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Theoretical fitting characteristics of typical soft contact lens designs

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ABSTRACT

Purose: To calculate theoretical fitting success rates (SR) for a range of typical soft contact lens (SCL) designs using a mathematical model.
Method: A spreadsheet mathematical model was used to calculate fitting SR for various SCL designs. Designs were evaluated using ocular topography data from 163 subjects. The model calculated SR based on acceptable edge strain (within range 0–6%) and horizontal diameter overlap (range 0.2–1.2 mm). Where lenses had multiple base curves (BCs), eyes unsuccessful with the steeper BC were tested with the flatter BC and aggregate SR calculated. Calculations were based on typical, current, hydrogel and silicone hydrogel SCLs and allowed for appropriate on-eye shrinkage (1.0–2.3%). Theoretical results were compared with those from actual clinical trials.
Results: Theoretical success rates for one-BC lenses ranged from 60.7% (95% CI 7.2%) to 90.2% (95% CI 3.7%). With two-BC designs, most combinations showed a SR increase with a second BC (84.0%–90.2%). However, one of the two-BC combinations showed only negligible increase with a second BC (72.4%–73.0%). For designs with lower SR, the greatest contributor to failure was inadequate lens diameter. For a given design, differences in shrinkage (i.e. on-eye bulk dehydration) had a significant effect on success rate. In comparison with historical clinical data, there was a positive correlation between small lens fitting prevalence and discomfort reports ($r = +0.95$, $P = < 0.001$) with a poor correlation between theoretical and actual tight/loose fittings.
Conclusions: Mathematical modelling is a useful method for testing SCL design combinations. The results suggest that judicious choice of additional fittings can expand the range of fitting success.

1. Introduction

Many of the important characteristics of soft contact lens performance can be anticipated from physical measurements, such as modulus, oxygen permeability, thickness, and coefficient of friction. Elastic modulus, coupled with thickness profile, gives some indication of the lens' handling characteristics and the likelihood of mechanical induced complications [1–3]. Oxygen transmission can be correlated to open-eye and closed-eye corneal swelling and limbal hyperemia [4]. Recently, coefficient of friction has been related to comfort [5].

Many clinical trials attempt to compare the clinical performance of different clinical designs. However, even with modest subject numbers, these are expensive, time-consuming and are only able to compare a limited number of lens designs. An obvious alternative to the clinical testing of soft lens fitting success is to use computer modelling which is routinely used in the commercial development of soft lens designs. A spreadsheet model has been described to evaluate effect of various aspects of soft lens parameters [6,7].

The main fitting characteristics governing the success of well-fitting soft contact lenses include tightness, and corneal coverage [8]. The model estimates tightness by calculating the increase in lens circumference, or edge strain, when a given lens design is fitted to a given eye shape. It estimates corneal coverage by calculating how much the lens overlaps the cornea when forced to align with the given ocular topography [7]. Lens centration, movement and edge alignment are also important lens fit characteristics, however, these are consequent on lens tightness and therefore not considered by the model.

The technique incorporates some obvious approximations which limit its accuracy but some effort has been made in this study to correlate the findings with actual clinical data.

The purpose of this project has been to use spreadsheet modelling to assess the theoretical fitting success of a wide range of currently available spherical soft contact lenses and to compare this with historical data from previous clinical trials.

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2. Method

This computer modelling study estimated the theoretical fitting success rates for a range of soft lenses using population data from a previous study [9]. The mathematical model calculated soft lens fit characteristics (tightness, corneal overlap) against pre-set acceptance criteria and determined whether given lenses on given eyes were acceptable. The theoretical data were compared with historical data from previous Johnson & Johnson Vision Care, Inc. clinical trials.

2.1. Subject database

The subject database comprised data from 163 eligible UK subjects who had been examined in a previous study [9]. To be included in the database, subjects were required to have a spectacle cylinder < 2.00D and no keratoconus or other severe corneal irregularity contraindicating lens wear.

Ocular topography data from only one eye per subject were used; this was the right eye data unless only the left eye data were available.

The ocular topography inputs were corneal apical radius, corneal asphericity (shape factor), corneal diameter and corneoscleral junction angle (Table 1). The corneal diameter was the true corneal diameter as opposed to the conventional clinical measurement of horizontal visible iris diameter (HVID) which underestimates the true diameter by approximately 1.5 mm [9,10].

2.2. Study lenses

A range of 15 current representative spherical soft lens designs were tested (Table 2). The base curve (BC) and diameter values were taken from manufacturer's specifications. The shrinkage factors were calculated from measurements of lens diameter at room and eye temperatures using an established method [3,11]. This represents the amount of change in BC and diameter when lenses are placed on the eye and raised to ocular surface temperature.

For the purposes of the theoretical analysis, it was assumed that the lens back surface design was monocurve and spherical.

These lens designs were based on currently available designs and therefore represent a cross-section of contemporary lenses. For the six lens brands currently available in two BCs, the aggregate overall success rate was calculated as well as the individual success rates.

2.3. Lens analysis

A spreadsheet computer model was used to calculate the lens fit success rates of various soft lens designs [7]. This updated version allows separate inputs for vertical and horizontal ocular topography. It allows calculations to be done for two lens designs and to give an overall success rate, for example, for a lens design incorporating two base curves.

The lens inputs include diameter, BC and shrinkage factor for the given lens material (Table. 2). The 15 lens designs were analysed using the database of 163 eyes (Table. 1).

Table 1
Summary of ocular topography data and demographics (N = 163).

Ocular variable	Mean (SD)	Median	Range	
Apical radius (mm)	7.78 (0.30)	7.78	7.01	8.77
Shape Factor	0.52 (0.16)	0.53	-0.01	0.91
Corneal Diameter (mm)	13.39 (0.44)	13.4	12.10	14.41
Corneoscleral Junction (°)	175.4 (2.3)	175.4	166.2	179.7
Age (years)	37.7 (15.6)	15.6	18	65
Sphere Refraction (DS)	-1.62 (2.3)	-1.25	+3.00	-9.25
Cylinder Refraction (DC)	-0.57 (0.45)	-0.50	0.00	-2.00
Ethnicity	White: 79%; East Asian British: 18%; 2% Mixed Race			

For a given lens and eye, the model determined whether the lens provides an acceptable fit based on two characteristics: i) edge tightness (or strain) and ii) horizontal corneal overlap. The edge strain was averaged for horizontal and vertical meridians. The lens' overlap of the cornea was based on only the horizontal meridian and the horizontal cornea is invariably larger than the vertical. For a lens to be judged acceptable, it was required to show mean edge strain falling within the range 0–6% and horizontal corneal overlap falling within the range 0.2–1.2 mm. These thresholds were estimated using historical clinical study data.

Success rates were based on the proportion of the 163 eyes showing as acceptable fit for tightness, diameter overlap and overall acceptance. The overall success rate, therefore, indicated the proportion of lens fittings that were acceptable for both diameter and tightness. In the case of those lenses with multiple BCs, those eyes not successfully fitted with the steeper BC, were tested with the flatter BC and the aggregate success rates calculated.

2.4. Historical clinical data comparison

In order to evaluate the reliability of the model, the theoretical results for specific lens types were compared with actual clinical data from historical unpublished study data. Key lens fit data were extracted from eight previous clinical studies. The previous studies involved a representative sample of ten of the reusable and daily disposable lens types analysed and sample sizes varied from 100 to 258 subjects per lens type. The following summary data relating to lens fitting results were extracted:

- Proportion of eyes reporting frequent/constant discomfort
- Proportion of eyes with non-optimal loose or tight fittings, i.e. Grade −1/−2 or Grade +1/ + 2 (−2 to +2 scale, 0-optimum), respectively.

2.5. Statistical analysis

The 95% confidence intervals were calculated for all success rates using the following formula: SQRT((p*(1-p))/N)*1.96 (where p = proportion, N = sample size)

Spearman's rank correlation coefficient was used to test for associations between selected variables.

3. Results

3.1. Lens analysis

The results are summarised in Table. 3, and in Fig. 1 (overall success rates) and Fig. 2 (multiple BCs).

For the single BC designs, the overall success rate ranged from 60.7% (Lens M & O) to 90.2% (Lens F & H). The ranges were similar for single BC design daily disposable (60.7–90.2%, Lens M & O and Lens F respectively) and for reusable lenses (68.7–90.2%, Lens K and Lens H respectively) (Table. 3, Fig. 1).

Six of the lens types comprised two BCs. In each case, the steeper BC was the most successful overall. The use of an additional flatter BC increased the success rate, on average by 6% (median). The greatest increase was for Lens B for which the combined success rate was 95.1% compared with 82.22% for the steep BC only. The least successful combination was Lens E for which the combined success rate was 73.0% compared with 72.4% for the steep BC only. With two BCs, high success rates were achieved with both daily disposable and reusable lenses (Table 3, Fig. 2).

The highest overall success rate was, therefore, achieved by the two-BC combination of daily disposable silicone hydrogel Lens A (95.7%). With reusables, the highest overall success rate was with Lenses C & D