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 (silicon 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 Jena, Germany, were included in this trial. Trial lenses were fitted to 33 subjects. One subject discontinued and data of three subjects were not evaluable due to control visits out of the time frame of the study protocol. For 28 evaluable subjects, 20 females and 8 males it ranges in age from 18 to 56 years with an average of 29.5 ± 5.1 years.

Inclusion and Exclusion Criteria

Exclusion Criteria

- Uncontrolled ocular disease
- History of corneal disease or surgery
- Use of any soft or hard contact lens
- VA < 20/40 in better or each eye
- Anterior segment photography: < 4 mm corneal thickness
- History of ocular allergy
- History of dry eye syndrome
- History of systemic illness
- Use of systemic immunosuppressive medication
- History of previous ocular surgery or trauma
- Histology of any types
- Use of ophthalmic medications
- Use of any ocular drops
- History of any ocular infection

Inclusion Criteria

- Healthy subject with eyesight within the range of 20/20 to 20/30
- No use of any soft or hard contact lens
- VA = 20/40 or better in each eye
- History of ocular allergy
- History of dry eye syndrome
- History of systemic illness
- Use of systemic immunosuppressive medication
- History of previous ocular surgery or trauma
- Histology of any types
- Use of any ocular drops
- History of any ocular infection

Material

Material Table 1 - Overview Trial Lens Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lens Diameter</td>
<td>10.0 mm</td>
</tr>
<tr>
<td>Material</td>
<td>Silicon</td>
</tr>
<tr>
<td>Water Content</td>
<td>46%</td>
</tr>
<tr>
<td>Modulus</td>
<td>300 D</td>
</tr>
<tr>
<td>Oxygen</td>
<td>82%</td>
</tr>
<tr>
<td>Smooth surface</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Fitting Instructions of Sifilcon A make to order Contact Lenses

The fitting procedure of an aspherical custom made silicone A lens differs from the fitting rule of a conventional soft hydrogel contact lens. Due to the design and the material, the lenses would be too loose on the eye if this lens type was 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 #9.

Study Design

The study was open and prospective and with approval of an IEC. FIT, VA, comfort, oil lamp findings, wearing time and exudability were assessed at baseline with the habitual lenses. The same parameters were assessed at dispersing visits respectively at the follow-up visits after one week, one month and three months.

3 Results

Comfort

The subjective difference in redness (p=0,014) between the initial period of the wearing time and the test lens was significant. Subjective comfort was also slightly better (p<0,05) for the test lens compared to the habitual lens. The subjective comfort was rated better than 4.00, but not significantly (p=0,21). The comfort of the test lens increased significantly (p<0,05) compared to the initial period of wearing time (p=0,001) at the first control visit. There was a slight increase in subjective comfort compared to the initial period of wearing time (p=0,01). There was also a slight increase in subjective comfort at the end of the study period (p=0,001). There was a slight increase in subjective comfort at the end of the study period (p=0,001).

Redness

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4 Conclusion

The results of this study demonstrate that existing conventional soft contact lens wearers would profit from silicone 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 silicone A material can be worn over three months without problems when the compliance is kept.