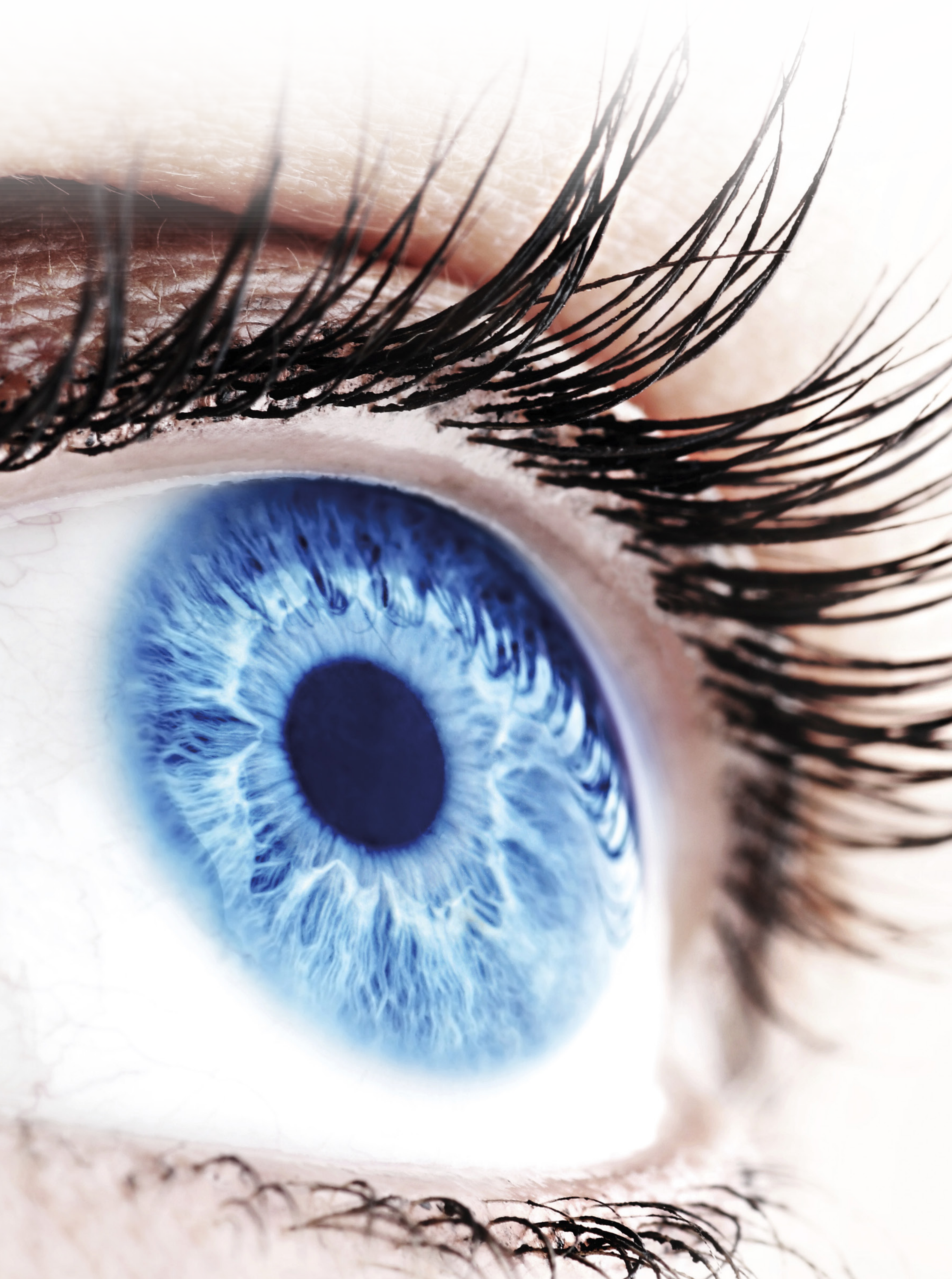

Fluid Dynamics Simulation Of Aqueous Humor In A Hole Implantable Collamer Lens Ks-Aquaporttm

Concept and development history of the Hole Implantable Collamer Lens

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Implantable collamer lenses (ICL) have many advantages in the treatment of refractive errors, especially for cases involving high and moderate ametropia. In addition, the ICL has been known to be effective for the correction of refractive errors when compared to the LASIK procedure. However, cataract development has been a concern after ICL implantation (Figure 1).

It has reported that the incidence of cataract formation was approximately 10 % after the implantation. One of the causes of the cataract was thought to be a change in the circulation of the aqueous humor to the anterior surface of the crystalline lens. Therefore, Prof. Kimiya Shimizu created a centrally perforated ICL in 2006 (i.e., the Hole-ICL KS-AquaPORTTM) to improve aqueous humor circulation in addition to work performed on the development of the Hole-ICL (Figure 2).

Basis examination in Hole ICL Aqueous humor circulation

After observing improved aqueous humor circulation with the use of the Hole-ICL, Fujisawa [1] reported that no cataracts were formed when Hole-ICLs were implanted into porcine eyes. The study concluded that the Hole-ICL allowed sufficient flow of aqueous humor and distribution over the anterior surface of the crystalline lens through its central hole. In addition, Shiratani et al. [2] showed the possibility of preventing cataracts with the Hole-ICL by using minipigs.

We investigated the fluid dynamics of the aqueous humor in a Hole-ICL using the thermal–hydraulic analysis software program FloEFD V5 (Mentor Graphics Corp.) (Figure 3).

The analysis confirmed an improvement in the aqueous humor circulation when using a Hole-ICL [3]. The total flow velocity between the anterior surface of the crystalline lens and the posterior surface of the Hole-ICL was higher than that between the crystalline lens and the conventional ICL (Figure 4).

The difference was of particular note in the center of the lens, as shown in the figure. An outward flow from the hole in the Hole-ICL by trajectory analysis was noted (Figure 5). The validity of the FloEFD software utilizing computational fluid dynamics was confirmed through the agreement between the theoretical and experimental data.

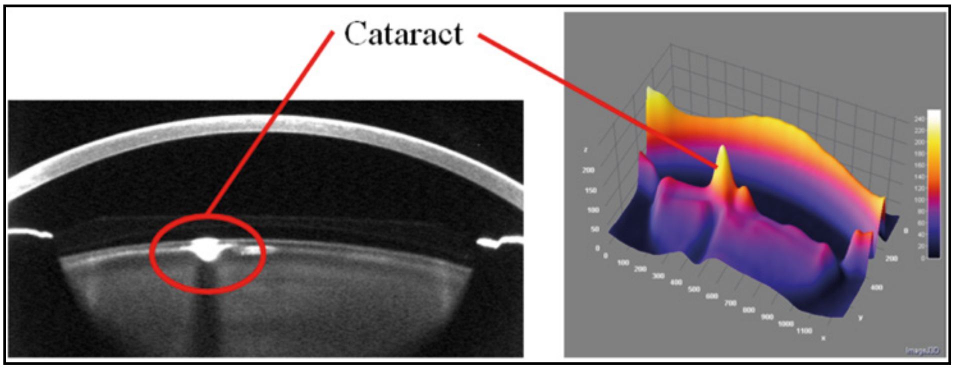

Figure 1. Cataract development of an eye with an ICL taken by Scheimpflug photography (left) and 3D densitometry by Image J 1.47v (NIH, USA) and the plug-in "Interactive 3D Surface Plot v2.33 by Dr. Barthel" (right)

In addition, many surgeons also perform peripheral laser iridotomy (LI) prior to ICL implantation to prevent the failure of aqueous humor circulation (Figure 6). The advantages of the Hole-ICL include improvements in aqueous humor circulation; hence, there is no need for the LI procedure as it may cause complications including the elevation of intraocular pressure.

There are several examples of optical systems with a centrally perforated lens, such as astronomical telescopes or special contact lens. Shiratani et al. [2] showed that the modulation transfer function of an ICL with a central hole of diameter 1.0 mm obtained using optical simulation software was similar to a conventional ICL. Uozato et al. [4] investigated the optical performance of the Hole-ICL with a diameter of 0.36 mm in an optical bench test as well as optical simulations. The authors concluded that a minimal central hole in an ICL may not have a significant impact on the optical performance for various ICL powers and pupil sizes. If the central hole size of the Hole-ICL were to increase, the circulation of aqueous humour in the surrounding crystalline lens would improve. However, the retinal image quality decreases. This indicates the existence of a trade-off between fluid dynamics and optical characteristics. Therefore, we investigated the ideal hole size in a Hole-ICL from the standpoint of the fluid dynamic characteristics of the aqueous humor using the FloEFD software (Figure 7) .

The results of the computer simulation determined the desirable central hole size as 0.2 mm or larger based on fluid dynamics. The current model, based on a central hole size of 0.36 mm, was close to the ideal size. The optimization of the hole size should be performed based on results from a long-term clinical study to allow for analysis of the optical performance and incidence rate of secondary cataracts. A slight decrease in optical properties is considered an effective measure of risk mitigation when compared to low retinal image quality that can occur because of the potential for secondary cataracts to develop. In the future, the optimum hole size should be determined based on these simulation results, the results of optical analysis containing illumination optics, and long-term clinical results regarding visual performance, optical performance and complications.

Clinical results of the Hole ICL

Our results suggest that Hole-ICLs improve the circulation of the aqueous humor to the anterior surface of the crystalline lens. The Hole-ICL is expected to continue to lower the risk of cataracts. Currently, the Hole-ICL

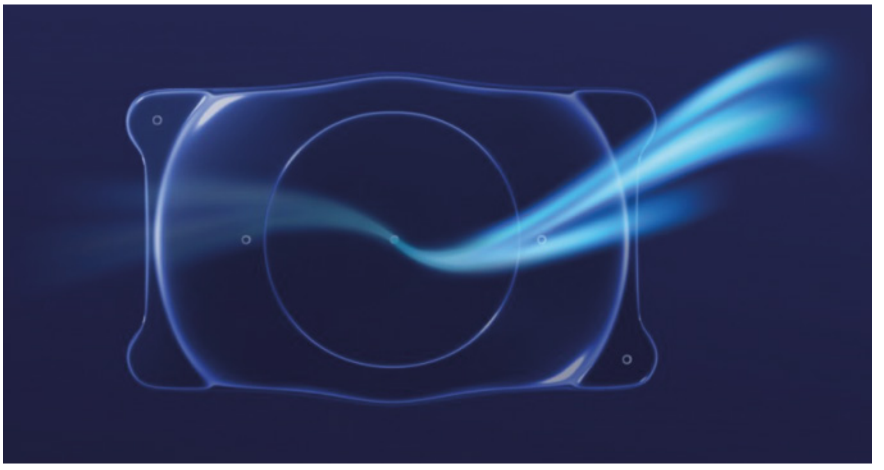

Figure 2. Illustration of the Hole-ICL KS-AquaPORTTM (STARR Surgical CO Ltd.)

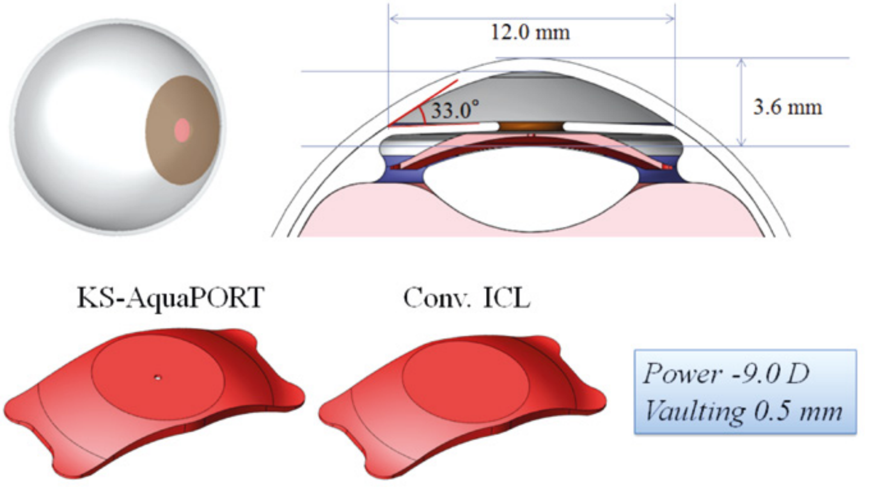

Figure 3. 3D models of eyes with ICLs created with FloEFD software. Appearance of the eye model (top left), Anterior ocular segment (top right), Conventional ICL (bottom left), Hole-ICL (bottom right)

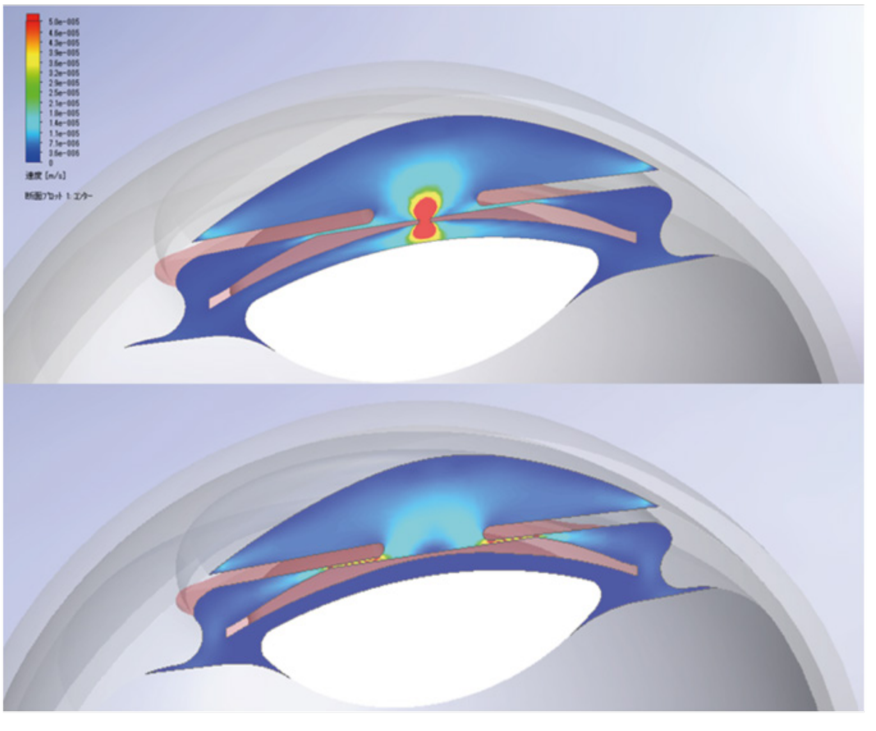

Figure 4. Flow distribution along the long axis of the cross-sectional surface of the Hole-ICL (upper) and the conventional ICL (lower)

has been used approximately 200,000 times with lenses from approximately 70 countries. There are useful clinical reports with similar visual functions as the conventional ICL (Figure 8) [5, 6]. In conclusion, the thermal–hydraulic analysis software program FloEFD contributed to the optimization of the lens design.

Acknowledgment

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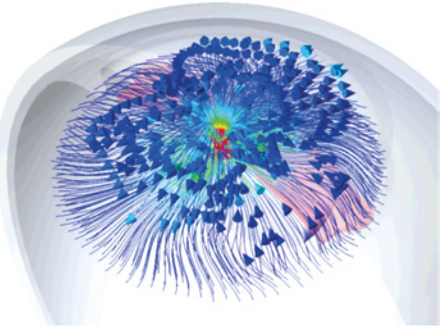

Figure 5. Trajectory analysis within the Hole-ICL

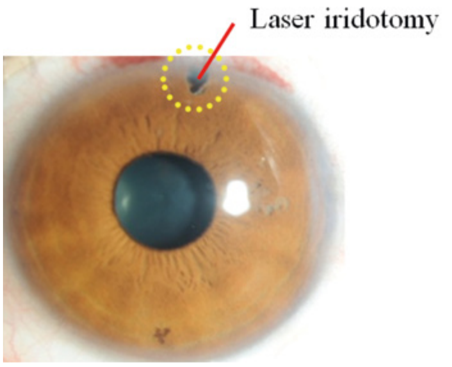

Figure 6. Photograph of laser iridotomy

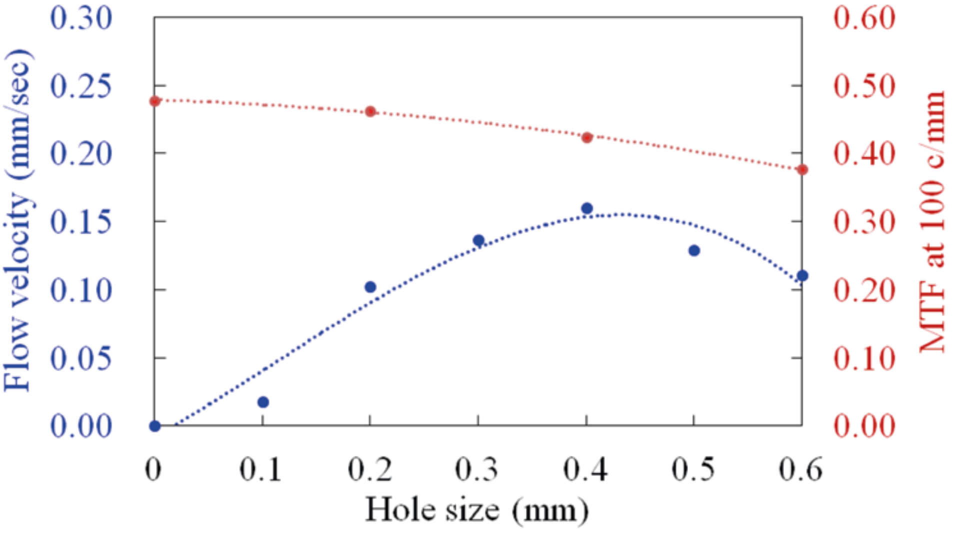

Figure 5. The relation between hole sizes and velocity of the aqueous humor fluid, including the modulation transfer function at a spatial frequency of 100 c/mm

Figure 8. Photograph of an eye implanted with the Hole ICL KS-AquaPORTTM (STARR Surgical CO Ltd.)