Clinical science

Prediction of spectacle refraction uncertainties with discrete IOL power steps and manufacturing tolerances according to ISO using a Monte Carlo model

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ABSTRACT

Purpose The purpose of this study was to develop a concept for predicting the effects of both discrete intraocular lens (IOL) power steps (PS) and power labelling tolerances (LT) on the uncertainty of the refractive outcome (REFU).

Design Retrospective non-randomised cross-sectional Monte Carlo simulation study.

Methods We evaluated a dataset containing 16 669 IOLMaster 700 preoperative biometric measurements. The PS and the delivery range of two modern IOLs (Bausch and Lomb enVista and Alcon SA60AT) were considered for this Monte Carlo simulation. The uncertainties from PS or LT were assumed to be normally distributed according to ±½ the IOL PS or the ISO 11979 LT. REFU was recorded and analysed for all simulations.

Results With both lenses the REFU from discrete PS ranged from 0.11 to 0.12 dpt. Due to the larger PS for low/high power lenses with the enVista/SA60AT, REFU is more dominant in initially myopic/hyperopic eyes. REFU from LT ranged from 0.18 to 0.19 dpt for both lenses. Since LT increases stepwise with IOL power, REFU is more prevalent in initially hyperopic eyes requiring high IOL power values, and for lenses with a wide delivery range towards higher powers.

Conclusions Since surgeons and patients are typically aware of the effect of discrete PS on REFU, these might be tolerated in cataract surgery. However, REFU resulting from LT is inevitable while the true measured IOL power is not reported on the package, leading to background noise in postoperative achieved refraction.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Discrete power steps and the delivery range of an intraocular lens (IOL) limit the flexibility of the surgeon in planning and achieving the desired target refractive outcome for the patient following cataract surgery, while power labelling tolerances as specified in ISO 11979 mean that IOLs are typically labelled with only nominal power values.

⇒ The actual measured power values are typically not disclosed by IOL manufacturers and may distort the refractive outcome after cataract surgery independently of the IOL power (IOLP) calculation scheme.

WHAT THIS STUDY ADDS

⇒ Larger power steps for low or high power lenses can limit the ability of the surgeon to customise the target refraction for initially myopic or hyperopic eyes.

⇒ Variations in IOLP within the labelling tolerances are typically not disclosed to the surgeon or patient and can induce stochastic variations (background noise) in the refraction after cataract surgery, making interpretation of study results in terms of comparisons of biometers, calculation concepts or different lens types difficult.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A straightforward measure that could easily be implemented would be for manufacturers to report the exact IOLP as measured during final quality checks by printing it on the IOL package, enabling the actual value to be factored into future scientific studies, eliminating this source of error.

INTRODUCTION

The reliability of ocular biometry before cataract surgery and of intraocular lens (IOL) power (IOLP) calculation has improved significantly in the last decade.[1–3] Using optical biometry clinicians can achieve highly repeatable and mostly user independent results. Modern IOLP concepts are trained to deal with these high performance measures. The IOLP formulae currently in use are remarkably consistent, with little difference between the spectacle refraction predictions of different formulae. This means that, in studies, very large sample sizes are required to distinguish systematically between these differences.[4 5]

However, there is still a gap between the search for perfection on the one hand and the classical standards of IOL power tolerances according to the ISO standard (Ophthalmic implants; EN ISO 11979-2:2014)[6] and the discrete power steps of modern IOLs on the market on the other hand. According to this ISO standard the equivalent power of an IOL could deviate from the labelled IOLP (deviation/uncertainty: ISOU in dpt) by ISOU=−0.3 dpt to 0.3 dpt for low power IOLs (IOLP ≤15 dpt) up to ISOU=−1.0 to 1.0 dpt for high power IOLs (IOLP>30 dpt). Some IOL manufacturers provide their IOLs with fixed IOLP steps (eg, ½ dpt) for the entire power range, whereas others provide low (and/or high) powered IOLs with larger power steps (eg, 1 dpt), with smaller power steps (eg, ½ dpt) being used only for the most commonly used lens powers (Ophthalmic implants; EN ISO 11979-2:2014).[6]

This discretisation of manufacturing power steps (instead of using the 'perfect' lens power) limits the ability to achieve a specific target refraction, requiring the surgeon to discuss with the patient the options for the postoperative refraction. Using the nearest available power step leads to a choice of whether to target the final refraction more to plus (with the next lower power) or more to minus (with the next larger power). This means that we always have a variation between the 'perfect' lens power and the next available power step (uncertainty STEPU in dpt). In general, this might not be a disadvantage given that both the surgeon and the patient are aware of the discrete power steps of the IOL and the consequent possible deviation of the achieved refraction from the target refraction. In contrast, the ISO tolerances for manufacturers are a different task: if during cataract surgery an IOL with any labelled power is implanted, the surgeon could be surprised on the refractive outcome if the 'real' equivalent IOLP somehow deviates from the power label. This can especially impact initially hyperopic eyes where surgery might in general be more challenging anyway due to limited space in the anterior chamber and where predictability of the refractive outcome is lower in any case. In this situation, the larger IOLP tolerances of the high power IOL may add some uncertainty to the refractive outcome.[5 7 8]

In the literature, we could find only limited studies addressing the effect of IOL power steps or labelling tolerances (LT) on the prediction of the refractive outcome or providing benchmarks for uncertainty of the refractive outcome (REFU).[9 10] However, as other error sources related to ocular biometry and IOLP calculation are reduced, IOLP steps and labelling errors gain more and more relevance and will be subject to discussions in the near future.[7 8]

The purpose of this paper is to investigate the effect of IOL power steps and ISO LT on the IOLP, as well as combinations of both on the formula predicted refraction after cataract surgery. The calculation is performed on a large dataset containing measurements from a modern optical biometer from a cataractous population, and a Monte Carlo simulation is used to propagate the IOLP deviation due to power steps or manufacturing/LT to a refraction uncertainty at the spectacle plane.

METHODS

Dataset for the prediction model

A large dataset containing 21 108 biometric measurements was considered in this study. All measurements were performed at the Augen- und Laserklinik, Castrop-Rauxel, Germany and Department of Ophthalmology and Optometry, Johannes-Kepler-University Linz, Austria with the IOLMaster 700 (Carl-Zeiss Meditec, Jena, Germany).

The data were anonymised by the source and transferred to a .csv data table using the software module for batch data export. Data tables were reduced to the relevant parameters required for our data analysis, consisting of the following measurements: from the measurement before cataract surgery we extracted the patient's age (age) in years, the laterality (left or right eye), sex (female or male), flat ($R1_a$) and steep ($R2_a$) corneal front surface radii of curvature both in mm, axial length (AL) in mm, central corneal thickness (CCT) in mm, anterior chamber depth (ACD) in mm (measured from corneal epithelium to lens), central thickness of the crystalline lens (LT) in mm and horizontal corneal diameter (CD) in mm. Only one eye from each subject was included in this study. Where measurements of both eyes were available, one eye was randomly selected. Subjects with missing data or data with a 'Failed' or 'Warning' in the internal quality check of the IOLMaster 700 for $R1_a$, $R2_a$, AL, CCT, ACD, LT, CD were excluded. The data were transferred to Matlab (Matlab 2022b, MathWorks, Natick, USA) for further processing.

Data preprocessing in Matlab

The mean corneal curvature R_a in mm was derived from the corneal curvature in the flat and steep meridians as $R_a=0.5\times(R1_a+R2_a)$. For the IOLP calculation, we implemented the Haigis formula[11] as an example of a fully disclosed fourth generation lens power calculation formula, as well as the Castrop formula[3 12 13] as a modern lens power calculation formula dealing with a thick lens model for the cornea and an effective lens position prediction which resamples the anatomically correct axial position of the IOL in the pseudophakic eye.[14–16] To simplify the data interpretation, instead of the measured corneal back surface data we used a corneal back surface derived from a fixed front to back surface ratio (7.77 mm/6.4 mm) and a fixed CCT=0.5 mm according to the schematic model eye of Liou and Brennan.[17] As examples we considered for our calculations two commonly used IOL models: enVista (MX60, Bausch & Lomb, Rochester, USA) and SA60AT (Alcon Laboratories, Fort Worth, USA). The respective formula constants for the Haigis formula (a0/a1/a2=0.1835/0.3153/0.1725 and −1.501/0.285/0.235 for the MX60 and SA60AT, respectively) and for the Castrop formula (C/H/R=0.3669/0.156/−0.1252 and 0.2907/0.1128/0.0138)

Table 1 Explorative data of the input parameters used for lens power calculation in terms of mean value, SD, median and 95% CI

N=16 669	Age in years	AL in mm	ACD in mm	LT in mm	CD in mm	$R1_a$ in mm	$R2_a$ in mm	R_a in mm
Mean	70.4927	23.7899	3.2253	4.4514	11.9906	7.7985	7.6337	7.7161
SD	9.5482	1.4129	0.3768	0.3956	0.4106	0.2821	0.2813	0.2725
Median	72.0000	23.5887	3.2155	0.5248	11.9873	7.7876	7.6314	7.7099
2.5% quantile	49.0000	21.5962	2.5058	3.3858	11.1955	7.2863	7.1016	7.2050
97.5% quantile	86.0000	27.1777	3.9791	4.9697	12.7984	8.3887	8.1887	8.2750

Age refers to the patient age at the time point of the biometric measurement before cataract surgery, AL to the AL of the eye, ACD to the phakic ACD as the distance between the front corneal apex and the front lens apex, LT to the central thickness of the crystalline lens, CD to the horizontal CD, $R1_a$ and $R2_a$ to the corneal radii of curvature in the flat and steep meridians, and R_a to the mean corneal radius.
ACD, anterior chamber depth; CD, corneal diameter; LT, labelling tolerances.

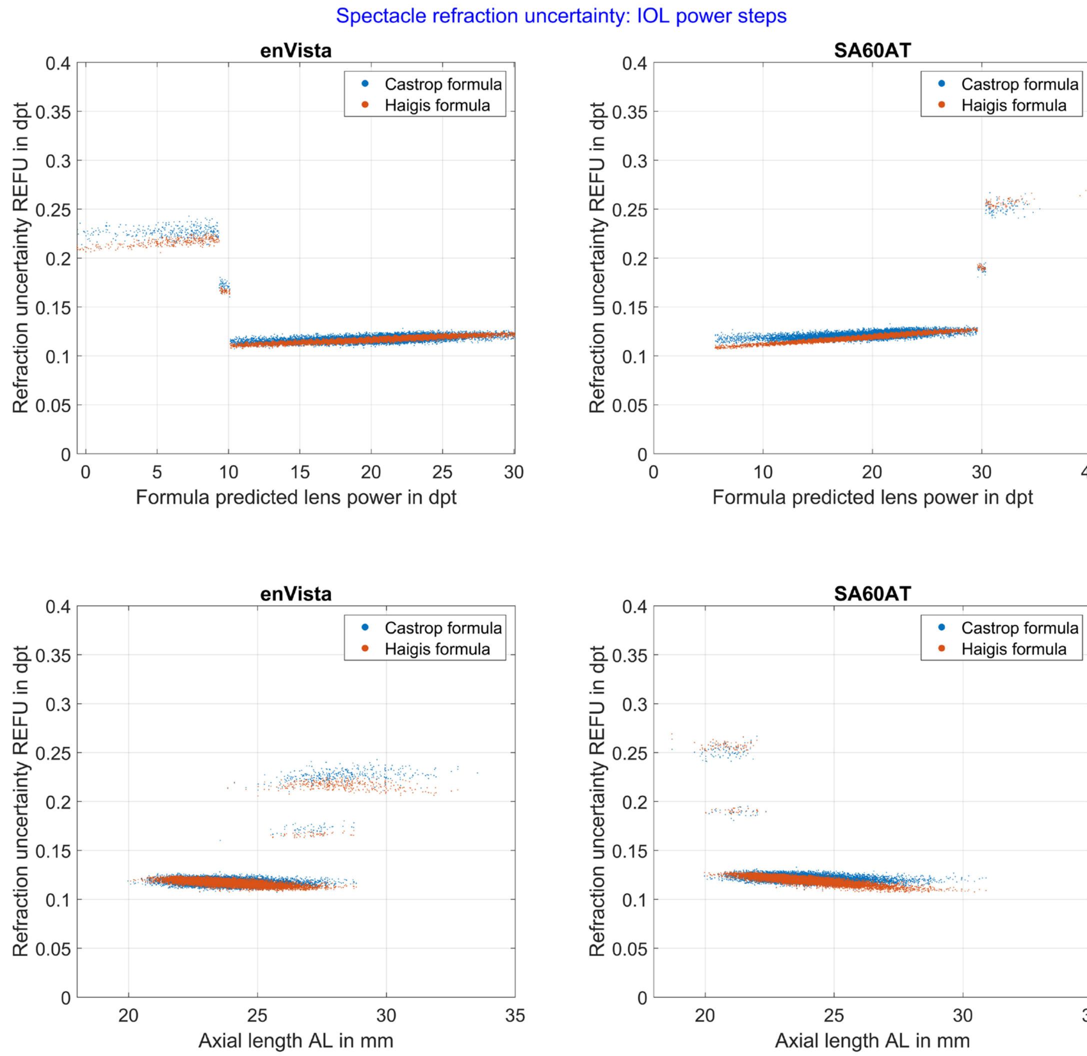

Figure 1 Refraction uncertainty at the spectacle plane REFU resulting from discrete power steps of the IOL as provided by the IOL manufacturer. REFU refers to half of this 68% CI interval is quoted as the 'target parameter' refraction uncertainty at the spectacle plane. For this Monte Carlo simulation, the difference between the 'perfect' lens power IOLPE and the discretised lens power IOLPQ was assumed to be uniformly distributed. The plots on the left/right graphs display REFU for the enVista IOL (Bausch and Lomb)/SA60AT (Alcon), respectively. In the upper graphs, REFU is shown as a function of the IOLPE without discretisation (calculated with either the Castrop or the Haigis formula) and in the lower graphs REFU is shown as a function of axial length (AL). In addition to the different delivery ranges of both IOLs (0–30 dpt for the enVista and 6–40 dpt for the SA60AT), the REFU shows larger values for the enVista in the lower power range (power steps 1.0 dpt instead of 0.5 dpt) and larger values for the SA60AT in the higher power range (power steps 1.0 dpt instead of 0.5 dpt). IOL, intraocular lens; IOLPE, IOL power or exact.

were extracted from the IOLCon WEB platform (https://IOLCon.org, accessed on 30 April 2023). The 'perfect' or 'exact' lens power (IOLPE) was calculated for each eye with both lens power calculation formulae.[3 11–13] In addition to the IOLCon optimised formula constants, we also extracted the manufacturer step sizes together with the delivery range for both lenses from the IOLCon WEB platform (https://IOLCon.org, accessed on 30 April 2023; MX60: 0–9 dpt in 1 dpt steps and 10–30 dpt in 0.5 dpt steps, SA60AT: 6–30 dpt in 0.5 dpt steps and 31–40 dpt in 1 dpt steps).

Monte Carlo simulation in Matlab

First we selected for the best fit lens for all eyes and both formulae. According to the practice of most surgeons, instead of searching for the closest power step within the delivery range, we added a tolerance value of TOL=0.15 dpt to IOLPE (to prevent postoperative hyperopia) and then searched for the closest available IOLP step (quantised power IOLPQ). For both tails of the delivery range, we decided to select the respective IOLPQ if IOLPE+TOL did not deviate more than half the power step size at the respective tail. This means that, for example, for the MX60 IOLPE was considered in a range between −0.65 dpt and 30.10 dpt and for the SA60AT of IOLPE was considered in a range between 5.60 dpt and 40.35 dpt. The uncertainty in IOLP due to discrete power steps STEPU was defined as the range from the lower boundary ($STEP_{lo}$: IOLPQ−½ the step to the next lower lens power) to the upper boundary ($STEP_{hi}$: IOLPQ+½ the next higher power step).

Both the uncertainty in IOLP due to the discrete IOLP steps STEPU (as provided from the manufacturers) and the variation due to the LT ISOU according to the ISO standard (EN ISO 11979-2:2014) were assumed to be uniformly distributed and uncorrelated to each other. For the manufacturer provided power steps, the lower and upper boundaries of the ranges for the uniform distributions were derived

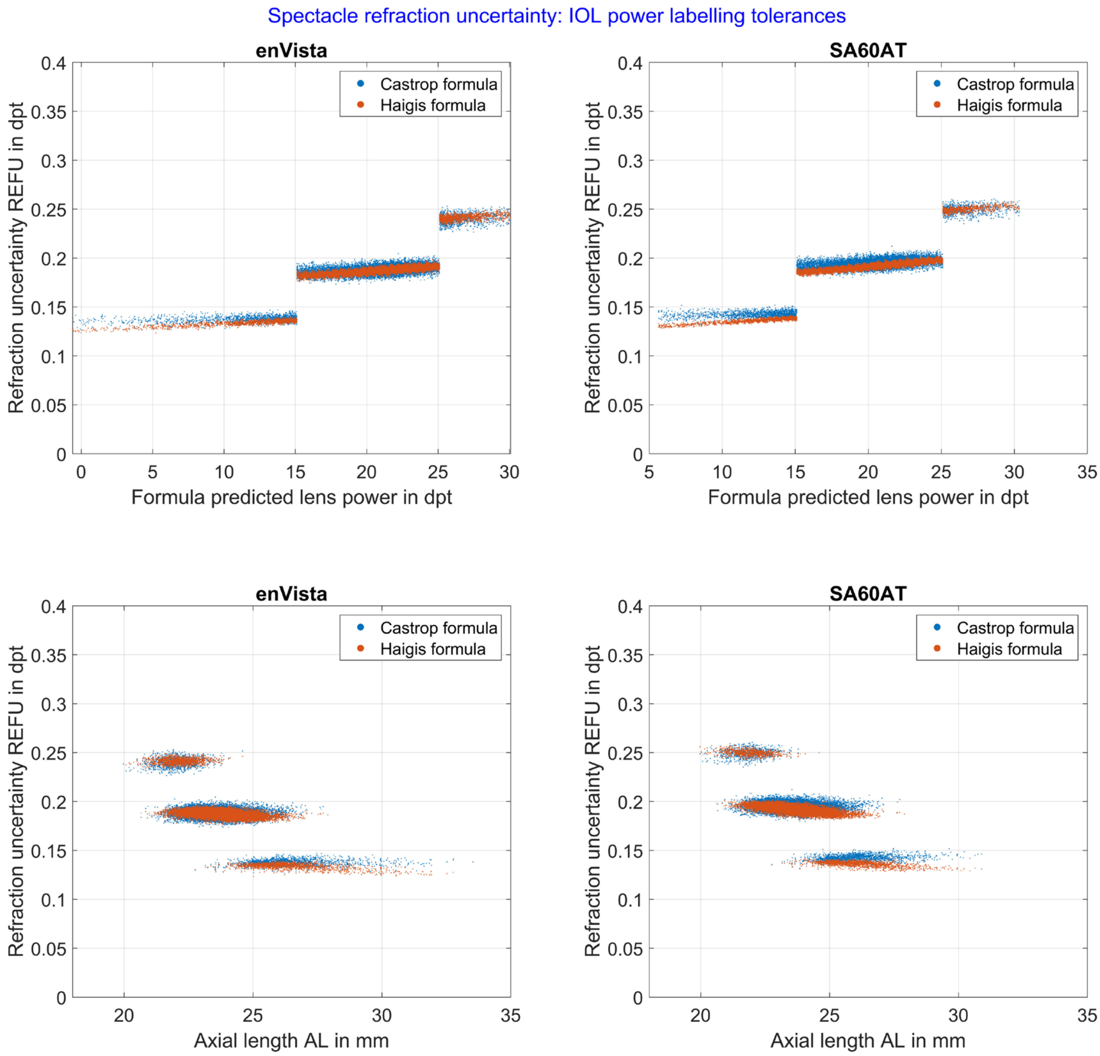

Figure 2 Refraction uncertainty at the spectacle plane REFU resulting from labelling tolerances according to EN ISO 11979-2:2014. For this Monte Carlo simulation the labelling error was assumed to be uniformly distributed within the limits. The plots on the left/right graphs display REFU for the enVista IOL (Bausch and Lomb)/SA60AT (Alcon), respectively. In the upper graphs, REFU is shown as a function of the 'perfect' lens power IOLPE without discretisation (calculated with either the Castrop or the Haigis formula) and in the lower graphs REFU is shown as a function of axial length (AL). Both lenses are available with different delivery ranges (0–30 dpt for the enVista and 6–40 dpt for the SA60AT); the labelling tolerances increase stepwise from 0.3 to 1.0 dpt for increasing IOLP values. IOL, intraocular lens; IOLPE, IOL power or exact.

from the step sizes (the IOLPQ neighbours of IOLPE). For the ISO LT the lower (ISO$_{lo}$) and upper (ISO$_{up}$) boundaries of the ranges for the uniform distributions was derived symmetrically from IOLPQ according to ISO 11979, with values depending on the lens power of: ISO$_{lo}$=IOLPQ–0.3 dpt to ISO$_{hi}$=IOLPQ+0.3 dpt for IOLPQ≤15 dpt, ISO$_{lo}$=IOLPQ–0.4 dpt to ISO$_{hi}$=IOLPQ+0.4 dpt for 15 dpt<IOLPQ≤25 dpt, ISO$_{lo}$=IOLPQ–0.5 dpt to ISO$_{hi}$=IOLPQ+0.5 dpt for 25 dpt<IOLPQ≤30 dpt, and ISO$_{lo}$=IOLPQ–1.0 dpt to ISO$_{hi}$=IOLPQ+1.0 dpt for IOLPQ>30 dpt (EN ISO 11979-2:2014).[6]

In the next step, a Monte Carlo simulation[18] was set up using the biometric data from the dataset and the quantised IOLPQ together with the lower and upper boundaries (STEP$_{lo}$ to STEP$_{up}$ and ISO$_{lo}$ to ISO$_{up}$) to calculate the effect of IOLP quantisation and LT on the refractive outcome at the spectacle plane. For each eye and for both formulae, NMC=100 000 uniformly distributed samples in a range STEP$_{lo}$ to STEP$_{up}$ and NMC=100 000 uniformly distributed samples in a range ISO$_{lo}$ and ISO$_{hi}$ were calculated. Additionally, we considered an overlay of both deviations (discrete power steps and LT) to investigate the combined effect. For the combined effect, the variation in IOLP follows a trapezoidal probability density distribution derived from a convolution of the two uniform (rectangular) probability density distributions for the power steps and the LT. In total, for each eye 100 000·2 (lens types)·2 (formulae)·3 (power steps, LT and combinations)=12 00 000 calculations were performed.

Statistical evaluation

From the NMC=100 000 samples, we extracted the 68% CI by individually searching for the shortest interval in the data containing 68% of the entire refraction data at the spectacle plane. (The 68% CI is typically used in the literature[19] for error propagation strategies since, in the simple case of a normal distribution, it corresponds to the SD). Half of this 68% CI interval is quoted as the 'target parameter' refraction uncertainty at the spectacle plane (REFU). Explorative data analysis in tables was performed with the arithmetic mean, the SD, the median, and the lower and upper boundary of the 95% CI (which refers to the 2.5% and 97.5% quantiles).

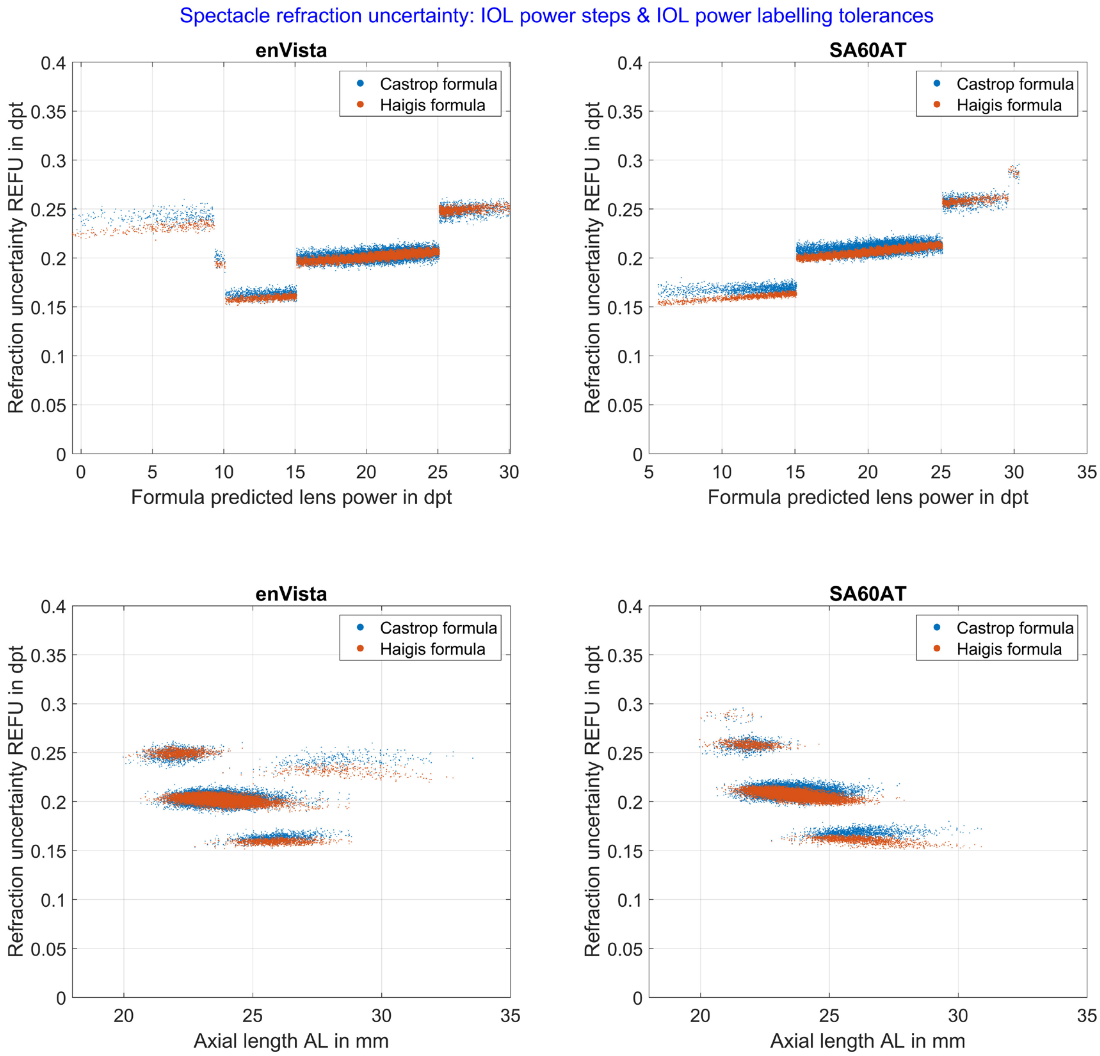

Figure 3 Refraction uncertainty at the spectacle plane REFU due to superposition of the effect of discrete power steps of the IOL provided by the IOL manufacturer and labelling tolerances according to EN ISO 11979-2:2014. For this Monte Carlo simulation the difference between the 'perfect' lens power IOLPE and the discretised lens power IOLPQ as well as the labelling error was assumed to be uniformly distributed, resulting in a trapezoidal distribution of the superposition. The plots on the left/right graphs display REFU for the enVista IOL (Bausch and Lomb)/SA60AT (Alcon), respectively. In the upper graphs, REFU is shown as a function of the IOLPE without discretisation (calculated with either the Castrop or the Haigis formula) and in the lower graphs REFU is shown as a function of axial length (AL). In addition to the different delivery ranges of both IOLs (0–30 dpt for the enVista and 6–40 dpt for the SA60AT) REFU shows larger values for the enVista in the lower power range (power steps 1.0 dpt instead of 0.5 dpt) and larger values for the SA60AT in the higher power range (power steps 1.0 dpt instead of 0.5 dpt), whereas the power labelling tolerances according to ISO are identical. IOLs, intraocular lens; IOLPE, IOL power or exact.

RESULTS

From the n=21 108 data transferred to us, and after considering the selection criteria, a dataset with n=16 669 eyes of 16 669 patients was selected for our analysis (n=9285 eyes from the Augen- und Laserklinik Castrop-Rauxel, n=7384 eyes from the Department of Ophthalmology, Johannes-Kepler-University Linz). In total, 8407 left and 8262 right eyes from 7107 male and 9562 female patients were included. In table 1, the descriptive data for the ocular biometry before cataract surgery are listed including age, AL, ACD, LT, CD, $R1_a$ and $R2_a$, and R_a. Since, for simplicity, we used a fixed CCTs and a fixed corneal front to back surface curvature ratio for calculating the IOLP with the Castrop formula, the CCT and corneal back surface radius data are not listed.

From the initial dataset of n=16 669 eyes, a total of 16 501 (99.00%)/16 477 (98.85%) eyes had calculated IOLP values within the delivery range of power steps for the enVista, and 16 523 (99.12%)/16 515 (98.08%) eyes had calculated IOLP values within the delivery range of power steps for the SA60AT, for IOLP calculations performed with the Castrop/Haigis formula, respectively.

Figure 1 displays the refraction uncertainty at the spectacle plane REFU resulting from the discrete power steps of the IOL provided by the IOL manufacturer STEPU. The plots on the left/right graphs display REFU for the enVista IOL (Bausch and Lomb)/SA60AT (Alcon), respectively. In the upper graphs, REFU is shown as a function of the IOLPE without discretisation (calculated with either the Castrop or the Haigis formula) and in the lower graphs REFU is shown as a function of AL. In addition to the different delivery ranges of both IOLs (0–30 dpt for the enVista and 6–40 dpt for the SA60AT), the REFU shows larger values for the enVista in the lower power range (power steps 1.0 dpt instead of 0.5 dpt) and larger values for the SA60AT in the higher power range (power steps 1.0 dpt instead of 0.5 dpt).

In figure 2, the REFU resulting from power LT ISOU is shown. The plots on the left/right graphs display REFU

Table 2 Explorative data of the predicted 'overall' refraction uncertainty at the spectacle plane REFU resulting from discretised IOL power steps STEPU and labelling tolerances ISOU according to EN ISO 11979-2:2014

	Bausch and lomb enVista				Alcon SA60AT			
	IOL power steps STEPU		Labelling tolerances ISOU		IOL power steps STEPU		Labelling tolerances ISOU	
REFU in dpt; N=16 669	Castrop	Haigis	Castrop	Haigis	Castrop	Haigis	Castrop	Haigis
Mean	0.1201	0.1193	0.1866	0.1865	0.1224	0.1206	0.1936	0.1913
SD	0.0162	0.0146	0.0217	0.0230	0.0103	0.0107	0.0308	0.0318
Median	0.1177	0.1174	0.1879	0.1874	0.1216	0.1201	0.1944	0.1921
2.5% quantile	0.1123	0.1117	0.1355	0.1324	0.1161	0.1123	0.1404	0.1347
97.5% quantile	0.1259	0.1237	0.2420	0.2427	0.1272	0.1255	0.2505	0.2505

The REFU values are derived using a Monte Carlo simulation based on N=16 669 datapoints in the dataset. Data where (according to the Castrop or Haigis formula) no appropriate lens power steps were available were excluded. The table lists the mean, SD, median, and the lower and upper boundary of the 95% CI (2.5% and 97.5% quantiles). STEPU refers to the range from the lower boundary (STEPlo: IOLPQ−½ the step to the next lower lens power) to the upper boundary (STEPhi: IOLPQ+½ the next higher power step), and .REFU to half of this 68% CI interval is quoted as the 'target parameter' refraction uncertainty at the spectacle plane.
IOL, intraocular lens.

for the enVista IOL (Bausch and Lomb)/SA60AT (Alcon), respectively. In the upper graphs, REFU is shown as a function of the 'perfect' lens power IOLPE without discretisation (calculated with either the Castrop or the Haigis formula) and in the lower graphs REFU is shown as a function of AL. In addition to the different delivery ranges of both lenses which results in a different scaling on the x axes, the LT increase stepwise from 0.3 to 1.0 dpt for increasing IOLP values.

Figure 3 gives an impression of the variation in spectacle refraction REFU when both effects (discrete power steps of the IOL and LT) are superimposed. The plots on the left/right graphs display REFU for the enVista IOL (Bausch and Lomb)/SA60AT (Alcon), respectively. In the upper graphs, REFU is shown as a function of the IOLPE without discretisation (calculated with either the Castrop or the Haigis formula) and in the lower graphs REFU is shown as a function of AL. The enVista (delivery range 0–30 dpt) shows larger power steps for low power lenses and a larger LT for high power lenses, whereas the SA60AT shows larger power steps and larger LT for high power lenses in both cases.

The average effects of discrete power steps of the IOL STEPU and LT ISOU on the uncertainty of spectacle refraction REFU are listed in table 2 for both lens types and both IOLP calculation formulae. This REFU data include all clinical cases in the dataset where the lens type offers an appropriate power step. The results for the superposition of IOLP steps and LT are not shown in the table. We see from table 2 that REFU is quite similar for both IOLP calculation formulae and for both lens types under test. In general, the effect of LT ISOU on REFU seems to be larger as compared with the effect of the manufacturing power steps STEPU.

DISCUSSION

In recent decades, optical biometry has become the gold standard in ocular biometry[2] and many new IOLP calculation concepts have been proposed to improve the prediction of the refractive outcome after cataract surgery.[1 3 5] These improvements in biometry and IOLP calculation can be seen as cornerstones for modern lens categories such as multifocal, enhanced depth of focus, monofocal plus or toric lenses. However, even for modern IOL types, the power steps have not changed too much compared with previous lenses on the market. Furthermore, the ISO TOL for the labelled power have not been upgraded with modern optical measurement techniques in the optics labs of IOL manufacturers.

However, the situation with discrete power steps is completely different to the situation with LT.[8 20 21] Knowing that IOLs are available in discrete power steps, the surgeon can discuss target refraction with the patient and decide for the next higher or lower power step depending on the requirements of the patient. Therefore, the refraction uncertainty resulting discrete power steps can be managed within the patient's expectations, and does not impact the quality metrics of biometry and IOLP calculation or formula performance when evaluating the postoperative results.[1 4] Power LTs are a completely different task, as the 'real' equivalent power value of the implanted IOL is not known. Both the surgeon and the patient have to rely on the validity of the labelled power, and especially in high power lenses where the LTs are quite large a clinically relevant 'stochastic' refraction error could occur which cannot be traced back. In other words, the clinical results after cataract surgery using any biometer, IOLP calculation concept, or any lens type is always biased by the uncertainty caused by the LT.[1 7]

In the present paper, we have addressed the effect of discrete IOLP steps and LT and translated these lens power uncertainties into a corresponding uncertainty in spectacle refraction after cataract surgery. In a Monte Carlo simulation based on a large clinical dataset with biometric measurements from a cataractous population,[18] we used the power step data, the delivery range (both provided by the manufacturer) and the LT according to the ISO standard to predict the effect of STEPU and ISOU on REFU. Since with an exact lens power IOLPE for any target refraction we could select either the next higher or lower lens power IOLPQ, the distribution of STEPU is clearly uniformly distributed with a variation of half the power step size to the next higher and lower IOLPQ. In contrast, the real LT of an IOL are unknown, and therefore, we assumed a uniformly distributed IOLP error within the ISO TOL. This might be the worst case scenario, and in real life the LT may not be fully exploited by the manufacturers. Therefore the 'real' LT might also be represented by a truncated normal distribution; however, such data are not disclosed by the IOL manufacturers.[8]

What can be seen from our results is that for the power step uncertainty STEPU the overall mean or median REFU is in a range of 0.11–0.12 dpt for both lens power calculation formulae and both lenses under test. If any lens types were provided in ½ dpt steps over the entire delivery range this value might be slightly smaller. The more eyes we have in our dataset which are treated with a lens power having 1 dpt manufacturing steps the larger the REFU value. This means that we expect the smallest REFU values in lenses with a reduced delivery range and/or ½ dpt steps over the entire range. In addition, we see from our results that for the LT uncertainty ISOU the overall mean or median REFU is in a range of 0.18–0.19 dpt for both lenses. As the SA60AT is available up to an equivalent power of 40 dpt, the LT adds more REFU on average as compared with the enVista, which is available only up to power values of 30 dpt. This means that the ISO LT of up to ±1 dpt do not contribute to the overall REFU mean as this lens is not available with power values of more than 30 dpt. However, as the number of eyes requiring a lens power of more than 30 dpt is rather small, the effect on the overall mean is also small (mean REFU 0.1936/0.1913 dpt for the SA60AT with the Castrop/Haigis formula compared with 0.1866/0.1865 dpt with the enVista). However, what we learn from our data is that if the IOL manufacturer fully exploits the LT according to the ISO standard then we could expect a stochastic error in the postoperative spectacle refraction of nearly 0.2 dpt for a normal cataract population, which seems to be the 'background noise' for the refraction predictability after cataract surgery irrespective of the biometer or IOLP calculation scheme used.

Given that we are dealing with uncertainty distributions other than normal distributions, classical strategies such as Gaussian error propagation using the gradients of the transfer function do not work properly.[19] Therefore, we used a Monte Carlo simulation model, where we can easily deal with any probability density function of the lens power uncertainty. Even superposition effects as shown in figure 3, where the uncertainty due to discrete power steps and due to LT are combined, can be simulated without restrictions. We restricted our Monte Carlo simulation model to NMC=100 000 iterations, which is expected to be a good trade-off between simulation time and accuracy of the result. For the entire simulation where 120 0000 Monte Carlo iterations where performed for each of 16 669 data points the process time on a standard office PC was around 8 min.

However, our study has some limitations. Even though the delivery ranges and power steps are fully known for all IOLs on the market, there are data on repeatability or reliability of IOLP measurements on optics labs but no reliable data on the 'real IOLP' or 'real' LT of IOL on the market.[7 20 21] Even if we try to measure the true lens power in a large set of lenses over the entire power range, the power label according to the ISO standard reflects the paraxial equivalent power (within a 3 mm central zone), but without the exact design data the image side principal plane is unknown as a reference for the measurement. Therefore, we decided to simulate the 'worst case scenario' assuming a uniformly distributed error within the LT according to EN ISO 11979-2:2014.[6] Further we assumed that the IOLP uncertainty due to discrete power steps is also uniformly distributed, which is not a systematic drawback as clinicians have to make a decision for the next higher or lower power step, and with any TOL value added to IOLPE such a decision will be made for IOLPE+TOL to the closest available power step. Using a different value for the TOL will simply shift the IOLPE range and is not expected to affect the REFU result significantly.

In conclusion, our data show that the discrete power steps and the delivery range of an IOL could individually affect the predictability of the refractive outcome after cataract surgery. Larger power steps for low power or high power lenses reduce the options of the surgeon to customise the target refraction for initially myopic or hyperopic eyes. However, and even worse, LT as not disclosed to the surgeon or patient induce stochastic variations in the refraction after cataract surgery and will lead to a background noise in all studies focussing on the refractive outcome after cataract surgery with comparisons of biometers, calculation concepts or different lens types. If the 'real' IOLP measured during final quality check of a lens were reported on the package, this error source could be easily eliminated from scientific evaluations in the future.

Correction notice The licence for this paper has been changed to Open Access since it was first published.

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