Error induced by the estimation of the corneal power and the effective lens position with a rotationally asymmetric refractive multifocal intraocular lens

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Abstract

- **AIM**: To evaluate the prediction error in intraocular lens (IOL) power calculation for a rotationally asymmetric refractive multifocal IOL and the impact on this error of the optimization of the keratometric estimation of the corneal power and the prediction of the effective lens position (ELP).

- **METHODS**: Retrospective study including a total of 25 eyes of 13 patients (age, 50 to 83y) with previous cataract surgery with implantation of the Lentis Mplus LS–312 IOL (Oculentis GmbH, Germany). In all cases, an adjusted IOL power (P_{IOLadj}) was calculated based on Gaussian optics using a variable keratometric index value (n_{kadj}) for the estimation of the corneal power (P_{kadj}) and on a new value for ELP (ELP_{adj}) obtained by multiple regression analysis. This P_{IOLadj} was compared with the IOL power implanted (P_{IOLReal}) and the value proposed by three conventional formulas (Haigis, Hoffer Q and Holladay). Further, ELP_{adj} was significantly lower than ELP calculated with other conventional formulas (P<0.01) and was found to be dependent on axial length, anterior chamber depth and P_{kadj}.

- **CONCLUSION**: Refractive outcomes after cataract surgery with implantation of the multifocal IOL Lentis Mplus LS–312 can be optimized by minimizing the keratometric error and by estimating ELP using a mathematical expression dependent on anatomical factors.

- **KEYWORDS**: Mplus; multifocal intraocular lens; keratometry; effective lens position; intraocular lens power

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**INTRODUCTION**

Several studies[1-8] have confirmed the ability of multifocal intraocular lenses (IOLs) of providing a good near and distance functional vision without the use of corrective lenses after cataract surgery. One modality of IOL multifocality is the use of a rotationally asymmetric refractive profile containing an aspheric distance-vision zone combined with a sector-shaped near-vision zone in the inferior area of the IOL. This concept of multifocality is the basis of the multifocal IOL Lentis Mplus LS–312 (Oculentis GmbH). Studies on this IOL have shown good near and distance visual outcomes, combined with postoperative contrast sensitivity within physiological ranges and positive impact on patient's quality of life [1,2,9–15]. Even some studies have reported good levels of intermediate visual acuity with this type of IOL[1,2].

Despite the good visual outcomes reported with this IOL[1,2,9–15], some studies have shown some level of variability in the refractive correction achieved[12,13,15]. Alió et al[18] found in a prospective comparative study evaluating a group of 21 eyes implanted with the Mplus IOL a mean 3mo postoperative sphere of -0.34±0.93 D, ranging from -3.00 to +1.25 D. In another sample of 9366 eyes implanted with this type of IOL, Venter et al[19] found that 91.8% of eyes had a postoperative spherical equivalent (SE) within ±1.00 D. In the same line, Muñoz et al[13] found that 6 eyes (9.4%) from a sample of 64 eyes had a postoperative myopic SE of more than 0.50 D (mean residual SE: -0.75±0.15 D). McAlinden and Moore[19] reported in another series of cases a percentage of 86.4% of eyes with an SE within ±0.50 D. Several factors may be in relation to this variable level of predictability, such as some
inaccuracies in IOL power calculation due to the use of not fully optimized formulae for this specific type of IOL. The aim of the current study was to evaluate the predictability of the refractive correction achieved with this refractive multifocal IOL and to develop an optimization of the predictability error by minimizing the error associated to the keratometric estimation of the corneal power and by developing a predictive formula of the effective lens position for this specific type of IOL.

SUBJECTS AND METHODS

Subjects This retrospective study included a total of 25 eyes of 13 patients. All eyes underwent cataract surgery with implantation of the rotationally asymmetric multifocal IOL Lentis Mplus LS-312 (Oculentis GmbH). Inclusion criteria for this study were patients with visually significant cataract or presbyopic/pre-presbyopic patients suitable for refractive lens exchange and demanding complete spectacle independence. Exclusion criteria were patients with active ocular diseases, illiteracy and topographic astigmatisms higher than 1.5 D. All volunteers were adequately informed about the surgery and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and was approved by the Local Ethical Committee.

Methods

Intraocular lens The Lentis Mplus LS-312 (Oculentis GmbH, Germany) is a rotationally asymmetric multifocal IOL that contains an aspheric distance-vision zone combined with a 3.00 D posterior sector-shaped near-vision zone to allow good transition between the zones. It has biconvex design with a 6.0 mm optic, a 12.0 mm overall length, and a C-loop haptic design with 0-degree angulation. The IOL is made of an acrylic copolymer comprising acrylates with a hydrophobic surface and ultraviolet-filtering components.

Surgical technique All surgeries were performed by the same experienced surgeon (Ramón ML) using a standard technique of phacoemulsification. In all cases, topical anesthesia was administered and pupillary dilation was induced with a combination of tropicamide and phenylephrine 10% every 15 min half an hour previous to the procedure. Iodine solution 5% was instilled on the eye 10 min before the operation. A 2.75-mm clear incision was made with a diamond knife on the steepest meridian to minimize post-surgical astigmatism. A paracentesis was made 60°-90° clockwise from the main incision and the anterior chamber was filled with viscoelastic material. After the crystalline lens removal, the IOLs were implanted through the incision into the capsular bag using a specific injector developed by the manufacturer for such purpose. Finally, the surgeon proceeded to retrieve the viscoelastic material using the irrigation-aspiration system. A combination of topical steroid and antibiotic (Tobradex, Alcon, Fort Worth, TX, USA) as well as a non-steroidal anti-inflammatory drops (Dicoabak, Laboratorios Thea, Barcelona, Spain) were prescribed to be applied four times daily for a week after the surgery and three times daily the second postoperative week. In addition, non-steroidal anti-inflammatory drops were also prescribed to be applied three times daily during 2 additional weeks after surgery.

Calculation of an adjusted intraocular lens power

Almost all theoretical formulae for IOL power ($P_{\text{new}}$) calculation are based on the use of a simplified eye model, with thin cornea and lens models [16]. According to such approach, $P_{\text{new}}$ can be easily calculated using the Gauss equations in paraxial optics [17].

$$P_{\text{IOL}} = \left( \frac{n_{\text{hy}}}{(AL - ELP)} \right) \left( \frac{n_{\text{ha}}}{R_{\text{des}} + P_{\text{c}} - ELP} \right)$$

(1)

where, $P_r$ is the total corneal power, ELP the effective lens plane, AL the axial length, $n_{\text{hy}}$ the aqueous humour refractive index, $n_{\text{ha}}$ the vitreous humour refractive index, and $R_{\text{des}}$ the postoperative desired refraction calculated at corneal vertex.

Our research group proposed the use of a variable keratometric index ($n_{\text{adj}}$) depending on the radius of the anterior corneal surface ($r_c$) expressed in millimetres for minimizing the error associated to the keratometric approach for corneal power calculation [18]. Specifically, the following expression was defined according to the Gullstrand eye model:

$$n_{\text{adj}} = -0.0064286r_c + 1.37688 \quad (2)$$

Using these algorithm, a new keratometric corneal power, named adjusted keratometric corneal power ($P_{\text{adj}}$), can be calculated using the classical keratometric corneal power formula [18]. In the current study, the adjusted IOL power ($P_{\text{adj}}$) was calculated, which was defined as the IOL power calculated from the equation 1 using the $n_{\text{adj}}$ value for the estimation of the corneal power ($P_{\text{adj}}$), and the $n_{\text{hy}}$ and $n_{\text{ha}}$ values corresponding to the Gullstrand eye model (1.336 for both indexes). In this IOL power calculation, the postoperative SE at corneal vertex was considered as the desired refraction ($R_{\text{des}}$). The $P_{\text{IOL}}$ calculation was performed by estimating the ELP using two different approaches: ELP calculation following the SRK/T formula guidelines (named $P_{\text{adj}}$) and ELP calculation using a mathematical expression obtained by multiple regression analysis (named $P_{\text{adj}}$), following a procedure described in the next section. These values of IOL power ($P_{\text{IOL}}$) were compared with the real power of the IOL implanted ($P_{\text{IOL}}$).

An $P_{\text{adj}}$ calculation was also performed using three conventional formulae (Haigis [20], Hoffer Q [21] and Holladay
I \textsuperscript{[25]} considering the ELP defined for each formula and $R_{\text{adj}}$-SE$_{\text{post}}$. All these values of $P_{\text{adj}}$ and $R_{\text{adj}}$-SE$_{\text{post}}$ are compared to $P_{\text{Unadj}}$. The calculation with the conventional IOL power formulas was performed by implementing them in an Excel software sheet version 14.0.0 for Mac.

**Estimation of adjusted effective lens position**

Considering the equation 1, $P_{\text{Kerato}}$, $P_{\text{Kerato}}$ and $R_{\text{Kerato}}$-SE$_{\text{post}}$, an estimation of ELP was obtained in each case. By means of multiple regression analysis, a mathematic expression was obtained for predicting the ELP in each specific case. This ELP was named as adjusted effective lens position (ELP$_{\text{adj}}$).

**Preoperative and postoperative examinations**

Preoperatively, all patients had a full ophthalmologic examination including the evaluation of the refractive status, distance and near visual acuities, slit lamp examination, optical biometry (IOL-Master, Zeiss), axial length measurement and fundoscopy. Distance (4 m) and near (40 cm) visual acuities were evaluated with ETDRS charts. Postoperatively, patients were evaluated at 1d, 1wk, 1mo and 3mo after surgery. In all visits, visual acuity, refractometry and the integrity of the anterior segment were evaluated. Fundoscopy was also performed at the postoperative revision at 3mo.

**Statistical Analysis**

The statistical analysis was performed using the SPSS statistics software package version 21.0.0.0 for Mac (IBM, Armonk, NY, USA). Normality of data samples was evaluated by means of the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student t test for paired data was used for comparing the different approaches for $P_{\text{Kerato}}$ calculation. When parametric analysis was not possible, the Wilcoxon rank sum test was applied to assess the significance of such comparisons. Differences were considered to be statistically significant when the associated $P$-value was less than 0.05.

Regarding the interchangeability between pairs of methods for obtaining $P_{\text{Kerato}}$, the Bland-Altman analysis was used\textsuperscript{[29]}

A multiple regression analysis was performed by using the backward elimination method for obtaining a mathematic expression allowing the prediction of ELP$_{\text{adj}}$ from different preoperative anatomical and clinical parameters. Model assumptions were evaluated by analysing residuals, the normality of non-standardized residuals (homoscedasticity), and the Cook distance to detect influential points or outliers. In addition, the lack of correlation between errors and multicolinearity was assessed using the Durbin-Watson test, the calculation of the collinearity tolerance, and the variance inflation factor.

**RESULTS**

This study evaluated 25 eyes of 13 patients [6 men (46.2%) and 7 women (53.8%),] with a mean age of 65.6y±7.6 SD (range, 50 to 83y). The sample comprised 12 (48%) and 13 (52%) right and left eyes, respectively. Table 1 summarizes some preoperative visual, refractive and anatomical data of the eyes evaluated as well as all the estimation performed for ELP and IOL power. According to axial length (AL), anterior chamber depth (ACD) and corneal power, and using the SRK-T formula, the mean power of the IOL implanted was 19.78 D±2.61 SD (range, 12.50 to 23.50 D).

**Agreement of $P_{\text{Real}}$ and $P_{\text{Haigis}}$**

Statistically significant differences were found between $P_{\text{KeratoSRK/T}}$ and $P_{\text{Real}}$, considering that ELP was calculated following the SRK/T formula guidelines and considering $R_{\text{adj}}$-SE$_{\text{post}}$ ($P < 0.01$, Wilcoxon test). A very strong and statistically significant correlation was found between $P_{\text{Kerato}}$ and $P_{\text{Real}}$ ($r = 0.86$, $P < 0.01$, Figure 1). According to the Bland and Altman analysis of interchangeability, the $P_{\text{KeratoSRK/T}}$ was higher than $P_{\text{Real}}$ (mean difference: 1.41 D) and the limits of agreement

<table>
<thead>
<tr>
<th>Parameters</th>
<th>$\bar{x}$ ± s</th>
<th>Range</th>
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<tbody>
<tr>
<td>SE$_{\text{post}}$ (D)</td>
<td>-1.27 ± 2.87</td>
<td>-7.50 to 3.00</td>
</tr>
<tr>
<td>SE$_{\text{pre}}$ (D)</td>
<td>-0.11 ± 0.56</td>
<td>-1.83 to 0.76</td>
</tr>
<tr>
<td>$r_{1c}$</td>
<td>7.61 ± 0.25</td>
<td>7.19 to 8.01</td>
</tr>
<tr>
<td>ACD</td>
<td>3.31 ± 0.28</td>
<td>2.61 to 3.79</td>
</tr>
<tr>
<td>AL</td>
<td>23.52 ± 1.04</td>
<td>22.02 to 27.36</td>
</tr>
<tr>
<td>ELPSRK/T</td>
<td>5.12 ± 0.45</td>
<td>4.60 to 6.83</td>
</tr>
<tr>
<td>ELPHolladay</td>
<td>4.31 ± 0.50</td>
<td>3.39 to 5.34</td>
</tr>
<tr>
<td>P$_{\text{Haigis}}$</td>
<td>5.01 ± 0.16</td>
<td>4.77 to 5.46</td>
</tr>
<tr>
<td>ELPHoffert</td>
<td>5.00 ± 0.27</td>
<td>4.63 to 6.01</td>
</tr>
<tr>
<td>ELPHolladay</td>
<td>4.59 ± 0.27</td>
<td>3.89 to 5.07</td>
</tr>
<tr>
<td>n$_{\text{adj}}$</td>
<td>1.328 ± 0.002</td>
<td>1.325 to 1.331</td>
</tr>
<tr>
<td>P$_{\text{Haigis}}$ (D)</td>
<td>44.37 ± 1.44</td>
<td>42.14 to 46.95</td>
</tr>
<tr>
<td>P$_{\text{adj}}$</td>
<td>43.57 ± 1.41</td>
<td>41.39 to 46.11</td>
</tr>
<tr>
<td>P$_{\text{Haigis}}$ (D)</td>
<td>43.11 ± 1.16</td>
<td>40.62 to 45.99</td>
</tr>
<tr>
<td>P$_{\text{Real}}$</td>
<td>19.78 ± 2.32</td>
<td>12.50 to 23.50</td>
</tr>
<tr>
<td>P$_{\text{AdjSRK/T}}$ (D)</td>
<td>21.18 ± 2.74</td>
<td>12.51 to 25.46</td>
</tr>
<tr>
<td>P$_{\text{Haigis}}$</td>
<td>19.71 ± 2.55</td>
<td>11.02 to 23.53</td>
</tr>
<tr>
<td>P$_{\text{Haigis}}$ (D)</td>
<td>20.40 ± 3.15</td>
<td>10.16 to 24.99</td>
</tr>
<tr>
<td>P$_{\text{Real}}$</td>
<td>19.30 ± 3.04</td>
<td>9.50 to 23.90</td>
</tr>
<tr>
<td>P$_{\text{Real}}$</td>
<td>19.57 ± 2.99</td>
<td>9.40 to 23.90</td>
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</tbody>
</table>
were clinically relevant (3.29 and -0.48 D). Figure 2 shows the Bland and Altman plot corresponding to this agreement analysis.

Estimation of ELPIOL
The multiple regression analysis revealed that the ELPIOL was significantly correlated with AL, ACD and \( P_{kadj} \) (\( P < 0.01 \)):
\[
ELP_{adj} = -17.333 + 0.612 \times ACD + 0.360 \times AL + 0.268 \times P_{kadj}
\] (3)

The homoscedasticity of the model was confirmed by the normality of the non-standardized residuals distribution (\( P = 0.20 \)) and the absence of influential points or outliers (mean Cook’s distance: 0.155±0.528). With this model, 56% of non-standardized residuals were 0.20 or lower and 76% were lower than 0.50. The poor correlation between residuals (Durbin-Watson test: 1.629) and the lack of multicolinearity (tolerance 0.805 to 0.560; variance inflation factors 1.785 to 1.243) was also confirmed.

A statistically significant difference was found between ELPIOL and the rest of ELP values obtained following the guidelines proposed by each of the formulas used (\( P < 0.01 \), unpaired Wilcoxon test). ELPIOL was the lowest ELP value (Table 1) among all values of ELP calculated (4.31±0.50 mm, range 3.39 to 5.34 mm).

Agreement of ELPIOL with other formulas
Statistically significant differences were found between ELPIOL and ELPIOLHoffer, and between ELPIOL and ELPIOLHolladay (\( P < 0.01 \), Wilcoxon test), but not between ELPIOL and ELPIOLHaigis (\( P = 0.20 \), Wilcoxon test).
Table 2 Bland and Altman analysis outcomes of the comparison between $P_{IOLadj}$ and the IOL power obtained with other commonly used formulas

<table>
<thead>
<tr>
<th>Comparison</th>
<th>$\Delta P_{IOL}$ ±SD (D)</th>
<th>LoA (D)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_{IOLHaigis}$ - $P_{IOLadj}$</td>
<td>0.68 ± 0.72</td>
<td>2.09 to -0.73</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>$P_{IOLHofferQ}$ - $P_{IOLadj}$</td>
<td>-0.43 ± 0.75</td>
<td>1.05 to -1.90</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>$P_{IOLHolladay}$ - $P_{IOLadj}$</td>
<td>-0.13 ± 0.67</td>
<td>1.01 to -1.28</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Table 2 shows the Bland and Altman analysis outcomes corresponding to all comparisons done. A very strong and statistically significant correlation was found between $P_{IOLadj}$ and $P_{IOLHolladay}$ ($r = 0.96$, $P<0.01$, Figure 5). According to the Bland and Altman [23] analysis, the mean difference between both $P_{IOLadj}$ and $P_{IOLHolladay}$ was -0.13 D, with limits of agreement of 1.01 and -1.28 D. Figure 6 shows the Bland and Altman plot corresponding to this agreement analysis.

Agreement of $P_{IOLreal}$ with other formulas Statistically significant differences were found between $P_{IOLreal}$ and $P_{IOLHaigis}$, and between $P_{IOLreal}$ and $P_{IOLHofferQ}$ ($P<0.05$, Wilcoxon test), but not between $P_{IOLreal}$ and $P_{IOLHolladay}$ ($P=0.29$, Wilcoxon test). Table 3 shows the Bland and Altman analysis outcomes corresponding to all comparisons done. According to the Bland and Altman method, the mean difference between $P_{IOLHolladay}$ and $P_{IOLreal}$ was -0.21 D, with limits of agreement of 1.96 and -2.37 D (Figure 7).

**DISCUSSION**

The refractive results obtained after cataract surgery with implantation of a multifocal IOL based on the concept of refractive rotationally asymmetry, the Lentis LS-312 IOL, have been evaluated in the current series. A significant variability in the postoperative SE was observed in the analyzed sample, with a mean value of -0.11 ±0.56 D. Specifically, the SE at 3mo after surgery ranged from -1.83 to +0.76 D, with a slight trend to some level of residual myopia, as in some previous series evaluating the results of the same type of multifocal IOL [21,18]. This confirms that an optimization in the algorithm of IOL power calculation is necessary in order to refine the refractive and visual outcomes with this premium multifocal IOL. The relative limitation of the predictability of the refractive correction in some cases implanted with the Mplus IOL may be attributable to the bias associated to the use of the keratometric approach for the calculation of the corneal power, errors in the determination of the axial length or inaccuracy in the estimation of the ELP for this specific IOL. However, the errors in the estimation of axial length with the technology used have been shown to be minimal and with a very limited impact on the refractive predictability [24]. Therefore, in the current study, the potential contribution of the corneal power and ELP factors to the limitation of the
refractive predictability with the multifocal IOL evaluated have been investigated.

First, the potential impact of the keratometric error was analysed by calculating the corneal power using an adjusted keratometric index aimed at minimizing the clinical error in the estimation of the corneal power. This adjusted corneal power was used to obtain an estimation of the IOL power considering the axial length and an EL expressed following the algorithm established for the SRK-T formula. With this approach, statistically significant and clinically relevant differences were found between the adjusted calculation and the real power of the IOL implanted that was selected according to the SRK-T formula. Therefore, the correction of this factor seems to have a minimal effect on the outcomes achievable with the multifocal IOL evaluated. Then, EL was thought to be a critical factor for the presence of a relatively limited predictability with the IOL evaluated. For such purpose, an expression for estimating an optimized EL according to some preoperative parameters was obtained by means of multiple linear regression. This new EL estimation was named adjusted EL (ELadj). The ELadj were compared to those EL values obtained with other predicting algorithms of EL. This analysis revealed that the ELadj was statistically lower compared to the values estimated with the Haigis, Hoffer Q and Holladay I formulas (ELadj, ELadj and ELadj respectively) in any case, differences between ELadj and ELadj were found to be the lowest in magnitude and this may be the reason for the absence of statistically significant differences between Padj and PHolladay. In contrast, the difference was statistically significant and clinically relevant when our IOL power was compared to Haigis or Hoffer Q formulas (PHaigis and PHolladay respectively). One factor attributable to the lower value of ELadj compared to those EL values obtained with conventional formulas is a more anterior position of the optic of the multifocal IOL evaluated due to the flexibility of the haptics. This more anterior position was better predicted with the Holladay formula and with our ELadj calculation algorithm (see equation 3). This may explain in part the trend toward myopia observed in our sample, in which the IOL power calculation was performed with the SRK-T formula that uses higher estimated values of EL. Indeed, considering equation 1, a longer EL would lead to the calculation of a higher value of IOL power that may potentially lead to the presence of postoperative myopia. Future studies should evaluate the real position of the IOL within the capsular bag by means of imaging techniques in order to confirm our hypotheses, as has been done for other types of IOLs.

In our linear regression analysis, ELadj was found to be related to some factors, such as the AL, PH and the ACD.

The anatomical factors were crucial determinants of the final position of the IOL evaluated within the eye. ELadj was higher in those eyes with longer AL and ACD, as happens in moderate to high myopic eyes. This finding was consistent with those reported by previous authors, reporting a linear dependence of the final position of the IOL on the AL.

Considering that ELadj and ELadj were not significantly different, this formula seems to be the most recommendable approach for IOL power calculation with the multifocal IOL evaluated. More studies with larger samples sizes should be performed to confirm all these outcomes.

Finally, it should be mentioned that when all IOL power formulas were compared with PHolladay and PHolladay did not differ significantly with PHol. The Bland-Altman plots showed less clinically relevant level of agreement of Padj with PHol than with PHolladay (Figures 4, 7). Therefore, PHol was able to reproduce more accurately Padj and therefore of the refractive outcome. This suggests that our approach may be a useful method for IOL power calculation with the multifocal IOL evaluated. This should be corroborated in future prospective studies.

There are several limitations in the current research, such as the limited sample size or the short follow-up. It should be considered that, although rare, changes in IOL position has been described more than 3mo after surgery, especially after Nd:YAG capsulotomy. This requires further analysis and investigation in future studies with the Mplus IOL. Another potential limitation is the determination of refraction with this multifocal IOL. Some difficulties have been described for obtaining an accurate refraction after implantation of different models of IOL, with a clear trend to overestimation of the sphere with positive sign. In any case, the manifest refraction was obtained using the same procedure described for refracting eyes with multifocal IOLs and without using the autorefraction as the basis because it has been shown to fail in eyes implanted with the Mplus IOL. Finally, it should be mentioned that the Holladay II formula was not used in our comparison as it was not available in our clinic. Possibly, our approach may be more similar to the results of the Holladay II formula as both types of calculation use an optimized algorithm for the estimation of EL, but this should be confirmed in future studies.

In conclusion, refractive outcomes after cataract surgery with implantation of refractive rotationally asymmetric IOL Lentis Mplus LS-312 may be optimized by minimizing the keratometric error using a variable keratometric index for corneal power estimation and by estimating EL using a mathematical expression dependent on anatomical factors. Future studies should be performed to validate this model of IOL power calculation for the Lentis Mplus IOL with larger
sample of sizes including more extreme cases (long and short AL).

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