Footnotes

1 Desquamation, displacement of dead skin cells
2 Programmed cell death of individual biological cells
3 Neither the test person nor the investigating fitter know which test version is being used, in order to eliminate the influence of expectation and behaviour which this knowledge would elicit.
4 The study data are collected after the establishment of the hypothesis solely for the purpose of testing the hypothesis. The data material can thus be adapted to the requirements of the study.
5 Random allocation, whereby known and unknown influencing variables of the study results are equally distributed.
6 contact lens-induced conjunctival stainings (CLICS) = arc-shaped edge impression in the conjunctiva
7 evaluated at a confidence interval of 95% (= confidence level, i.e. the calculated interval boundaries contain the true value in 95 out of 100 cases); p<0.05
8 Reduced tear exchange rate because the exchange of nutrients on the surface of the eye is reduced with larger diameters. Reduced tear exchange under the lens can encourage infections or inflammation of the eye. On the other hand, good tear exchange ensures unimpeded desquamation, regular apoptosis and maintenance of the tear film as a multifunctional barrier. Thus it ensures essential supplies to the tissue under the contact lens, the removal of deposits such as shed off epithelial cells, bacteria, other tear film components and metabolic waste products which would otherwise accumulate under the lens.
9 More attention should be paid to the edge geometry of soft contact lenses, because the edge zone plays a decisive role in the way the tear fluid washes under the lens, in the mobility of the lens over the conjunctiva and cornea, and in the way the eye lid glides over the edge of the lens. The lens edge has a considerable influence on objective compatibility and wearing comfort, as has been demonstrated in a number of studies on rigid gas permeable lenses (RGP).
10 An edge profile with a smooth, tapered and well rounded lens edge with a more pronounced flattening on the back surface is described as theoretically ideal. An edge profile with a back surface part as „water ski“ (diagram)

But does this also apply to the edge geometry of soft contact lenses? This question was examined in the present study, which was performed as a diploma thesis. The aim was to obtain an overview of all available edge profiles, to classify them, and to examine the most common edge profiles with regard to their influence on fitting and wearing characteristics.
Method

27 different lens systems (daily wear, weekly and monthly exchange lenses) from 10 contact lens manufacturers were examined and categorized with regard to their different edge profiles using a special cutting method. 2 lenses of each contact lens type were cut into 2 quadrants and the profile was assessed and measured at 4 locations. Since there is no standard specification for edge shaping\[11,12\], the manufacturers’ designs are based on their own experience and feedback. It was therefore not surprising that a wide variety of edge profiles was found.

It became clear that most contact lenses manufactured by less complex moulding methods and with shorter exchange intervals (daily wear, weekly exchange) have one-sided edge flattening. Monthly exchange lenses frequently had two-sided edge profiles and a few had rounded ones. The results of the measurements of hydrogel and silicone hydrogel lenses corresponded with the profiles determined in the studies by LØFSTRØM\[13\] and NOSCH\[14\].

In order to be able to make a direct comparison of the edge profiles of the 4 categories with regard to wearing and fitting characteristics throughout the course of the study, the following contact lens parameters had to be guaranteed: uniform material properties, a lens geometry with constant edge zone independent of the base curve and power, and a reproducible edge profile. As these criteria could not be guaranteed for the commercially available lenses, special test lenses were developed. They had the basic geometry of the Weflex 55 (Wöhlk), with a lenticular zone in the periphery of the front surface specially developed for this study, which guarantees a constant edge thickness independent of power, base curve and edge profile.

These test lenses were produced by Wöhlk-Contact-Linsen GmbH using the precise and flexible CNC-controlled nanoform lathe cutting method.

These specially manufactured test lenses were assessed in a randomised, double blind, right-left comparison prospective study on 19 soft lens wearers (63 % female, 37 % male, average age 26.3 ± 4.9 years) using objective measurements and subjective questioning. The 4 contact lens edge profiles were distributed randomly for each eye\[5\]. The prerequisite for the choice of the test lens parameters was the good fit of the fitting lens, ensuring comparability between the different test persons.
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Fig. 3 The 4 most frequent edge profile categories of commercially available exchange lenses

Tab. 1 Illustration of the 4 edge profiles

<table>
<thead>
<tr>
<th>Technical drawing</th>
<th>Cross section of edge profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. One-sided edge profile with pointed apex on the back surface</td>
<td><img src="image1" alt="Cross section of edge profile" /></td>
</tr>
<tr>
<td>II. Two-sided edge profile with pointed apex</td>
<td><img src="image2" alt="Cross section of edge profile" /></td>
</tr>
<tr>
<td>IIa. long side on the back surface</td>
<td><img src="image3" alt="Cross section of edge profile" /></td>
</tr>
<tr>
<td>IIb. long side on the front surface</td>
<td><img src="image4" alt="Cross section of edge profile" /></td>
</tr>
<tr>
<td>III. Edge profile with rounded apex</td>
<td><img src="image5" alt="Cross section of edge profile" /></td>
</tr>
<tr>
<td>IV 1 UV</td>
<td><img src="image6" alt="Cross section of edge profile" /></td>
</tr>
</tbody>
</table>

These specially manufactured test lenses were assessed in a randomised, double blind\(^3\), right-left comparison prospective study\(^4\) on 19 soft lens wearers (63 % female, 37 % male, average age 26.3 ± 4.9 years) using objective measurements and subjective questioning. The 4 contact lens edge profiles were distributed randomly for each eye\(^5\). The prerequisite for the choice of the test lens parameters was the good fit of the fitting lens, ensuring comparability between the different test persons.
The fit of the contact lenses was assessed using the objective classification criteria of mobility, centration and wettability. Since the state of hydration of the contact lens changes during the course of the wearing period, measurements were taken after 10 min, 30 min and at least 6 hours. The physiology of the eye was documented before, during and after lens wearing. A special assessment criterion was the impression of the lens edge on the bulbar conjunctiva as an arc-shaped staining, which was assessed according to location (quadrants) and severity. There is direct contact between the edge of the lens and the bulbar conjunctiva. Lens forces, lid pressure, adhesion and negative pressure particularly affect that part of the conjunctiva on which the thin edge zone of the lens rests. These forces, in conjunction with the mobility of the lens, can result in mechanical stress and irritation, e.g. of raised blood vessels in the conjunctiva. In addition, in the case of hydrophilic lenses, the combined water volume evaporates to a greater or lesser extent during the course of the day. The curvature of the contact lens alters with the changes in the water content. This causes the radii to become steeper and the lens edge to dig into the bulbar conjunctiva, resulting in reddening of the eye as a consequence of more blood injection in the blood vessels, and staining in the area of the bulbar conjunctiva. Stainings are slight, clearly defined, epithelial cell defects. The edge impression is clearly visible with fluorescein, from dot-like staining to arc-shaped build-up of fluorescein in the area of the lens edge. The extent of the manifestation varies with the movement of the lens. If it is pushed by the blinking action of the eyelid, mechanical pressure can result in a broad band around the limbus. If the lens is immobile, this may result in pressure causing indentations on the conjunctival tissue.

In addition the test persons use a questionnaire to subjectively assess compatibility, wearing comfort and sensitivity to the lens edge. All assessments were undertaken separately for the right and left eye.

**Assessment criteria**

<table>
<thead>
<tr>
<th>CLICS - type (T. Hübner)</th>
<th>CLICS - location (T. Hübner)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = no impression</td>
<td>1 = nasal</td>
</tr>
<tr>
<td>1 = slight impression</td>
<td>2 = temporal</td>
</tr>
<tr>
<td>2 = moderate impression</td>
<td>3 = superior</td>
</tr>
<tr>
<td>3 = deep impression</td>
<td>4 = inferior</td>
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</table>

**Results**

**Mobility**

If one compares the degree of mobility of the lenses with the 4 different edge profiles, it is clear that the rounded edge and the two-sided edge profile are most frequently graded between 0 and 1 (see Tab. 3). On the other hand, the one-sided, pointed edge profile is between 0 and -1, which means that these lenses generally fit somewhat tighter (statistically significant). As was to be expected, it was also seen that mobility of the lenses decreased over time, regardless of the edge profile.

**Summary - influence on mobility**

Mobility of the lenses decreases over time, regardless of the edge profile. A comparison of edge geometries showed that the one-sided, pointed profile had always a tighter fit.

**Conjunctival impression**

Edge impressions were seen in all four quadrants of the eye, but no locally significant differences were observed. There was a connection with time, the longer the wearing time the impression became deeper. As can be clearly seen in Fig. 6, the one-sided, pointed edge geometry causes a deeper impression in the conjunctiva (p<0.01). Clinically relevant 3rd and 4th degree impressions were seen here. The mean value for this pointed edge is almost twice as high compared with the other profiles. The two-sided and rounded edge profiles were in the middle of the range from ‘no impression’ (0) to ‘slight impression’ (1).
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Summary - influence on mobility

Mobility of the lenses decreases over time, regardless of the edge profile. A comparison of edge geometries showed that the one-sided, pointed profile had always a tighter fit.
Other assessment criteria, such as centring and wettability of the contact lens show no significant differences between the 4 different edge profiles, i.e. the edge profile has no effect on them. Examination of the external eye (cornea and tarsal conjunctiva) also shows no difference between the edge profiles. Only in the case of the one-sided, pointed edge profile, staining on the entire conjunctiva was significantly increased, which correlates with the appearance of a visible impression.

**Assessing comfort**

Hardly any difference is noticeable on a finely graduated scale (0 to 100) because all values (see Fig. 8) lie in the range between: good, occasionally slightly noticeable (75) and excellent, not noticeable (100), regardless of the time of the assessment.

The rounded edge scores slightly less well with regard to spontaneous comfort in the edge profile comparison (p < 0.006), but is still considered comfortable, and no difference is noticed after a brief adaptation period of 30 minutes.

In the assessment of comfortable wearing time the rounded edge profile is considered less comfortable and the one-sided, pointed edge profile is considered most comfortable.

**Conclusions**

Lenses from commercially available exchange systems can be assigned to 4 characteristic edge profile groups and, depending on the lens material and design, the edge profile influences the fitting behaviour, physiological compatibility and wearing comfort of the lens. The modulus of the lens material is very important. “The YOUNG modulus is a material constant which states how pliable or rigid a material is”[15]. The higher the modulus, the more rigid the contact lens. Silicone hydrogels have inherently higher modulus values than hydrogels. The results of all 10 assessment criteria in this test lens wearing study showed that two-sided and rounded edge profiles had the best fitting and wearing characteristics, and they should therefore be preferred, especially for lens materials with a higher modulus. A one-sided edge profile with pointed apex on the back surface is objectively less mobile, so that the lens is spontaneously less noticeable for the wearer, but after a longer wearing period it has a noticeable effect on the physiology of the conjunctiva (CLICS). The more rigid the contact lens (combination of high modulus and lens thickness), the more important is the quality of the edge profile. Individually lathed lens systems generally have rounded edge profiles.

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Edge profiles of hydrogel contact lenses and their effect on fitting and wearing characteristics

The diameter of a soft contact lens and its ability to adapt to the shape of the eye have an enormous influence on the tear exchange rate because the exchange of nutrients on the surface of the eye is reduced with larger diameters [1, 2]. Reduced tear exchange under the lens can encourage infections or inflammation of the eye. On the other hand, good tear exchange ensures unimpeded desquamation [3], regular apoptosis [4] and maintenance of the tear film as a multifunctional barrier. Thus it ensures essential supplies to the tissue under the contact lens, the removal of deposits such as scaled off epithelial cells, bacteria, other tear film components and metabolic waste products which would otherwise accumulate under the lens.

More attention should be paid to the edge geometry of soft contact lenses, because the edge zone plays a decisive role in the way the tear fluid washes under the lens, in the mobility of the lens over the conjunctiva and cornea, and in the way the eye lid glides over the edge of the lens. The lens edge has a considerable influence on objective compatibility and wearing comfort, as has been demonstrated in a number of studies on rigid gas permeable lenses (RGP) [5-10].

An edge profile with a smooth, tapered and well rounded lens edge with a more pronounced flattening on the back surface is described as theoretically ideal [5, 11] (see Fig. 1 & 2).

But does this also apply to the edge geometry of soft contact lenses? This question was examined in the present study, which was performed as a diploma thesis. The aim was to obtain an overview of all available edge profiles, to classify them, and to examine the most common edge profiles with regard to their influence on fitting and wearing characteristics.