

Gas permeable contact lens fitting in keratoconus: Comparison of different guidelines to back optic zone radius calculations

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Purpose: Compare the agreement between the finally fitted back optic zone radius (BOZR) of a spherical gas permeable (GP) contact lens (CL) with those proposed by different guidelines currently available to fit GP CLs in keratoconus. **Methods:** The BOZR fitted in 81 keratoconus eyes (46 patients) were recorded and compared with the BOZR calculated with ten different guidelines (identified after a literature review) proposed to calculate the first diagnostic lens BOZR to be fitted in keratoconus. Arithmetic and absolute mean difference between both BOZR were calculated (paired *t*-test). The success rate of each guideline (difference between both BOZR ≤ 0.05 mm) was calculated for different keratoconus stages (Amsler–Krumeich classification). Agreement between BOZR was evaluated using Bland-Altman analysis. **Results:** The BOZR proposed by all guidelines correlated with the final BOZR that was fitted ($R^2 > 0.71$; $P < 0.01$). A statistically significant difference was found between the BOZR suggested by all guidelines and the BOZR that was prescribed ($P < 0.05$), except for three Guidelines ($P \geq 0.11$). CALCULENS.com presented the best agreement (mean difference of 0.00 ± 0.12 mm), and 50.6% of cases showed ≤ 0.05 mm of difference with the BOZR that was fitted. However, the worst guideline showed an agreement of -0.38 ± 0.22 mm, and just 3.8% of cases had ≤ 0.05 mm of difference with the final fitted BOZR. **Conclusion:** BOZR calculated with most of the analyzed guidelines shows statistical differences with final fitted BOZR, suggesting a lack of clinical validation of these guidelines. The selection of the BOZR with CALCULENS.com could provide a better starting point for spherical GP CL fitting in keratoconus eyes.

Key words: Contact lens, fitting, gas permeable, guidelines, keratoconus

Rigid gas permeable (GP) contact lenses (CLs) are the first option in keratoconus patient management^[1-3] because they provide better visual rehabilitation and improve the quality of life of these patients.^[1-5] Fitting of GP lenses in keratoconus patients and achieving an acceptable fit can be considered challenging for eye care practitioners due to keratoconus being a progressive corneal disorder characterized by central and paracentral corneal steepening, corneal thinning, irregular corneal topography, and irregular astigmatism, which provoke spectacle visual acuity impairment.^[1,5,6] Therefore, this procedure often requires a long practitioner and patient chair time to achieve optimal centration, minimum impact on the ocular surface, and the best comfort and vision with the final GP lens fit.^[7-10]

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Classically, three GP corneal design fitting philosophies for keratoconus have been described in the literature:^[11] steep or apical clearance (lens support or bearing on the peripheral cornea), flat or apical touch (lens support or bearing on the apex of the cornea), and three-point-touch or divided support (lens support or bearing is shared between the apex and the paracentral cornea), with this last philosophy being the safest technique for GP fitting in keratoconus.^[11]

Currently, there are several methods or guidelines to select the parameters of the GP lens in keratoconus eyes to achieve three-point-touch fitting based on the corneal curvature values (K readings). Each CL manufacturer provides specific fitting guidelines according to the lens geometry, and different “CL fitting software programs” have been proposed to simplify this procedure.^[2,12-18] However, an analysis of the accuracy of most of these recommendations has not been reported previously to provide evidence-based information that permits improved GP lens fitting in keratoconus eyes.

The aim of this study was to compare the agreement between the back optic zone radius (BOZR) proposed by different

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manufacturers' guidelines, nomograms, or CL fitting software programs designed to fit a spherical GP CL in keratoconus eyes with the BOZR final fit in a sample of keratoconus eyes.

Methods

Fitting guidelines search

We performed an extensive electronic search of the Medline and PubMed databases, Google Scholar database, Science Direct database, Cochrane database, metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com) and ClinicalTrials.gov (www.clinicaltrials.gov) using individual and combinations of key words ("Keratoconus contact lenses", "Keratoconus fitting guideline", "Keratoconus GP fitting", "Keratoconus GP management") in December 2017 to identify 618 relevant publications in this field. We did not use any date or language restrictions in the electronic search. We also included additional references (from different sources, books, books chapters, manufacturers' websites, etc.) that were cited or included in these articles (15 additional results). Case reports were not assessed. To refine search results, references without information to how calculate or select the BOZR of the first diagnostic lens, or focused for fitting soft CL, piggy-back, corneo-scleral, semi-scleral, mini-scleral, scleral or hybrid CL designs were excluded, and just 11 references [Table 1] were chosen that allow to identify 10 guidelines or general recommendations to select/calculate the BOZR of the spherical

GP lens to fit in keratoconus eyes. We chose each reference only if they included a clear description of the formula to choose or calculate the BOZR of the diagnostic lens to start with.

Study population

Clinical records of 81 keratoconus eyes of 46 patients [(25 men and 21 women) with a mean age of 38.6 ± 11.7 years (range 19–66 years)] who were successfully fitted with spherical GP CLs specifically designed for keratoconus eyes (spherical tetra-curve; KAKC GP, Conoptica–Hecht Contactlinsen, Germany) were used. Three different experienced CL practitioners conducted all GP CL fittings following manufacturer recommendations to achieve a three-point-touch fluorescein pattern. Each one of these CL practitioners has more than 10 years of clinical experience fitting CL and managing patients with irregular cornea as keratoconus patients. The Human Sciences Ethics Committee of the University approved the study and informed consent was obtained from each subject, and all subjects were treated in accordance with the Declaration of Helsinki.

Records of patients with any active ocular-surface disease (except keratoconus), medication use that could affect ocular physiology or with a history of acute corneal hydrops, any type of ocular surgery, or any other ocular disease were excluded.

The following data were collected for all eyes included in the study: patient's age, refraction, best corrected visual acuity (BCVA) with spectacles and with CL, manual keratometry

Table 1: Description of guidelines used in the study

Guideline	Description
Guideline #1	Suggested by the APEX software CL fitting (APEX, version 1.1.0.6, developed by Hecht Contactlinsen in association with Oculus, which displays a simulated fluorescein pattern of the specified GP design to aid the fitting procedure). ^[13] Recommend 3-touch fitting philosophy.
Guideline #2	$BOZR = (BOZR_{APEX} * 0.88) + 0.77$ Improvement of BOZR proposed by APEX software CL fitting. ^[13] Recommend 3-touch fitting philosophy.
Guideline #3	$BOZR = \text{Horizontal K (mm)} - 0.10$ Recommended by Conoptica-Hecht Contactlinsen, (Germany) to fit KAKC lens. ^[19] Recommend 3-touch fitting philosophy
Guideline #4	If corneal astigmatism < - 3.75 D: $BOZR = Kf (D) - 0.61 \times \text{Astigmatism}$ If corneal astigmatism -4.00 to -7.50 D: $BOZR = Kf (D) - 0.50 \times \text{Astigmatism}$ If corneal astigmatism > - 7.50 D: $BOZR = Kf (D) - 0.35 \times \text{Astigmatism}$ *Calculated to diameter of 9.40 mm Proposed by Centre of Contact Lens Research (University of Waterloo, Canada). ^[15] Recommend 3-touch fitting philosophy
Guideline #5	If $Kf < 7.00$ mm: $BOZR = 0.211 * Kf (mm) + 5.904$ If Kf 7 to 8 mm: $BOZR = 0.465 * Kf (mm) + 4.16$ Recommended by Rajabi MT <i>et al.</i> ^[12] Recommend 3-touch fitting philosophy.
Guideline #6	$BOZR = Km (mm) - 0.20$ Recommended to fit RoseK2 GP lens (Menicon, Co., Ltd., North Billerica, MA, USA) ^[20] Recommend 3-touch and apical clearance fitting philosophy.
Guideline #7	$BOZR = Kf (mm) - [1/3 \text{ astigmatism (mm)}]$ Proposed by Bausch & Lomb ^[21] to fit their keratoconus lens design or OP8 GP lens (Soflex, Israel). ^[22] Recommend 3-touch fitting philosophy (with slight central touch).
Guideline #8	$BOZR = K_{mean} (mm)$ Recommended to fit ACL KERA lens (Australian Contact Lenses, Australia), FlexCone (SwissLens, Switzerland), Keracon (Gelflex, Australia), McGuire lens (Ultravision, United Kingdom) and Nissel K2 lens (Cantor+Nissel, United Kingdom). ^[18] Recommend 3-touch fitting philosophy.
Guideline #9	$BOZR = K_s (mm)$ Proposed to fit Comfort Kone lens (MetroOptics, USA) ^[23] or iKone lens (Valley Contax, USA). ^[24] Recommend slight apical clearance fitting philosophy.
Guideline #10	Calculens.com Algorithm developed to select the first diagnostic lens in keratoconus. ^[14] Recommend 3-touch fitting philosophy.

Kmean=Mean corneal curvature; Kf=Flattest corneal meridian; Ks=Steepest corneal meridian

readings (OM-4 Topcon, Japan), corneal topography data (simulated keratometry, astigmatism power, axis of astigmatism, achieved with a placido-based topographer (Oculus Keratograph, Oculus Optikgeräte GmbH, Wetzlar, Germany), Amsler–Krumeich keratoconus severity stage, and definitive BOZR and total lens diameter of the GP lens that was fitted.

BOZR GP fitting guidelines comparison

Ten guidelines were identified after the literature review [Table 1]. BOZR following each spherical GP fitting guideline was calculated and compared with the final BOZR fitted in each patient's eye.

Data analysis

Statistical analysis was performed using the SPSS 15.0 (SPSS, Chicago, IL, USA) statistical package for Windows. A normal distribution of variables was assessed using the Kolmogorov–Smirnov test, and *P* values >0.05 indicated that the data were normally distributed.

The difference between the BOZR proposed by each guideline and the BOZR that was finally fitted was calculated using a paired *t*-test (*P* values <0.05 were considered statistically significant). A linear regression quantified the R^2 correlation coefficient between the BOZR proposed and that finally fitted (*P* value <0.05 was considered statistically significant). In order to guarantee statistical comparison, the equivalent lens was calculated to guarantee the same sagittal height and allow BOZR statistical comparison in cases fitted with different total lens diameter.^[14,25]

The arithmetic and absolute mean difference between the BOZR calculated by each guideline and the BOZR finally fitted were calculated. The absolute difference was calculated to avoid the effect of positive and negative differences that could affect

the mean value. An absolute difference was clearly represented when the BOZR proposed by each method was closer to the final fitted BOZR. We calculated the success rate of the GP guideline fitting when the difference between the BOZR of the diagnostic lens proposed with the final BOZR prescribed was ≤ 0.05 mm. Additionally, we calculated the success rate of the GP guideline fitting for different keratoconus stages according to the Amsler–Krumeich classification, and they were compared using a Chi-squared test (*P* values of <0.05 were considered significant).

Agreement between the BOZR of the final fitted GP lens with the BOZR of the first diagnostic lens calculated by the guidelines was evaluated using Bland–Altman analysis.^[26] Differences between the BOZR fitted and that proposed by each method were plotted against the means of each BOZR. The 95% limits of agreement (LoA) were calculated (mean of the difference $\pm 1.96 \times$ standard deviation). The relationship between the mean value (*x*) and the difference (*y*) was determined using linear regression analyses. The R^2 correlation coefficient was calculated to test-retest reliability (*P* values of <0.05 were considered statistically significant).

Results

The mean spherical equivalent refractive error was -4.20 ± 3.82 D (range 0.25 D to -13.25 D), with a mean keratometry (Kmean) reading of 7.16 ± 0.47 mm. The flattest corneal curvature (Kf) was 7.43 ± 0.42 mm, and the steepest corneal curvature (Ks) was 7.04 ± 0.44 mm. The BCVAs with spectacles and CL were 0.67 ± 0.29 and 0.96 ± 0.15 (Snellen chart), respectively. According to the Amsler–Krumeich classifications, we included 18 eyes in stage 1, 35 eyes in stage 2, and 28 eyes in stage 3.

The mean BOZR fitted in keratoconus eyes was 7.19 ± 0.38 mm. Table 2 shows the mean BOZR of the

Table 2: Summary of the means and standard deviation (SD) of the BOZR proposed by each guideline. The correlation, arithmetic, and absolute mean and SD of the BOZR differences between each guideline and the BOZR that was fitted are shown

<i>n</i> =81	Guideline BOZR proposed	Mean difference* and correlation between BOZR proposed and BOZR fitted	Absolute difference between proposed and fitted BOZR (mm)	Success rate† (95% CI)
Guideline #1	7.34±0.39	-0.14±0.14 (<i>P</i> <0.01) $R^2=0.869$ (<i>P</i> <0.01)	0.16±0.12	26.3% (16.5-36.0%)
Guideline #2	7.23±0.34	-0.03±0.14 (<i>P</i> =0.04) $R^2=0.869$ (<i>P</i> <0.01)	0.10±0.10	41.3% (30.4-52.1%)
Guideline #3	7.05±0.48	+0.15±0.26 (<i>P</i> <0.01) $R^2=0.719$ (<i>P</i> <0.01)	0.23±0.18	19.8% (11.0-28.5%)
Guideline #4	7.16±0.40	+0.03±0.17 (<i>P</i> =0.11) $R^2=0.822$ (<i>P</i> <0.01)	0.14±0.11	26.3% (16.5-36.0%)
Guideline #5	7.58±0.23	-0.38±0.22 (<i>P</i> <0.01) $R^2=0.714$ (<i>P</i> <0.01)	0.39±0.21	3.8% (0.2-9.7%)
Guideline #6	6.96±0.47	+0.23±0.18 (<i>P</i> <0.01) $R^2=0.870$ (<i>P</i> <0.01)	0.24±0.16	12.3% (5.1-19.6%)
Guideline #7	7.31±0.41	-0.11±0.20 (<i>P</i> <0.01) $R^2=0.765$ (<i>P</i> <0.01)	0.16±0.16	23.4% (15.2-34.1%)
Guideline #8	7.16±0.47	+0.03±0.18 (<i>P</i> =0.15) $R^2=0.870$ (<i>P</i> <0.01)	0.13±0.12	34.6% (24.1-45.0%)
Guideline #9	7.04±0.44	+0.15±0.22 (<i>P</i> <0.01) $R^2=0.740$ (<i>P</i> <0.01)	0.20±0.18	29.6% (19.6-39.6%)
Guideline #10	7.19±0.40	0.00±0.12 (<i>P</i> =0.95) $R^2=0.912$ (<i>P</i> <0.01)	0.09±0.08	50.6% (39.7-61.6%)

*Paired *t*-Test (*P*<0.05 statistically significant). †Percentage of cases with a difference ≤ 0.05 mm with definitive BOZR fitted

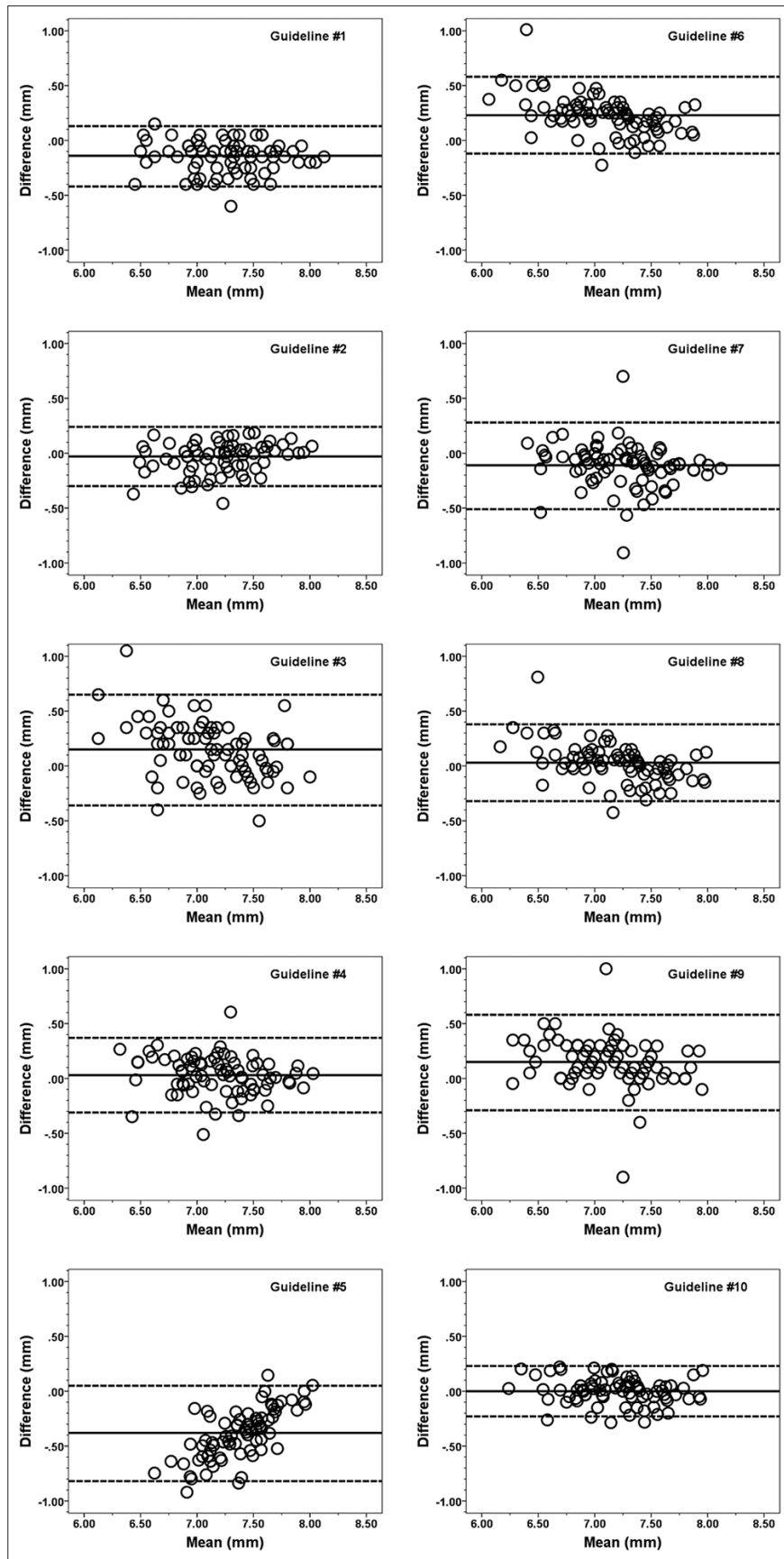


Figure 1: Agreement between the BOZR proposed by each guideline and the final BOZR fitted. Guideline #10 exhibiting better agreement with lower LoA

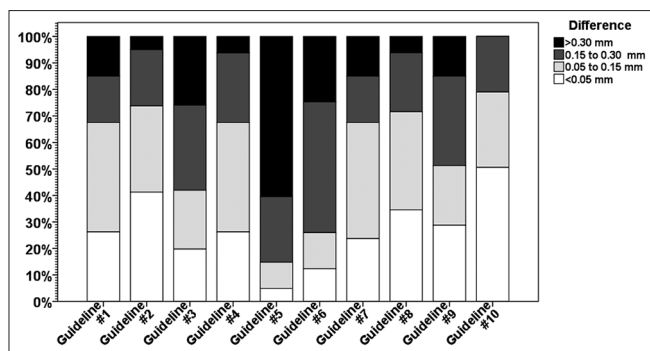


Figure 2: Cumulative percentages of the differences between the BOZR proposed by each guideline and the final BOZR fitted

diagnostic lens proposed by each guideline. The BOZR of the diagnostic lens proposed by all guidelines was well correlated with the final fitted BOZR ($r^2 > 0.71$; $P < 0.01$). However, a statistically significant difference was found between the BOZR suggested by all guidelines analyzed with the BOZR prescribed ($P < 0.05$), except for Guidelines #4, #8, and #10 ($P \geq 0.11$).

The arithmetic and absolute mean difference between the BOZR proposed by each guideline and BOZR that was finally fitted [Table 2] revealed the best agreement with Guideline #10 (0.00 ± 0.12 and 0.09 ± 0.08 mm, respectively), and the greater difference was with Guideline #5 (-0.38 ± 0.22 and 0.39 ± 0.21 mm, respectively).

Fig. 1 summarizes the agreement between the BOZR proposed by each guideline with the final fitted BOZR. Guideline #1 showed LoA from -0.42 to 0.13 ($R^2 < 0.01$; $P = 0.50$); Guideline #2, LoA from -0.3 to 0.24 ($R^2 = 0.07$; $P = 0.02$); Guideline #3, LoA from -0.36 to 0.65 ($R^2 = 0.17$; $P = < 0.01$); Guideline #4, LoA from -0.31 to 0.37 ($R^2 = 0.03$; $P = 0.12$); Guideline #5, LoA from -0.82 to 0.05 ($R^2 = 0.51$; $P < 0.01$); Guideline #6, LoA from -0.12 to 0.58 ($R^2 = 0.25$; $P = < 0.01$); Guideline #7, LoA from -0.51 to 0.28 ($R^2 = 0.03$; $P = 0.15$); Guideline #8, LoA from -0.32 to 0.38 ($R^2 = 0.25$; $P < 0.01$); Guideline #9, LoA from -0.29 to 0.58 ($R^2 = 0.07$; $P = 0.02$), and Guideline #10, LoA from -0.23 to 0.23 ($R^2 = 0.03$; $P = 0.12$).

Guideline #10 showed the best success rate by proposing a BOZR with a difference ≤ 0.05 mm in 50.6% of cases [Fig. 2 and Table 2] with a smaller difference with the final BOZR that was fitted (no one case with a difference higher or 0.30 mm). The rest of the guidelines (except Guideline #2 and Guideline #8 with a success rate of 41.3% and 34.6%, respectively) showed a success rate lower than 30%, and Guideline #5 presented a success rate of 3.8% with a difference higher than 0.30 mm in more than 60% of the cases. According to Amsler–Krumreich classifications, the success rate of the GP calculation was better with Guideline #10 in Stage 1 (61.1%), Guidelines #2 and #10 in Stage 2 (40%), and Guideline #10 in Stage 3 (57.1%) [Fig. 3]. In contrast, the worst results were presented by Guideline #6 (0%) in Stage 1, Guidelines #3 and #5 in Stage 2 (8.6%), and Guideline #5 in Stage 3 (0%). No statistically significant difference was found between stages of keratoconus in success rates with any guideline ($P \geq 0.10$) except for Guideline #3 ($P < 0.01$).

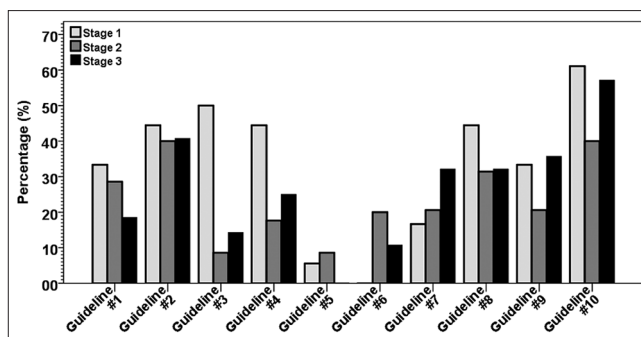


Figure 3: Success rate of the GP guideline fitting (difference between the BOZR of the diagnostic lens proposed with the final BOZR prescribed was ≤ 0.05 mm) according to Amsler–Krumreich classifications

Discussion

Keratoconus is a bilateral and asymmetric ectatic condition affecting approximately 1/2000 people in the general population.^[1,5] This disease commonly appears during the second decade of life and during puberty and progresses until the fourth decade of life, when it generally stabilizes.

In the early stages of keratoconus, the refractive error can be managed with spectacles or soft CL, but when it progresses, the corneal irregularities induce higher-order aberrations that cannot be corrected with traditional ophthalmic lenses.^[1,5] For this reason, GP CLs are the first option in keratoconus patient management because they supply adequate visual correction by providing a smooth optical surface to correct irregular astigmatism. However, fitting GP CLs in keratoconus eyes is considered a challenge because the development of irregular astigmatism increases the number of diagnostic lenses and practitioner times or patient chair times required to achieve a final acceptable fit compared with healthy eyes.^[6,9]

Manufacturers of GP lenses or recent investigations published in the literature provide different guidelines to select the BOZR in keratoconus fittings; nevertheless, it is uncommon that these guidelines include a posterior analysis of their accuracy or precision of the suggested BOZR in a different sample of patients. To the best of our knowledge, this is the first report on different fitting guidelines to select the BOZR of GP lenses in keratoconus eyes and comparisons to provide evidence-based information on the accuracy of their recommendations.

Guideline #10 (CALCULENS.com) showed better agreement with the BOZR that was finally fitted compared with other guidelines. This open-access website allows the CL parameter calculation with a simple method with clinical data of keratoconus eyes (corneal keratometry or topography), and it has been clinically validated with a sample of 50 keratoconus eyes, which was different from the patients used for this calculation.^[14] The BOZR calculated on this website shows a difference from the BOZR that was finally fitted that was equal to or less than 0.05 mm in 50.6% of the fittings, with no one case showing a difference greater than 0.30 mm. Next, Guideline #2^[13] used the BOZR proposed by APEX software, and it achieved a success rate of 41.3%, doubling the APEX software (Guideline #1) success rate (26.3%). Nevertheless,

Guidelines #1 and #2 have not been clinically validated with keratoconus eyes and both require the use of APEX software CL fitting (Oculus – Hecht Contactlinsen) and corneal topography achieved with some of the Oculus topographers (Pentacam, Keratograph or Easygraph), so these technology could not be available for all CL practitioners. In contrast, Guideline #10 is an open-access website that is easy to use for any CL practitioner and has been clinically validated.^[14]

Based on the absolute difference with the final BOZR that was fitted, Guideline #8 showed a success rate of 34.6% of the fittings. Guideline #8 is proposed to fit several GP lenses designed for keratoconus that share the same recommendation to calculate the BOZR of the first diagnostic lens, with a BOZR halfway between Ks and Kf readings, or Kmean. Following this recommendation, better results were obtained than from other manufacturer guidelines that propose a starting point with Ks (Guideline #9 with success rate of 28.7%), based on Km-0.20 (Guideline #6 with success rate of 12.3%), based on Kf-(1/3 *Astigmatism) (Guidelines #7 with a success rate of 23.7%) or horizontal K-0.10 (Guidelines #3 with a success rate of 19.8%). It is important to highlight that none of these guidelines provided by the manufacturers of GP lens included information about their clinical validation with keratoconus patients to provide objective and evidence-based information on their usefulness.

Other methods to calculate the BOZR of the first diagnostic lens in GP keratoconus fittings have not been proposed by CL manufacturers. In 2010, the Centre of Contact Lens Research of University of Waterloo (Canada) published the manual "Correction of keratoconus with GP lenses",^[15] which proposed a brief guideline to select the BOZR for keratoconus eyes (Guideline #4). This guideline presented a small difference between the BOZR that was suggested and the BOZR that was finally fitted (0.14 ± 0.11 mm), with a success rate of 26.3%. On the other hand, in 2011, Rajabi *et al.*^[12] proposed a new prediction formula to calculate the BOZR based on manual keratometry (Guideline #5). This predicting formula was calculated retrospectively after 400 GP CL fitting assessments in keratoconus eyes. Although Guideline #5 was calculated with a great keratoconus sample, their BOZR that was proposed was very far from the BOZR that was finally fitted (0.39 ± 0.21 mm), and only 3.8% of the fittings achieved success. To the best of our knowledge, these formulas were not validated with a new sample of keratoconus eyes to double-check their precision.

Evaluation of the fluorescein pattern in keratoconus GP fittings requires experience, practice, and knowledge of CL design parameters by practitioners.^[27] It is generally accepted that a three-point-touch provides acceptable vision and is the safest technique to fit keratoconic eyes.^[11,20] There is evidence that the apical touch induced by a BOZR that is too flat may cause staining or scarring.^[11] On the other hand, excessive apical clearance (too steep BOZR) could interfere with comfort and acuity due to bubbles that may be trapped in the optic zone area.^[11]

The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study described the concept of the First Definite Apical Clearance Lens (FDACL) as the flattest lens that showed an apical clearance fluorescein pattern in keratoconus and developed a standardized protocol to fit GP lenses in

keratoconus.^[28] In the CLEK study, the initial BOZR matched the steeper keratometry reading (Guideline #9) and was adjusted flatter or steeper until the FDACL was reached. The use of FDACL was a valid and reliable standardized method for GP CL and monitoring the disease progression.^[29] However, this requires practice and long practitioner times to achieve the FDACL due to the starting point (Guideline #9) showing a wide limit of agreement range (0.87 mm), and it provided a success rate less than 30%.

Other guidelines or protocols to fit a GP CL in keratoconus have been proposed and could not be analyzed due to the nature of our study. Romero-Jiménez *et al.*^[20] followed the CLEK study standardized method to fit GP lenses (Rose K2 design, Menicon Inc., North Billerica, MA, USA) in 119 keratoconus eyes using the FDACL as a starting point to achieve an optimal lens, and they compared two different CL fitting techniques (three-point-touch versus apical touch) with BOZRs of 0.10 and 0.40 mm that were flatter than the FDACL. Following this protocol, 77% of the eyes achieved an optimal lens fit with the first lens ordered (83% with three-point-touch and 71% with apical touch fitting approaches). However, no comparisons of the BOZR of the first diagnostic lens were conducted, but 2.3 ± 1.7 diagnostic lenses were necessary to obtain the FDACL, with another extra trial lens to obtain the three-point-touch (0.10 mm flatter than FDACL) or apical touch (0.40 mm flatter than FDACL).

Mandathara *et al.*^[30] proposed a formula to calculate the BOZR in keratoconus eyes using the software FITSCAN (Orbscan II topography) [BOZR = (BOZR suggested by FITSCAN (mm) $\times 0.86563$) + 0.78738]. Nevertheless, this study has not been clinically validated, and it used a specific corneal topographer (Orbscan) and software, so it was not possible to be included in our study.

Our study has different limitations. First, it is not a clinical study in which different patients were fitted using different guidelines in a random and masked way. Because conducting this clinical research could be expensive and requires a large sample of keratoconus eyes, we conducted a comparison of the BOZR calculated by different guidelines proposed to fit GP lenses specifically designed for keratoconus eyes. This approach could provide relevant information to eye care and CL practitioners who fit GP lenses in keratoconus patients to improve the selection of the BOZR of the first diagnostic lens. Moreover, the use of a single design of spherical keratoconus GP CL could influence the fitted BOZR because different philosophies for fitting GP in keratoconus exist, making it difficult to find the definitive end point of the GP that was fitted. Therefore, small variations in the final BOZR would be clinically accepted, and practitioner practice and expertise should be necessary, so the impact of three different practitioners involved in fitting procedure conducted in this study should have a limited impact in study results, because these CL practitioners had larger experience (>10 years) fitting CL and managing irregular cornea patients with CL. However, this study demonstrated a lack of evidence to support some of the guidelines recommended by the manufacturers or some research reports. These results will be of great interest to help CL practitioners reduce chair times and the number of trial lenses, providing the best vision rehabilitation to keratoconus

patients by improving their vision and quality of life.^[14] However, further research including different lens designs and fitting philosophies will be necessary in the future to provide evidence-based guidelines to calculate lens parameters to be fitted in keratoconus eyes.

Conclusion

Several guidelines have been proposed to choose the BOZR of the first diagnostic lens to fit in keratoconus eyes with a lack of clinical validation of their recommendations. The selection of the BOZR for the first diagnostic lens with CALCULENS.com provided a better starting point for GP CL fitting in keratoconus than other methods or guidelines assessed, showing a difference of ≤ 0.05 mm compared to the final BOZR in 50.6% of the patients. This study provides evidence-based information to CL practitioners who fit or prescribe GP lens in keratoconus patients and demonstrate a lack of evidence to support some of the current guidelines recommendations provided by some manufacturers or some research reports.

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Conflicts of interest

There are no conflicts of interest.

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