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Original article

Repeatability and comparability of simulated K values between a grid projection-based device and a Placido/dual Scheimpflug device

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Abstract

Purpose: To evaluate the repeatability and comparability of simulated K values obtained by the Galilei G4 Corneal Tomographer and the iDesign Wavefront Abberometer.
Methods: The right eyes of 100 consecutive pre-laser-assisted *in situ* keratomileusis (LASIK) patients were included in this study. Patients with a history or signs of previous corneal or ocular trauma and infection were excluded. Paired corneal measurements for flat (K1) and steep (K2) meridians were obtained with both the Galilei and the iDesign. Repeatability was evaluated by calculating the coefficient of variation (CV) of the paired measurements. The comparability between platforms was evaluated by calculation of the mean differences followed by the construction of Bland-Altman plots and calculation of limits of agreement (LOA).
Results: While the mean CV for both devices was low (0.17% *versus* 0.57% for the Galilei and iDesign, respectively), a large proportion of eyes measured by the iDesign (22%) showed an absolute difference of > 0.5 D between paired readings, compared to 1% as measured by the Galilei. The Galilei consistently measured higher than the iDesign. Although the mean difference did not exceed 0.17 D, the LOAs were unacceptably wide at -0.52 D to 0.85 D and -0.69 D to 0.89 D for K1 and K2, respectively.
Conclusion: As regards keratometry, the iDesign demonstrated clinically unacceptable repeatability. Both platforms demonstrated sufficiently wide LOA that we could not recommend that they are used interchangeably.

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Keywords: comparability, Galilei, iDesign, keratometry, LASIK, repeatability

Kebolehulangan dan perbandingan nilai K seleppas simulasi antara peranti berasaskan unjuran grid dan peranti Placido/dual Scheimpflug

Abstrak

Tujuan: Untuk menilai kebolehulangan dan perbandingan nilai K simulasi yang diperoleh oleh Galilei G4 Corneal Tomographer dan iDesign Wavefront Abberometer.
Kaedah: Mata kanan 100 pesakit pra-laser in-keratomileusis in situ (LASIK) disertakan dalam kajian ini. Pesakit dengan riwayat atau tanda-tanda trauma dan jangkitan kornea atau okular sebelumnya disisihkan. Pengukuran kornea berpasangan untuk meridian rata (K1) dan curam (K2) diperolehi dengan Galilei dan iDesign. Kebolehulangan dinilai dengan mengira pekali variasi (CV) pengukuran berpasangan. Perbandingan antara platform dinilai dengan pengiraan perbezaan min diikuti dengan pembinaan plot Bland-Altman dan pengiraan had perjanjian (LOA).
Dapatan: Walaupun CV rata-rata untuk kedua-dua peranti rendah (masing-masing 0,17% berbanding 0,57% untuk Galilei dan iDesign), sebilangan besar mata yang diukur oleh iDesign (22%) menunjukkan perbezaan mutlak > 0,5 D antara bacaan berpasangan , dibandingkan dengan 1% yang diukur oleh Galilei. Galilei secara konsisten diukur lebih tinggi daripada iDesign. Walaupun perbezaan min tidak melebihi 0.17 D, LOAs lebarnya tidak dapat diterima pada -0,52 D hingga 0,85 D dan -0,69 D hingga 0,89 D untuk K1 dan K2, masing-masing.
Kesimpulan: Mengenai keratometri, iDesign menunjukkan kebolehulangan yang tidak dapat diterima secara klinikal. Kedua-dua platform menunjukkan LOA yang cukup luas sehingga kami tidak dapat mengesyorkan agar platform tersebut digunakan secara bergantian.

Kata kunci: Galilei, iDesign, kebolehulangan, keratometry, LASIK, perbandingan

Introduction

Precise corneal measurements are critical to the success of laser and lens refractive surgery. When planning for laser refractive surgery, precise keratometry is required to screen for ectatic corneal disorders,[1-3] detection of postoperative complications, and to allow planning for repeat treatments. Precise keratometry is also critical for the success of refractive cataract surgery,[4,5] with keratometric errors accounting for as many as 23% of refractive surprises after cataract surgery.[6]

Available corneal topographers can generally be classified into Placido disc systems and Scheimpflug-based systems. Placido disc systems project the image of a Placido disc off the anterior corneal surface. A video camera then analyses the distance between the reflected mires to calculate corneal power by direct determination of corneal slope. However, the ability of Placido disc systems to measure central corneal power is limited due to the central placement of the video camera. In contrast, Scheimpflug platforms employ a rotating Scheimpflug camera that indirectly calculates corneal power by measuring corneal elevation. Single and dual camera platforms like the Pentacam (Oculus, Germany) and Galilei G4 (Ziemer, Switzerland), respectively, have demonstrated good comparability with manual keratometry.[7,8]

The Galilei G4 combines a dual Scheimpflug camera system with a Placido disc that allows calculation of anterior corneal power and axes, as well as posterior and total corneal powers and axes, amongst other parameters. The Galilei G4 measures approximately 100,000 data points[9] and obtains data (weighted in favour of Placido disc) from the central 4 mm to calculate anterior corneal power.

Unlike Placido or Scheimpflug systems, the iDesign Wavefront Aberrometer (Johnson & Johnson, NJ, USA) measures anterior corneal power by utilising a grid projection based on raster photogrammetry. Instead of a Placido disc, the iDesign projects a 37 x 37 spot grid onto the anterior corneal surface, capturing approximately 1400 data points. The system then uses non-coaxial cameras to analyse the reflected grid pattern. In contrast to Placido disc systems, this method measures gradient of surface elevation to calculate the corneal power. In contrast to the Galilei, the iDesign takes into account the central 3 mm to determine corneal power.

This study evaluated the repeatability and comparability of corneal power values measured by the Galilei and the iDesign to determine if they may be used interchangeably in clinical practice.

Materials and methods

The study protocol was prospectively approved by the Borneo Medical Centre Institutional Review Board (IRB) and adhered to the tenets of the Declaration of Helsinki. One hundred consecutive healthy pre-laser-assisted in situ keratomileusis

(LASIK) patients at the Eye and LASIK Clinic, Borneo Medical Centre, Malaysia were enrolled in the study. The objective of the study, the process of data collection, and the potential side effects of the examination were explained to patients, after which written consent was obtained. Patients who had a history or signs of ocular trauma or surface disease were excluded from our study. A single experienced technician (CC) performed a set of measurements on the iDesign followed by measurements on the Galilei. All measurements were conducted in a darkened room before any slit-lamp examination or refraction was performed. No pre-test lubrication was utilised. On each platform, each person had their head comfortably secured with a soft elastic headband. They were instructed to blink immediately before, then to hold their eyes open wide during the measurement. They did not lift their head off the chin rest until the set of measurements was complete. All sets of measurements were completed within 10 minutes. The right eyes of selected patients were included in this study.

The iDesign software evaluates the validity of scans by evaluating the quality of the following three components: the amount of iris detail available, total ocular wavefront, and corneal topography. Poor quality scans are flagged and deemed non-valid.

Three valid scans are required before the machine selects, via proprietary algorithms, the scan on which it deems best to base a laser refractive treatment. For this study, the first two valid scans were selected.

For the Galilei, the 'Standard' resolution option was selected. Upon image capture, an algorithm is employed to determine the overall quality of the image. The quality of the following components determines overall image quality: camera compensation for eye motion, Placido image quality, Scheimpflug image quality, and the amount of motion in the Z-axis.

Each of the components is then graded with either a 'tick', indicating that it passes an internally set standard for quality, or a 'question mark', indicating that it has failed the set standard. Poor quality scans were flagged and discarded. We selected the first two valid scans.

Statistical Analysis

Statistical analysis was performed with Microsoft Excel 2011. The mean and absolute differences, standard deviation (SD), and coefficient of variation (CV) were calculated for each pair of K1 and K2 measurements to determine the repeatability of each platform. Finally, the mean CV (%) ± SD for each platform was calculated and compared.

We evaluated comparability by calculating the mean of each pair of readings as measured by both platforms, followed by the paired t-test. Bland-Altman plots demonstrating 95% limits of agreement (LOA) were constructed for the differences between the mean readings of both platforms.

Results

Demographics

The right eyes of 100 consecutive pre-LASIK patients were included in this study. Thirty-three patients were men and 67 were women. Sixty patients were Chinese, 19 were Malay, 9 were Dayak, and 12 were Indonesian. The mean age was 30.88 ± 6.7 years. The mean refractive sphere was -4.78 ± 2.21 D and the mean refractive cylinder was -1.07 ± 0.89 D.

Repeatability

The range of absolute differences between paired measurements was low with the Galilei (only 1% of eyes (1/*n* = 100), having a difference of > 0.50 D in at least one of paired K1 or K2 measurements. In contrast, the range of absolute differences for the iDesign was more extensive, with 22% of eyes (22/*n* = 100) having a measured difference of > 0.50 D in at least one of paired K1 or K2 measurements. The Galilei demonstrated superior repeatability for both K1 and K2 with CV of 0.16% and 0.17%, compared to 0.55% and 0.56% by the iDesign. The results are shown in Table 1.

Table 1. Results for two consecutive measurements from the Galilei and iDesign by mean difference, absolute range of differences, and coefficient of variation (*n* = 100)

	Galilei		**iDesign**	
	K1	**K2**	**K1**	**K2**
Mean difference of 2 readings (D) ± SD	0.1 ± 0.08	0.11 ± 0.1	0.34 ± 0.36	0.36 ± 0.36
Range of absolute difference between 2 readings (D)	0.00–0.44	0.00–0.55	0.00–2.46	0.00–2.35
Mean CV (%) ± SD	0.16 ± 0.13	0.17 ± 0.15	0.55 ± 0.57	0.56 ± 0.56

Coefficient of variation (CV) calculated for the mean difference between paired readings of both platforms to calculated dispersion.
CV: coefficient of variation; D: dioptres; K1: flat meridian; K2: steep meridian; SD: standard deviation

Comparability

For K1, the Galilei and iDesign measured a mean ± SD of 43.47 ± 1.37 D and 43.31 ± 1.39 D, respectively. For K2, the Galilei and iDesign measured a mean ± SD of 44.88 ± 1.60 D and 44.74 ± 1.63 D, respectively. The iDesign consistently measured lower compared to the Galilei. The mean values for both devices were compared with the paired t-test. The differences were statistically significant ($p < 0.001$ for both K1 and K2).

Table 2. Results for comparison of 100 paired K1 and K2 measurements between devices

Parameter	Galilei	iDesign	*p*-value
Mean K1 (D) ± SD	43.47 ± 1.37	43.31 ± 1.39	< 0.001
Mean K2 (D) ± SD	44.88 ± 1.60	44.74 ± 1.63	< 0.001
Galilei vs iDesign Mean K1 Difference (D) ± SD	0.16 ± 0.34		-
Galilei vs iDesign Mean K2 Difference (D) ± SD	0.14 ± 0.38		-
LOA K1 (D)	-0.50 to 0.83		-
LOA K2 (D)	-0.60 to 0.88		-

Paired t-test used in statistical analysis to compare mean values of K1 and K2 for both platforms.
D: dioptres; K1: flat meridian; K2: steep meridian; LOA: limits of agreement; SD: standard deviation

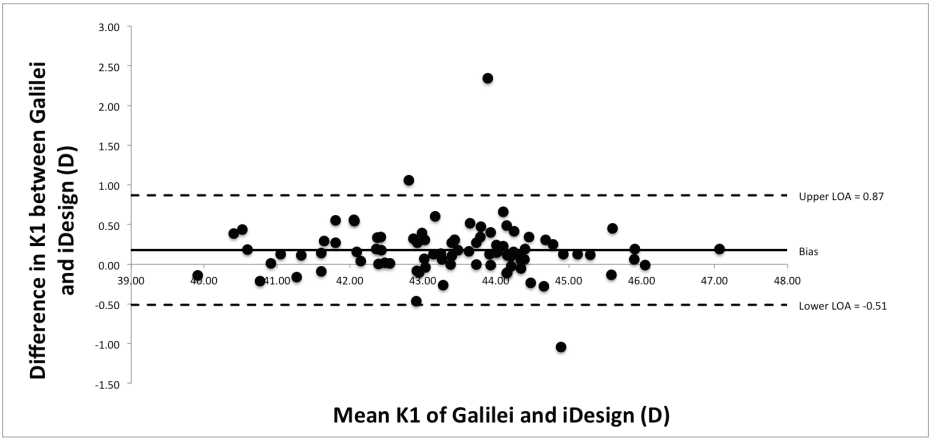

Fig. 1. Bland-Altman plot demonstrating the difference in mean corneal power measurements between the Galilei and iDesign for K1.

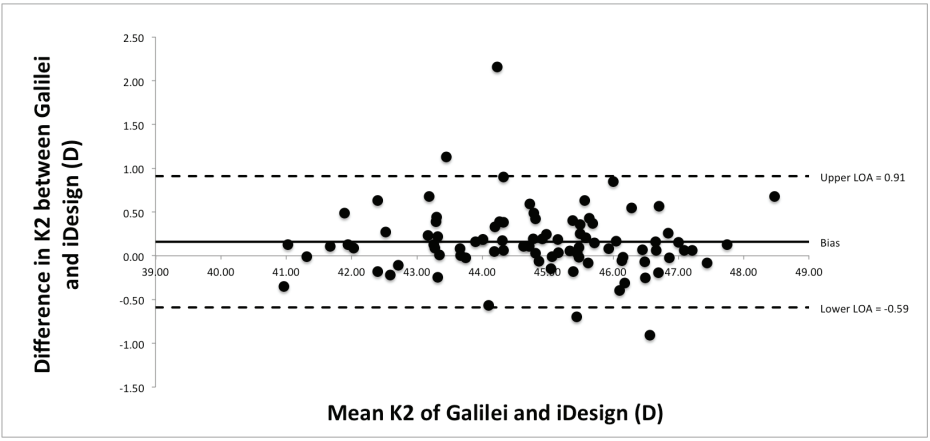

Fig. 2. Bland-Altman plot demonstrating the difference in mean corneal power measurements between the Galilei and iDesign for K2.

For K1 and K2, the mean difference ± SD between measurements for the Galilei and iDesign was 0.16 ± 0.34 D and 0.14 ± 0.38 D, respectively. The LOA were wide, ranging from -0.50 to 0.83 D for K1 and -0.60 to 0.88 D for K2. The results are shown in Table 2 and Figures 1 and 2.

Discussion

The success of cataract and corneal refractive surgery hinges upon the precision of corneal power measurements. This study examined the repeatability and comparability of the Galilei and iDesign in measuring anterior corneal power. We found that, while both devices demonstrated low CV, the poorer recorded repeatability of the iDesign was more likely to be clinically significant. Our findings loosely mirror reports regarding the repeatability of the Galilei, alternately reported to be as low as 0.12% by Shirayama[8] and as high as 0.29% by Crawford.[10] These discrepancies between studies may be due to various factors, including variation in examination order, ocular laterality, and the number of measurement sets performed. In the two cited studies as well as in our own, a single observer recorded all the measurements. In our study, in order to avoid the potential for bias, we ceased measurements once there were two acceptable scans. In comparison, three measurements were recorded per patient in the above-mentioned studies, but it was not clear whether these were the first three that were acceptable, or whether they were selected from a pool of acceptable scans. It is apt to consider any inter-study agreement with caution due to differing methodologies in data collection.

We are unaware of similar studies that assess the repeatability of the iDesign. However, data regarding the Accugrid platform (PAR Vision Systems, NY, USA) is

available. The Accugrid is similar in that it directly determines the curvature of a surface by analysing a projected grid pattern.

Belin and associates reported the measured variability of the Accugrid to be as low as 0.06 D when examining diameter calibrated test spheres over an 8 mm test area.[11] However, the accuracy and variability were reported to be worse with smaller test areas.

While the Accugrid has not been examined *in vivo*, Jindal and associates reported an average of 0.28 D difference between readings when examining cadaveric eyes over various area sizes that ranged from 3–6 mm in diameter.[12] Differences between methodologies notwithstanding, we report similar average differences between paired iDesign readings (0.34 D and 0.36 D) for K1 and K2 in our study. Given the dearth of *in vivo* studies regarding the iDesign, we would be prudent to hesitate in drawing firm conclusions regarding the repeatability of the iDesign.

Our study findings, however, suggest that the repeatability of the Galilei is superior, measuring > 0.5D between paired readings in only 1% of eyes as opposed to 22% by the iDesign. During the calculation of intraocular lens powers, for example, this difference in repeatability is likely to be clinically significant.

We also evaluated comparability between platforms. While the mean difference between platforms did not exceed 0.16 D, which is of minimal clinical significance, there was a clinically significant measured difference of > 0.5 D between platforms in 18% of evaluated eyes (18 eyes). The iDesign also consistently measured lower than the Galilei. Because the iDesign measures the central 3 mm, it would be expected to measure higher than the Galilei, which measures the central 4 mm. This discrepancy may be due to Galilei's camera placement excluding measurement of the central 1 mm.

To date, comparability between the iDesign and other platforms has not been examined. Available studies involving the Galilei suggest good comparability with the Placido disc-based Zeiss Atlas (Carl Zeiss AG, Oberkochen, Germany). Shirayama and associates found a mean difference ± SD of 0.08 ± 0.14 D with an LOA of 0.54 D.[8] This similarity could be due to Galilei depending primarily on Placido disc data for anterior corneal power values.

In contrast, the comparability between the Galilei and the Orbscan II (Bausch and Lomb, Rochester, NY, USA) has been reported to be poorer. The Orbscan II combines slit scanning with a Placido disc. Menassa and associates compared the Galilei to the Orbscan II and found a mean difference (D) ± SD of 0.04 ± 0.37 and 0.09 ± 0.44 for K1 and K2, respectively.[13] It is unclear if data collected by the Orbscan II is weighted in favour of data collected by the slit scan, upon which the earlier iteration of the platform was wholly dependent. This difference in measurement method could be the reason for the larger standard deviation.

When comparing the Galilei and the Orbscan II, Crawford and associates reported LOA of 1.7 D and 1.5 D for Mean K and K1.[10] When comparing the Mean K

Table 3. Summary of comparison between devices in the current study and other automated devices

Study	Devices	Mean difference (D) ± SD	Range of 95% LOA (D)
Crawford[10]	Galilei *vs* Pentacam (K1)	-0.1 ± 0.2	0.9
	Galilei *vs* Pentacam (K2)	0.0 ± 0.3	N/A
	Galilei *vs* Orbscan II (K1)	± 0.4	1.5
	Galilei *vs* Orbscan II (K2)	0.2 ± 0.5	N/A
Menassa[13]	Orbscan II *vs* Galilei (K1)	0.04 ± 0.37	N/A
	Orbscan II *vs* Galilei (K2)	0.09 ± 0.44	N/A
Shirayama[8]	Galilei *vs* IOLMaster (Mean K)	-0.12 ± 0.07	0.27
	Galilei *vs* Atlas (Mean K)	-0.08 ± 0.14	0.54
	Galilei *vs* Manual Keratometer (Mean K)	0.05 ± 0.13	0.51
Current study	Galilei *vs* iDesign (K1)	0.16 ± 0.34	1.33
	Galilei *vs* iDesign (K2)	0.14 ± 0.38	1.48

D: dioptres; K1: flat meridian; K2: steep meridian; LOA: limits of agreement; N/A: not available; SD: standard deviation

and K1 of the Galilei and the Scheimpflug-based Pentacam, they recorded slightly lower but still unacceptable LOA of 1.1 D and 0.9 D.[10]

The above studies demonstrate that the Galilei is capable of producing near-identical mean K values when compared to the Orbscan II and Pentacam (Table 3). However, variability between platforms as reflected by standard deviation and LOA were beyond clinically acceptable limits.

Conclusion

In summary, we studied the repeatability and comparability of the Galilei and iDesign platforms in measuring anterior corneal power. The repeatability of the Galilei was suggested to be superior compared to the iDesign. Whilst the iDesign was found to be less repeatable, there were obvious limitations in our study design. These shortcomings included the use of a single observer and non-randomisation of selected eyes. These may have inadvertently affected outcomes. We look forward to further studies that address these limitations.

When examining comparability between platforms, LOA between platforms was sufficiently wide as to be clinically unacceptable. Other studies examining

concordance between the Galilei and other platforms offer conflicting reports.[7,8,10,13]

As the true 'gold standard' of corneal power measurement is unknown, and there are no prior studies comparing the iDesign to other platforms, we are currently unable to offer a conclusion as to whether the Galilei or iDesign is closest to actual corneal power. They appear to be sufficiently disparate that we cannot recommend that they be used interchangeably in clinical practice.

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