improvement of the total and comfortable wearing time with the trial lenses (**p<0.01**). Wilcoxon matched pairs signed rank test

Figure 9 Deposits

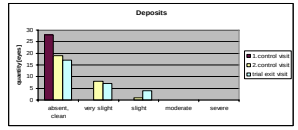
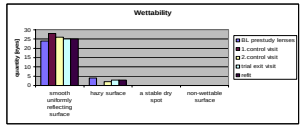


Figure 10 Wettability



Due to the three monthly replacement of the sifilcon A lens a manual cleaning procedure was recommended. The majority of the subjects was very compliant. Mixed deposits and a hazy surface were found on the trial lenses of a low number of subjects. That means that compliant contact lens wearers will have nearly no deposits and a smooth contact lens surface even at the last day before scheduled lens replacement.

4 Conclusion

The results of this study demonstrate that existing conventional soft contact lens wearers would profit from sifilcon A lenses. The comfort will increase as well as the comfortable wearing time. Limbal redness and vascularization will decrease. Up to now only wearers of 2-weekly and monthly silicone hydrogel lenses were able to profit from the benefits provided by silicone hydrogels. For contact lens wearers with prescriptions out of the power range of standardized lenses or with special corneal parameters it was not possible to combine an individual lens design with a high oxygen transmissible soft lens material. Furthermore it is shown that the sifilcon A material can be worn over three months without problems when the compliance is kept.