Changes of the corneal endothelial cell count after Artisan phakic intraocular lens implantation

Mohamed O. Mekhlef Mohamed, Ashraf K. Al-Hussaini, Gamal R. Osman, Mahmoud F. Rateb

Department of Ophthalmology, Faculty of Medicine, Assiut University, Assiut, Egypt

Correspondence to Mohamed O. Mekhlef Mohamed, MSC,
Department of Ophthalmology, Faculty of Medicine, Assiut University, Assiut 71515, Egypt.
Tel: +20 106 717 3648;
e-mail: mekhlef22mo@gmail.com

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Introduction
Corneal refractive procedures are widely used by refractive surgeons for the treatment of myopia and other errors of refraction. However, these procedures are restricted by corneal thickness, corneal curvature, and the risk of postoperative ectasia. When dealing with high degrees of myopia, phakic intraocular lenses (pIOLs) can correct a wider range with a more superior quality of vision and refractive outcomes. However, the potential risk of damage to corneal endothelial cells remains one of the main concerns regarding pIOL implantation.

Aim
To evaluate the possibility and magnitude of endothelial cell loss following implantation of Artisan pIOL for the treatment of high myopia.

Patients and methods
The study comprised twelve eyes with high myopia implanted with Artisan pIOL. In this prospective interventional study, preoperative and postoperative specular microscopy (NIDEK CEM-530 Specular Microscope) was conducted to assess changes in endothelial cell count over 6 months.

Results
Preoperative mean endothelial cell count was 2748.33 ± 73.594 cells/mm^2. It was 2736.75 ± 82.275 cells/mm^2 at 1 month after surgery, which changed to 2567.50 ± 104.458 cells/mm^2 at 6 months postoperatively. The mean cell loss after 6 months was 6.19%. No significant changes were found in other endothelial parameters, including average cell size, percentage of hexagonality, and coefficient of variation. The mean uncorrected visual acuity improved from 0.033 ± 0.005 preoperatively to 0.708 ± 0.08 after surgery, and the mean spherical equivalent improved from −16.729 ± 1.303 D preoperatively to − 0.354 ± 0.161 D after surgery.

Conclusion
Implantation of Artisan lens is a safe way for dealing with high myopia. No significant change was observed in endothelial cells over 6 months of observation. It also had excellent results regarding its predictability and efficacy. A longer follow-up period is required to monitor the effect on the corneal endothelium on the long term.

Keywords:
artisan, endothelium, high myopia, iris-claw, phakic intraocular lens

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Introduction

Laser ablative refractive surgery has been used for the last 30 years for dealing with refractive errors and has proven to be safe and predictable in most cases [1]. However, these procedures have a limited range of safe dioptric correction, particularly when dealing with high refractive errors. Possible complications include corneal ectasia, regression, corneal haze, or poor visual quality [2,3]. In cases where corneal refractive surgery is not appropriate, owing to high error, thin cornea, or both, one can consider either phakic intraocular lens (pIOL) implantation or refractive lens exchange [1].

Owing to total loss of accommodation and an increased risk of retinal detachment, refractive lens exchange is less appropriate in younger patients. [1]. On the contrary, pIOLs are potentially reversible procedures that can correct high levels of myopia with immediate improvement in visual acuity while preserving accommodation [4]. Thus, in the absence of contraindications, implantation of pIOL is a good option for the treatment of young patients with high myopia [5].

The earliest iris-claw lens was designed in 1977 for the management of aphakia. The design was then changed into a convex–concave model for the correction of myopia [6]. Compared with other pIOLs, the iris-claw lens maintains an appropriate distance from the angle

of anterior chamber, crystalline lens, and corneal endothelium [7]. In addition, the lens haptic enclavates a fold of the iris to achieve a good centration of the lens [8].

Several studies have shown that implantation of iris-fixated pIOLs yields stable and predictable results [9]. However, their effect on corneal endothelium has remained an issue of controversial debate [10].

Aim

The aim was to evaluate the possibility and magnitude of endothelial cell changes following Artisan phakic lens implantation for the treatment of high myopia.

Patients and methods

In this prospective interventional study, 12 eyes of seven patients with high myopia were implanted with Artisan pIOL during the period from June 2018 to October 2019. Endothelial cells' evaluation using specular microscopy was done for all the participants before and after surgery. An informed consent was obtained as well as the approval of the ethical committee of Faculty of Medicine, Assiut University, carrying the number 17100324. ClinicalTrial.gov identifier: NTC03266354.

Inclusion criteria

The following were the inclusion criteria:

(a) Patients with myopia, not suitable for laser ablative refractive surgery owing to high error, thin cornea, or both; (b) minimum age of 20 years; (c) preoperative endothelial cell density above 2000 cells/mm^2; (d) stable refraction; (e) best-corrected visual acuity (BCVA) better than 6/60 (0.1); (f) clear cornea; (g) anterior chamber depth more than 3.00 mm; and (h) normal peripheral retina.

Exclusion criteria

The following were exclusion criteria:

(a) Previous corneal or intraocular surgery, (b) any form of cataract, (c) glaucoma, (d) corneal opacity, (e) uveitis, (f) iris atrophy, (g) history or evidence of retinal disease, and (h) pregnancy.

Preoperative evaluation

It included the following: (a) uncorrected visual acuity (UCVA) and BCVA; (b) refraction; (c) complete anterior segment examination using slit-lamp for detection of any anterior segment abnormalities with particular attention to corneal clarity and crystalline lens examination; (d) fundus examination for evaluation of the vitreous and assessment of the retina; (e) intraocular pressure measurement using Goldmann's applanation tonometer; (f) anterior chamber depth from pentacam measures, biometry, or both; (g) keratometry; and (h) central corneal thickness measurement.

Endothelial cells' evaluation

Noncontact specular microscopy was performed using NIDEK CEM-530 (NIDEK inc., Japan) Specular Microscope. Endothelial cell count was performed before surgery and 1 and 6 months after surgery. IOL power was calculated using the Van der Heijde's formula aiming for emmetropia.

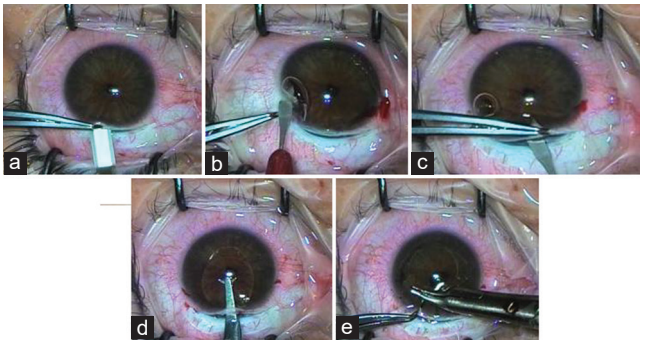
The procedure

All surgeries were conducted by one surgeon after performing a complete surgical fitness (Fig. 1). A 5.5 or 6.5-mm limbal incision was made superiorly and two paracenteses aiming toward the enclavation area. After injection of healon, the IOL was introduced and then oriented horizontally. The pIOL was then fixated to mid-peripheral zone of the iris. A 12-o'clock peripheral iridotomy was then performed. The corneal wound was closed with four interrupted 10-0 nylon sutures. OVD was aspirated.

Postoperative follow-up

Initial examination was done on the first postoperative day followed by regular follow-up on the first week, and then after 1, 3, and 6 months. Evaluation included UCVA, refraction, slit-lamp examination of the anterior segment (Fig. 2) to evaluate intraocular lens position, anterior chamber inflammation as well as assessment of lens clarity, applanation tonometry, and fundus examination.

Figure 1



Main surgical steps of Artisan pIOL implantation: (a) limbal incision. (b) Paracentesis. (c) Opening the limbal incision. (d) Artisan implant is introduced into AC. (e) Implant fixated to iris followed by closure of limbal incision. pIOL, phakic intraocular lens.

Statistical analysis

Statistical Package for the Social Science, version 20 was used to collect and analyze the data. The qualitative data were presented in the form of numbers and percentages, whereas the quantitative data were presented as mean, SEs, and ranges. To assess the changes, we used paired *t* test. *P* value was considered significant if less than 0.05.

Results

The study comprised 12 eyes with high myopia implanted with Artisan pIOL. Nine (75%) eyes belonged to females and three (25%) eyes to males. The age of the patients ranged from 21 to 32 years, with a mean of 26.14 ± 3.58 years. Baseline characteristics and preoperative parameters are shown in Table 1.

Postoperative results

Visual acuity outcome

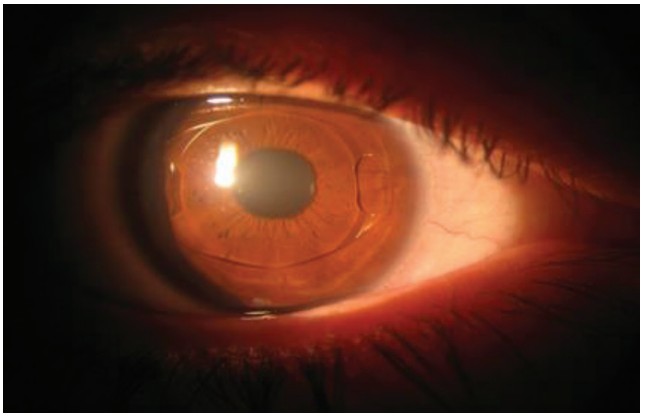
Mean preoperative UCVA improved from 0.033 ± 0.005 preoperatively to 0.708 ± 0.08 postoperatively, which was statistically significant.

Table 1 Baseline ophthalmological characteristics before phakic intraocular lens implantation

	Range	Mean±SD
UCVA	0.01-0.07	0.033±0.005
BCVA	0.17-0.67	0.369±0.058
SE (D)	−9.5-−22	−16.729±1.303
ACD (mm)	3.11-3.66	3.47±0.045
CCT (μm)	455-557	502.25±8.856
IOP (mmHg)	10-21	13.083±0.957
IOL power (D)	−9.5-−20	−15.292±1.084

ACD, anterior chamber depth; BCVA, best-corrected visual acuity; CCT, central corneal thickness; IOP, intraocular pressure; SE, spherical equivalent; UCVA, uncorrected visual acuity.

Figure 2



Postoperative slit-lamp appearance of the Artisan implant.

Preoperatively, no eye had UCVA for more than 4/60 (0.07), whereas at 6 months postoperatively, two eyes had UCVA of 6/18 (0.33), three eyes had UCVA of 6/12 (0.5), two eyes had UCVA of 6/9 (0.67), and five eyes had UCVA of 6/6 (1.00).

Efficacy

The efficacy index (mean postoperative UCVA/mean preoperative BCVA) was 1.91 after 6 months; no eye had postoperative UCVA less than the preoperative BCVA. Fig. 3 shows mean preoperative UCVA, preoperative BCVA, and postoperative UCVA.

Postoperative refractive outcome

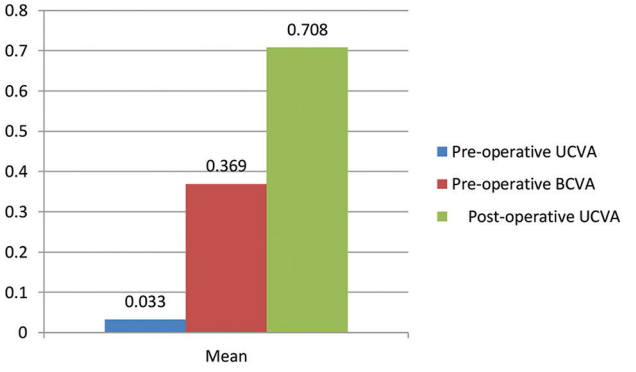
Postoperative spherical error had a statistically significant improvement from preoperative value (−15.667 ± 1.378 preoperatively to 0.542 ± 0.179 postoperatively). Mean postoperative cylindrical error at the end of follow-up period had no statistically significant change from preoperative value.

At the end of the postoperative observation period, the spherical equivalent was less than 1.00 D in 10 eyes, equal or more than 1.00 D in two eyes. No eye had a spherical equivalent of more than 1.5 D at 6 months postoperatively, indicating high predictability of the procedure. Table 2 shows the change in mean postoperative SE from the preoperative value.

Complications

High postoperative astigmatism occurred in three eyes and was managed by selective suture removal. Mild lens decentration occurred in one (8.3%) case only. No sight-threatening complications occurred during the follow-up period.

Figure 3



Clustered column chart showing mean preoperative UCVA, preoperative BCVA, and postoperative UCVA. BCVA, best-corrected visual acuity; UCVA, uncorrected visual acuity.

Endothelial cell density

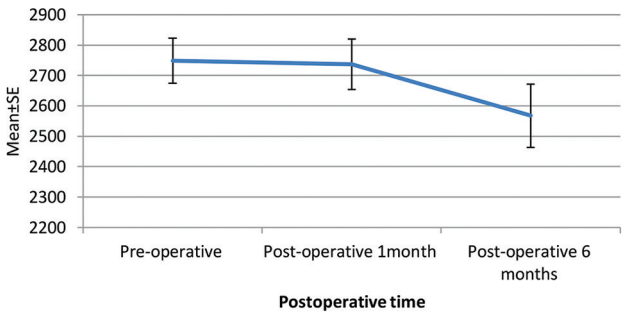
Preoperative mean endothelial cell count was 2748.33 ± 73.594 cells/mm^2 (range, 2227–3262 cells/mm^2). It was 2736.75 ± 82.275 cells/mm^2 (range, 2380–3318 cells/mm^2) at 1 month after surgery, and 2567.50 ± 104.458 cells/mm^2 (range, 2059–3008 cells/mm^2) at 6 months after surgery. No statistically significant decrease was observed in endothelial cell density at 1 and 6 months postoperatively, as shown in Tables 3 and 4.

The mean endothelial cell loss was 6.19% at the end of the 6 months, with 2.72% at 1 month postoperatively and 3.62% from 1 to 6 months postoperatively. Fig. 4 shows the change of mean endothelial cell density over 6 months.

Substudy of endothelial parameters

No statistically significant changes were seen in the other endothelial parameters compared with preoperative levels, including, average cell size, percentage of hexagonality, and coefficient of variation, as shown in Table 5. Changes in endothelial parameters in one of the study cases are shown in Fig. 5.

Figure 4



Line chart showing mean ECD over 6 months. ECD, endothelial cell density.

Table 2 Changes in the mean postoperative spherical equivalent from the preoperative value

Spherical equivalent	Preoperative	Postoperative	*t*	*P*
Mean±SE	−16.729±1.303	−0.354±0.161	−11.954	<0.001**
Range	−9.5-−22	−1.5-0.75		

**means this p-value is statistically significant ($P < 0.05$)

Table 3 Changes in the mean postoperative endothelial cell density 1 month after surgery from the preoperative value

ECD	Preoperative	Postoperative 1 month	*t*	*P*
Mean±SE	2748.33±73.594	2736.75±82.275	0.214	0.834
Range	2227-3262	2380-3318		

ECD, endothelial cell density.

Table 4 Changes in the mean postoperative endothelial cell density 6 month after surgery from the preoperative value

ECD	Preoperative	Postoperative 6 months	*t*	*P*
Mean±SE	2748.33±73.594	2567.50±104.458	0.756	0.152
Range	2227-3262	2059-3008		

ECD, endothelial cell density.

Discussion

In our study, we assessed the change in endothelial cells after Artisan pIOL implantation as well as the visual and refractive outcomes.

Regarding visual acuity outcome, we found a significant improvement in UCVA relative to the preoperative value. All patients had UCVA less than 0.10 before surgery. However, all eyes achieved UCVA of 0.33 or better at 6 months after surgery. Regarding final refraction at 6 months postoperatively, all eyes were within ±1.50 D of emmetropia, which indicates high predictability of these lenses.

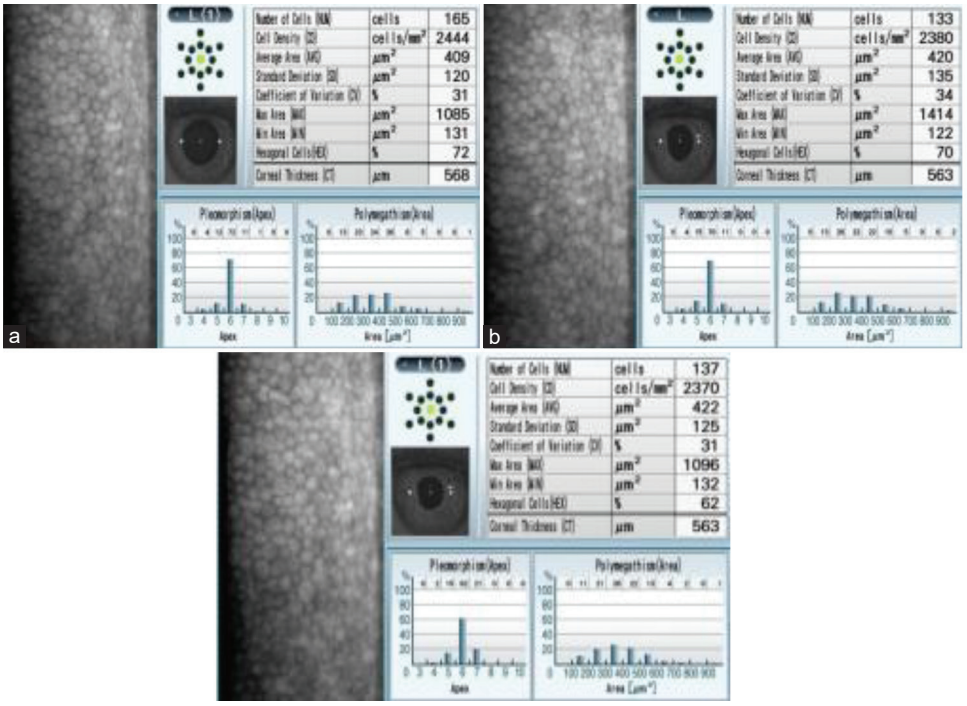
According to the results of this study, we found that the change of endothelial cell density at 6 months after surgery was not significant statistically. Similar to our findings, Morral *et al.* [11] did not find significant endothelial loss at any time point after iris-claw pIOL implantation. Similarly, Nassiri *et al.* [12] reported no statistically significant difference in endothelial cell count at 6 months postoperatively relative to the preoperative value.

These results were in line with that of Tahzib *et al.* [13] who found no significant endothelial loss at 1 and 6 months after Artisan implantation. In addition, Senthil and Reddy [14] reported mean endothelial cell loss of 5.2% at 6 months postoperatively. In their study, Yuan *et al.* [15] observed no significant loss of endothelial cells after 6 months of implantation, and the mean cell loss after 1 year was 5.3%.

In contrast to our findings, Pérez-Santonja *et al.* [16] reported continuous loss of endothelial cells with a drop of 7.2% at 3 months, 10.6% at 6 months, and 13% at 12 months after surgery. Coullet *et al.* [17] reported a 9.4% decrease in endothelial cell count following Artisan implantation at 1 year postoperatively. Karimian *et al.* [18] observed endothelial cell loss of 10.1% 3 years following iris-claw implantation.

Throughout the literature, there is a large variation in the reported cell loss, which may be owing to variability of the measurement techniques and more importantly, the effect of the surgical procedure itself. Many reports found that the highest reduction of cell density occurs in the early postoperative period, and the rate of loss markedly decreased after certain period, which suggests that endothelial damage occurred

Figure 5



One of the study cases (a) preoperatively showing ECD2444. (b) 1 month postoperatively showing ECD2380. (c) 6 months postoperatively showing ECD2370. ECD, endothelial cell density.

Table 5 Summary of the substudy of endothelial cell parameters

	Maximum cell size (µm²)	Average cell size (µm²)	Minimum cell size (µm²)	Percent of hexagonality	Coefficient of variation
Before surgery	1013	367.667	135.917	67.5	29.417
1 months postoperatively	1020.5	368.167	123.75	64.583	29.417
6 months postoperatively	995	388.5	112	68.625	29

mainly during the surgical procedure [19]. In a cohort study conducted by Na *et al*. [20], intraoperative manipulation during Artisan pIOL implantation had a direct effect on corneal endothelium, which emphasizes the importance of surgical skill, including the process of lens enclavation.

In the present study, no significant changes were observed in the substudy of endothelial cell parameters. Both the percentage of hexagonality and the coefficient of variation showed no significant change postoperatively. These results are in line with the data reported by Yuan *et al*. [15] and Benedetti *et al*. [21].

The loss of endothelial cells might be attributed to corneal endothelium damage owing to direct contact with the IOL either during Artisan implantation or changes in the IOL position postoperatively. In addition, chronic subclinical inflammation postoperatively could lead to further endothelial damage [22].

3 eyes showed high post-operative astigmatism. This was managed by selective suture removal (SSR) one week after surgery (removing the sutures responsible for this high astigmatism). Mild lens decentration occurred in one case which did not require additional surgical intervention. No pupillary block, retinal complications, or other major complications were seen during the follow-up period.

Conclusion

Artisan lens implantation is a safe method for dealing with high myopia. No significant change was observed in endothelial cell density over 6 months of follow-up. It had excellent results regarding its predictability and efficacy. A longer follow-up period is mandatory to assess the long-term effect of these lenses.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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