Ultrasound biomicroscopy of the Artisan phakic intraocular lens in hyperopic eyes

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Purpose: To study in situ the intraocular position of the Artisan iris-claw intraocular lens (IOL) (model 203) (Ophtec) in phakic hyperopic eyes using ultrasound biomicroscopy (UBM).

Methods: Echograms of the anterior chamber were taken preoperatively and 24 to 317 days postoperatively in 4 eyes implanted with the Artisan IOL (power +4.0 to +6.0 diopters). The preoperative anterior chamber depth (ACD) and the postoperative distance between the IOL and the corneal endothelium (endothelium–optic distance) and between the IOL and the lens were measured. The echograms were assessed for the effect of the IOL on iris tissue.

Results: The preoperative ACD ranged from 3.10 to 3.56 mm and the postoperative endothelium–optic distance, from 2.03 to 2.54 mm. The distance between the lens and the posterior surface of the IOL ranged from 0.35 to 0.79 mm. Several UBM echograms showed indentation of iris tissue by the IOL haptics and optic edge, although no pigmentary dispersion was noted.

Conclusions: Adequate space was maintained between the Artisan hyperopic IOL and the corneal endothelium, angle, and crystalline lens. Haptic indentation of the iris, which could lead to pigment erosion, was observed. Preoperative gonioscopy and maintenance of normal intraocular pressure postoperatively suggest the indentation was secondary to inadequate lens vaulting relative to the high natural arch of the iris in hyperopic eyes. Shortening the haptics or increasing the lens vault might resolve this problem.

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In 1986, the first iris-claw intraocular lens (IOL) was implanted in a phakic eye by Worst and Fechner. Since then, several models of this IOL have been developed. To date, models for the treatment of myopia have been implanted in eyes worldwide without reports of abnormal pupil function or contact between the phakic IOL and the natural lens.[1,2] Still, some authors have expressed concern about the potential for this iris-claw IOL to damage the iris or the corneal endothelium.[3–5]

There is a preliminary report of the Artisan iris-claw IOL for hyperopia (model 203) (Ophtec),[6] which was evaluated in clinical trials in the United States in 2000 and 2001. The present study investigated the position of this phakic IOL relative to adjacent structures in the anterior segment. The anterior chamber was examined with ultrasound biomicroscopy (UBM). This is a simple technique that has been used to determine the postoperative fixation of other phakic IOLs including the Artisan iris-claw lens for myopia, the Collamer posterior chamber ICL (Staar) for myopia and hyperopia, and the ZSAL-4 anterior chamber IOL (Morcher GmbH) for myopia.[2,7–9]

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Patients and Methods

Patients

The Artisan iris-claw phakic IOL was implanted in 4 eyes of 3 patients. In patient 1, a +4.0 diopter (D) IOL was implanted in the left eye, which had a refraction of +3.00 –1.25

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× 108. Patient 2 had bilateral IOL implantation. A +5.0 D IOL was implanted in the right eye, which had a refraction of +5.00 –1.00 × 180, and a +6.0 D IOL was implanted in the left eye, which had a refraction of +8.50 –1.25 × 177. In patient 3, a +4.0 D IOL was implanted in the left eye, which had a refraction of +3.75 –0.75 × 70.

All patients received approval to have surgery from Health Canada on the Special Access Program by the Therapeutic Product Medical Devices Bureau. The surgeries were approved by the Ethics Review Board, and all patients signed an informed consent form. A comprehensive ophthalmic screening examination including gonioscopy and iris examination was performed before surgery. Patients with any of the following findings were ineligible for the procedure: intraocular pressure (IOP) greater than 21 mm Hg; endothelial cell count less than 2000 cells/mm^2; a history of glaucoma, uveitis, diabetic retinopathy, or iris atrophy.

Iris-Claw Phakic IOL for High Hyperopia

The Artisan IOL for hyperopia is available in 1.0 D increments from +3.0 to +12.0 D. It is constructed of poly(methyl methacrylate) and is 8.5 mm long and 5.0 mm wide; the 5.0 mm optic has a convex–concave shape with a height of 1.0 mm. Each of the IOL's 2 haptics is composed of 2 arms with merging claws at the ends that are used to fixate the IOL to the midperipheral iris stroma. The opening created by the merging claws of the haptic is 2.2 mm wide and 1.55 mm long.

The Artisan IOL is inserted with the pupil constricted and the anterior chamber filled with viscoelastic material. After it is introduced into the anterior chamber, the IOL is rotated with the haptics at 3 and 9 o'clock using a Sinskey-type IOL manipulating instrument. The optic is centered over the pupil. Iris entrapment is performed by holding a knuckle of iris with a specially designed, disposable enclavation needle (Ophtec OD-125) while gently pressing the center of 1 haptic over the knuckle, thus grasping iris tissue with both claws. The same procedure is repeated with the other haptic. Once the IOL is fixated, a manual peripheral iridectomy is performed.

Ultrasound Biomicroscopic Examination

Preoperative and postoperative examinations were performed using the Humphrey® ultrasound biomicroscope, model 840. This system uses a 50 MHz transducer with a probe and has an axial and lateral resolution of 50 μm that provides a sampling resolution of 5 μm on scans, as described by the manufacturer.

For the examination, the cornea was anesthetized with topical proparacaine 0.5% (Alcaine®). Depending on the size of the eye's aperture, a 20 mm, 22 mm, or 24 mm eyecup filled with a sterile gonioscopic solution was inserted between the upper and lower eyelids. The patient was asked to fixate on a ceiling target with the fellow eye to maintain accommodation and fixation.

All eyes were scanned by a single operator. Cross-sectional images were taken through the cornea, iris, ciliary body, and lens, starting from the nasal to the temporal side and from the superior to the inferior side, providing 360-degree coverage of the anterior chamber. Axial vertical and axial transverse sections were examined through the central cornea to the central lens. All measurements were made using the calipers provided by the UBM system software on the 2-dimensional image recorded by the ultrasound biomicroscope. The brightness of the echogram represented the intensity of the original echo.

Echograms were taken where needed in the anterior chamber to measure the preoperative anterior chamber depth (ACD) and the postoperative distance between the IOL and the corneal endothelium (endothelium–optic distance). The ACD was measured from the corneal endothelium to the anterior surface of the lens capsule and the endothelium–optic distance, from the corneal endothelium to the anterior surface of the IOL. The distance between the IOL and the lens was also measured from the posterior surface of the IOL to the anterior surface of the lens capsule. In addition, the shortest distance from the farthest point of the haptic to the angle of the anterior chamber was measured.

The ACD and axial length were also determined by ultrasonography using the Ocuscan® standard ultrasonograph (Alcon). The ultrasonograph measured the ACD from the corneal epithelium to the anterior lens capsule; the axial length was measured from the corneal epithelium to the macula.

Results

The preoperative gonioscopic examination was normal in all eyes, although the natural iris arch appeared more pronounced than in myopic eyes. One month after surgery, the IOP ranged from 16 to 18 mm Hg and there were no signs of postoperative pupillary block or other postoperative complications.

The postoperative UBM examination was performed between 24 days and 317 days. The preoperative and postoperative anterior segment measurement data are summarized in Table 1. The UBM-determined ACD ranged from 2.70 to 3.25 mm preoperatively, and the pseudo-ACD (endothelium–optic distance) ranged from 2.03 to 2.54 mm postoperatively. A space was maintained between the anterior lens capsule and the posterior surface of the IOL in all eyes (range 0.35 to 0.79 mm). The distance from the end of the haptic to the angle of the anterior chamber ranged from 1.46 to 2.47 mm.

Figures 1 to 4 depict the position of the IOL's optic edge and haptics relative to the iris. In Figure 1, which

Table 1. Mean preoperative and postoperative anterior segment measurements.

			Preoperative		Postoperative			
Eye	Patient/Eye	IOL Power	ACD* (mm)	ACD† (mm)	Pseudo ACD (mm)	IOL to Lens (mm)	Haptic to Angle of Anterior Chamber (mm)	Follow-up (d)
1	1/OD	+4.0	3.56	3.25	2.22	0.79	1.75	317
2	2/OD	+5.0	3.10	2.95	2.16	0.59	2.47	66
3	3/OS	+4.0	2.76	3.05	2.54	0.57	1.46	24
4	2/OS	+6.0	3.22	2.70	2.03	0.35	1.47	66

ACD = anterior chamber depth

*Performed with the standard ultrasonograph from the corneal epithelium to the anterior lens capsule

†Performed with the UBM from the corneal endothelium to the anterior lens capsule

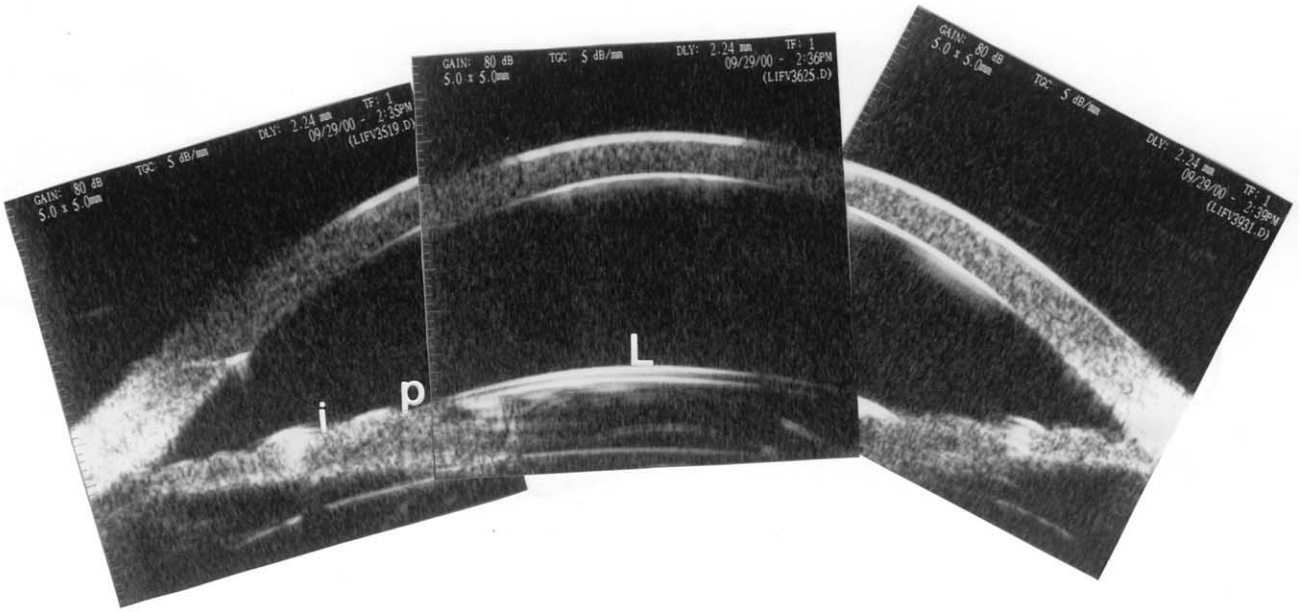

Figure 1. (Pop) Postoperative composite picture of 3 longitudinal axial UBM echograms of the iris-claw phakic IOL in patient 1. The IOL (*L*) indentation (*p*) into the iris (*i*) can be seen. Scale is 1:17.

combines the postoperative longitudinal axial UBM picture of the IOL position through the central cornea in 3 separate echograms, the optic edges are seen to indent the iris.

Figure 2 shows the marginal optical zone of the IOL and haptic at the edge of the iris and indicates indentation of the iris by the optic edge.

Figures 3 and 4 illustrate the postoperative lateral vertical UBM echograms of the IOL's haptic in 2 eyes. The portion shown is between the haptic and the optical zone. The optical zone of the IOL is anterior to the image. The pigment layer and the anterior stroma of the iris are visible, and the 2 arms of the haptic and the shadowing behind it through the iris and lens capsule can be seen.

In the echograms, the optic edge could be seen to indent the iris (Figures 1 and 2). Indentation of the iris by the haptic arms was also observed (Figures 3 and 4). A comparison of Figures 3 and 4 indicates that the magnitude of the latter indentation was greater closer to the site of iris entrapment.

Discussion

Several observations were made in this early evaluation of 4 eyes implanted with the Artisan iris-claw pha-

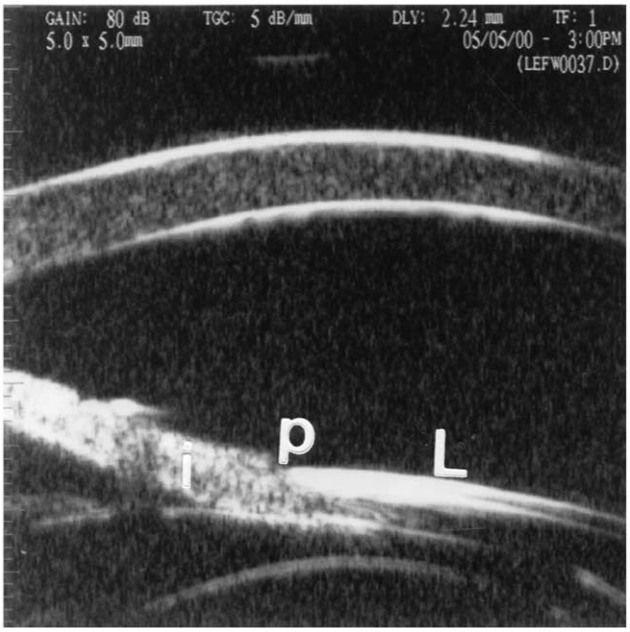

Figure 2. (Pop) Postoperative longitudinal transverse echogram of the iris phakic IOL (*L*) for patient 2 showing the edge of the IOL optic protruding (*p*) into the iris (*i*).

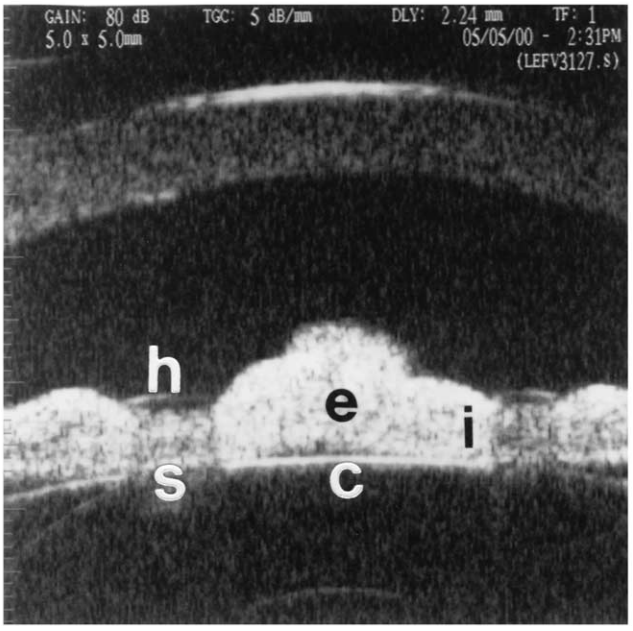

Figure 3. (Pop) Postoperative lateral transverse UBM echogram of the iris-claw phakic IOL in patient 3 showing the 2 arms of the haptics (*h*) near the site of iris entrapment and the shadowing (s) behind it through the iris (*i*), the iris entrapment (e), and the lens capsule (*c*). Haptics are beneath the iris tissue, showing indentation of the arms.

kic IOL for the treatment of hyperopia. The depth of the pseudo anterior chamber created after IOL implantation was approximately 30% less than that of the natural anterior chamber. However, a distance of 2.03 to 2.54 mm was still maintained between the anterior surface of the IOL optic and the corneal endothelium. In no eye did the IOL touch the lens capsule, and the distance between the anterior surface of the lens capsule and the posterior surface of the IOL ranged from 0.35 to 0.79 mm. These measurements of the distance between the IOL and both the endothelium and the crystalline lens are similar to those we reported in myopic eyes implanted with the Artisan iris-claw phakic IOL.[2]

Examination of the echograms, however, showed that the optic edge and haptics of the hyperopic phakic IOL appeared to indent iris tissue. Comparison of the echograms of 2 eyes indicated that the magnitude of the indentation increased closer to the site of iris entrapment. This indentation was not observed in our study of myopic eyes.[2] As the preoperative gonioscopy indicated, these hyperopic eyes had a more pronounced natural iris arch than their myopic counterparts. One might postulate that the lens indentation in the iris tissue was secondary to inadequate vaulting of the hyperopic phakic IOL relative to the natural iris arch of the hyperopic eye.

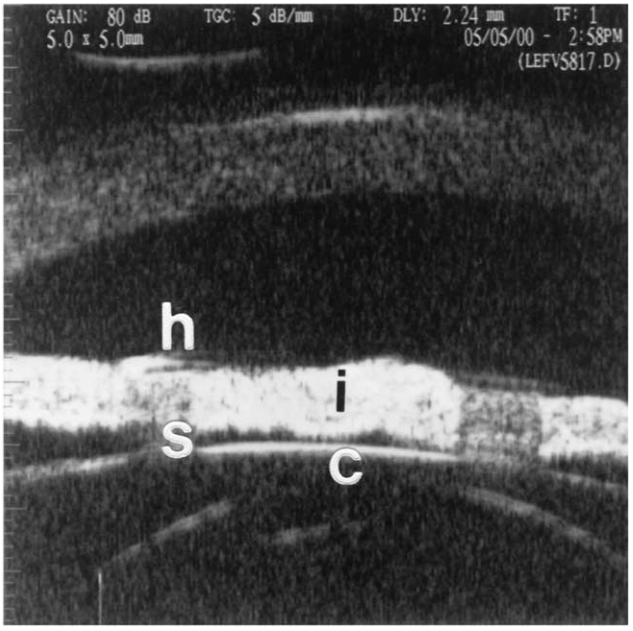

Figure 4. (Pop) Postoperative lateral transverse UBM echogram of the iris-claw phakic IOL in patient 2 showing the 2 arms of the haptics (*h*) near the IOL optic and the shadowing (s) behind it through the iris (*i*) and the lens capsule (*c*). The haptic at the left appears to be in close contact with the iris.

An alternative explanation might be that IOL indentation of the iris was due to pupillary block. However, this explanation would be refuted because the postoperative IOP remained normal.

Although the iris was indented by the optic edge and haptics, the iris pigment layer appeared to be undisturbed except within a small area of the iris entrapment. The UBM echograms also showed the pigment layer was slightly folded on itself within the iris entrapment, and that may present an area from which pigment dispersion could occur. Complications from pigment dispersion, ie, pigmentary dispersion glaucoma, have not occurred in this small group of eyes with limited follow-up. Based on the echogram findings, however, we expect some eyes to develop pigment erosion secondary to phakic IOL indentation, and complications from this IOL–intraocular tissue interaction remain to be studied in a larger group of eyes.

Based on this preliminary study, future pigment erosion seems probable with the phakic Artisan IOL for hyperopia, but no conclusions can be drawn about the potential long-term consequences of the IOL indentation of the iris. As a precaution, we recommend that gonioscopy and iris-vaulting assessment be part of the preoperative evaluation of candidates for the hyperopic iris-claw phakic IOL. In performing these examinations, surgeons should be aware that individuals with a natural highly vaulted iris might be particularly susceptible to IOL indentation of the iris tissue. In the future, refinements in IOL design, ie, shortening the haptics or increasing the IOL vaulting, might eliminate the potential for iris indentation.

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