

Edge Profiles of Currently Available Intraocular Lenses and Recent Improvements

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Abstract

We evaluated the microstructure of the edges of currently available foldable intraocular lenses (IOLs). The methodology used assisted an IOL manufacturer (Hoya, Japan) to optimise the edge profile of its lenses. Ten designs of hydrophobic acrylic, six designs of silicone and 24 designs of hydrophilic acrylic IOLs were imaged under scanning electron microscopy (SEM), and the photographs were imported to a digital computer program. The area above the posterior-lateral edge, representing the deviation from a perfect square, was measured in square microns. There was a large variation of the area values measured in currently available foldable IOLs labelled as square-edged lenses. As a group, the edges of hydrophilic acrylic lenses were less square than those of hydrophobic acrylic and silicone lenses. Hydrophobic acrylic AF-1 Hoya lenses had a high area value (329.7 μ^2). Through manufacturing changes, the edges of the lenses were then optimised to a value down to 39.1 μ^2 , which represents the most square hydrophobic acrylic edge currently available.

Keywords

Intraocular lens (IOL), hydrophobic acrylic, silicone, hydrophilic acrylic, poly(methyl methacrylate), posterior capsule opacification

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Posterior chamber intraocular lenses (IOLs) with a square posterior optic edge have been associated with better results in terms of posterior capsule opacification (PCO) prevention, regardless of the material used in their manufacture.¹⁻³ Although this IOL design feature can be appropriately assessed in morphological studies using scanning electron microscopy (SEM), such studies of new IOLs have generally focused on the quality of the optic surface or optic finishing.^{4,5} At the Berlin Eye Research Institute, a series of studies were carried out to define and quantify the edge of square-edged IOLs.⁶⁻⁸ The methodology used in these studies can be used to optimise the square edge profile of IOLs.

Study on Experimental Polymethylmethacrylate Intraocular Lenses

Tetz and Wildeck made the first attempt to evaluate and quantify at a microscopic level how sharp the optic edge must be to effectively prevent lens epithelial cells (LECs) from growing onto the posterior capsule.⁶ Plano +0.0D polymethylmethacrylate (PMMA) IOLs with 11 defined edge designs were specially manufactured for use in this preliminary *in vitro* study. To obtain different edge designs, the IOLs were removed from the tumble-polishing machine at different times. To evaluate the optic edges, standardised SEM pictures with an enlargement of x500 were taken of one IOL in each group. A digital computer system (Evaluation of Posterior Capsule Opacification System [EPCO] 2000 program) was used to evaluate the area above the edges on the SEM photographs. To achieve this, the area had to be defined as the deviation from an ideal square. The edge's ability to stop cell growth was evaluated by placing each IOL into cell culture

and observing bovine LEC growth over 18 days on average. Results demonstrated that the lower the area value, the better the cell blockage in culture.

Study on Commercially Available Hydrophobic Acrylic and Silicone Intraocular Lenses

Commercially available lenses manufactured from hydrophobic acrylic and silicone materials were obtained for use in this series of studies through letters sent to IOL manufacturers.⁷ All of them were marketed as having a square optic edge for PCO prevention. Generally, two IOLs of each design were evaluated: +20.0D and +0.0D whenever available for a particular design. If +0.0D was not available, the lowest dioptric power was used for that particular design. We used an improved methodology to evaluate the optic microedge structure of currently available lenses.

Each IOL was carefully removed from its original packaging with a toothless forceps and mounted on a support for SEM analysis. During SEM examination, the analysis of each optic edge was performed from a perpendicular view. Photographs of the optic edge of each IOL were obtained at three magnifications: x25 or x100, x300 and x1,000. The first two magnifications were used to document the overall orientation of the specimen and the x1,000 magnification photographs were used for the microedge analysis. The SEM photographs of each IOL were saved as high-resolution JPEG files. They were then imported into the AutoCAD LT 2000 system (Autodesk). This program, which is commonly used in engineering and architecture, allows accurate area calculations. The first step was to adjust the scale of the photograph

into the program using the reference bar incorporated on the right bottom corner of each SEM photograph. After the scale on each photograph was confirmed by measuring the reference bar and obtaining the corresponding value, a reference circle of known radius, divided into four quadrants by two perpendicular lines passing through its centre, was projected onto the photograph. The position of the circle was adjusted so that the end of each perpendicular line touched the lateral and posterior IOL optic edges. The area of the lateral–posterior IOL edge deviating from a perfect square defined by the two perpendicular lines inside the reference circle was easily delineated using the computer mouse. The measurement of the area was then calculated by the program and provided in square microns. The minimum circle radius size of 40µm was chosen as a function of the size of the human LEC (see Figure 1).

The commercially available IOLs were compared with an experimental square-edged PMMA IOL (reference IOL) manufactured for use in the preliminary *in vitro* study. The edge design of the experimental IOL effectively stopped cell growth in culture. Two silicone IOLs (+20.0D and +0.0D) manufactured with round optic edges were used as controls. For the square-edged PMMA IOL, the value of the area measured with the AutoCAD system with the 40µm-radius circle was 34.0µ². The respective value for the +20.0D control silicone IOL was 729.3µ² and for the +0.0D control silicone IOL, 727.3µ².

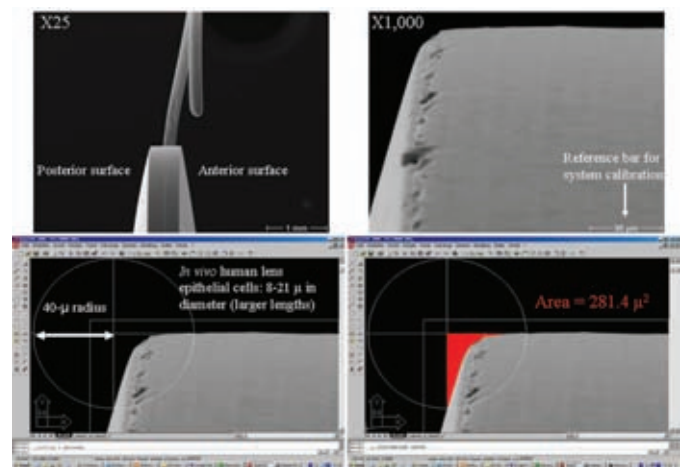
There was a large variation in the deviation area from a perfect square, not only between different IOL designs but also between different powers of the same design. Considering the measurements taken with the 40µm-radius circle, the values for hydrophobic acrylic (n=19) and silicone (n=11) lenses were 183.38±82.18 and 74.39±88.54µ², respectively (all dioptric powers evaluated included). The hydrophobic IOLs used labelled as square-edged IOLs had an area of deviation from a perfect square ranging from 4.8 to 338.4µ². Of the 30 commercially available square-edged hydrophobic IOLs evaluated, only seven silicone lenses of five designs had area values that were smaller than, or close to, those of the reference square-edged PMMA IOL.

Study on Commercially Available Hydrophilic Acrylic Intraocular Lenses

We used the same methodology described above for the hydrophilic acrylic lenses.⁸ However, it is important to highlight that an environmental SEM technique was used for the hydrophilic acrylic lenses in order to evaluate them under low vacuum conditions, preventing dehydration. The microedge structure of modern hydrophilic IOLs, most of which have a water content in the vicinity of 26%, may be significantly modified during the vacuum required in standard SEM procedures.

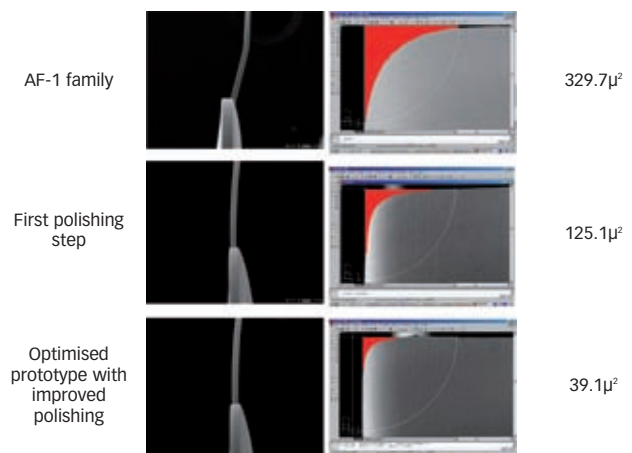
The study lenses had an area of deviation from a perfect square ranging from 60.84 to 871.51µ² for the +20D lenses (n=24: 379.01±188.26), and from 35.52 to 826.55µ² for the low-diopter lenses (n=23: 281.71±241), as measured with the 40µm-radius circle (p=0.12; not significant). The area of deviation from a perfect square ranged from 35.52 to 826.55µ² for the single-piece lenses (n=33: 280.44±189.85), and from 130.2 to 871.51µ² for the three-piece lenses (n=14: 451.51±242.29), as measured with the 40µm-radius circle (p=0.01; significant). Considering all lenses included in the study (n=47), the area of deviation from a perfect square ranged from 35.52 to 871.51µ² (331.39±218.90). We found that the area

Figure 1: Measurement of the Area Deviating from a Perfect Square in Scanning Electron Photomicrographs with the AutoCAD Program*



*Used in commercially available intraocular lenses.

Figure 2: Three Versions of an Intraocular Lens (Hoya AF-1 Family) Showing Progressive Decrease in the Value of the Area Representing the Deviation from a Perfect Square



The edge of the optimised prototype with improved polishing is the most square of the currently available hydrophobic acrylic lenses.

measurement values of hydrophilic acrylic lenses as a group were higher than the values reported for hydrophobic acrylic or silicone lenses in part two. The differences among the three groups of materials were found to be statistically significant.

Optimising the Edge Profile of the Hoya Intraocular Lenses

In a recently published prospective, single-surgeon, fellow-eye comparison study, the authors found a significantly higher rate of PCO with the Hoya AF-1 YA-60BB IOL compared with the Alcon AcrySof SN60AT.⁹ The results were based on 36 patients who were followed for 24 months. This is not surprising considering the differences in edge design between these lenses found in our study. The area deviating from a perfect square measured 329.7µ² for the Hoya lens and 97.2µ² for the Alcon lens (+20D).⁷ Through manufacturing changes, including variations in the polishing process, Hoya optimised the edge profile of several AF-1 models very quickly. All AF-1 lenses are of the same design and manufactured with high-end lathe-cut and polished surfaces.

Different prototypes were sent to the BERI for evaluation following the same protocol described above (see *Figure 2*). The area deviating from a perfect square of the current Hoya AF-1 family measured $39.1\mu^2$. This is the lowest value measured among currently available hydrophobic acrylic lenses and therefore the most square of all. The edge surface characteristics of the lenses remained unchanged, i.e. the surfaces are smooth and regular. The IOLs with the optimised edge profile are currently under clinical investigation. The modified square edge is commercially available in selected countries for the new AF-1 models iSymm aspheric and iMics Microincision lenses.

Other Edge Profile Studies

Nanavaty et al. performed an SEM study comparing the edge profile of commercially available square-edged IOLs.¹⁰ Their study included a total of 17 square-edged designs of +20.0D, with five hydrophobic acrylic, seven hydrophilic acrylic and five silicone lenses. Perpendicular images with a magnification of x500 were obtained and analysed using purpose-designed software to produce a line tracing of the edge profile of the lenses. The sharpness of the edge profile was then quantified by measuring the local radius of curvature at the point on the posterior edge with the smallest radius. Their conclusions are similar to ours in that as a group, hydrophilic acrylic lenses appeared to have relatively rounder edges compared with hydrophobic acrylic and silicone lenses. This is probably due to the manufacturing process of hydrophilic acrylic lenses, which involves being lathe-cut from dehydrated blocks that are then re-hydrated. Water absorption by the IOL material may render the final aspect of the edge rounder as the IOL swells.

Clinical Significance

The factor that may play the most important clinical role in evening out the differences in the microedge profiles observed in our study is shrink-wrapping of the IOL by the capsular bag, which enhances contact between the posterior IOL surface and the posterior capsule. However, this factor may not even out large differences in edge profile. The results of all of the above-mentioned studies are

interesting in light of some clinical studies comparing square-edged IOLs manufactured from different materials and reporting higher rates of PCO with hydrophilic acrylic lenses.^{11–15} In many instances the authors concluded that this was related to a 'material' effect; however, the edges of the lenses included were perhaps just not comparable. Our study confirms that all square edges in the market are not the same, and perhaps large variations in edge profile may account for differences in clinical outcomes of post-operative PCO.

Conclusions

In summary, analysis of the microstructure of the optic edge of currently available square-edge IOLs revealed a large variation of the deviation area from a perfect square, as well as mean values that were higher for hydrophilic acrylic lenses in comparison with values reported for hydrophobic acrylic and silicone lenses. Only existing and future clinical data will help us better understand the effect of microedge structure and design on reducing PCO, but perhaps a cut-off value to clinically label an IOL as square-edged should be sought. The methodology used in such studies can help optimise the edge profile of IOLs. ■



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- Schuaersberger J, Amon M, Kruger A, et al. Comparison of the biocompatibility of two foldable intraocular lenses with sharp optic edges, *J Cataract Refract Surg*, 2001;27:1579–85.
- Buehl W, Findl O, Menapace R, et al., Effect of an acrylic intraocular lens with a sharp posterior optic edge on posterior capsule opacification, *J Cataract Refract Surg*, 2002;28:1105–11.
- Prosdocimo G, Tassinari G, Sala M, et al., Posterior capsule opacification after phacoemulsification: silicone CeeOn Edge versus acrylate AcrySof intraocular lens, *J Cataract Refract Surg*, 2003;29:1551–5.
- Kohnen T, Maqdowski G, Koch DD, Scanning electron microscopic analysis of foldable acrylic and hydrogel intraocular lenses, *J Cataract Refract Surg*, 1996;22:1342–50.
- Mencucci R, Ponchiotti C, Nocentini L, et al., Scanning electron microscopic analysis of acrylic intraocular lenses for microincision cataract surgery, *J Cataract Refract Surg*, 2006;32:318–23.
- Tetz M, Wildeck A, Evaluating and defining the sharpness of intraocular lenses: Part 1: Influence of optic design on the growth of the lens epithelial cells *in vitro*, *J Cataract Refract Surg*, 2005;31:2172–9.
- Werner L, Müller M, Tetz M, Evaluating and defining the sharpness of intraocular lenses. Microedge structure of commercially available square-edged hydrophobic lenses, *J Cataract Refract Surg*, 2008;34:310–17.
- Werner L, Tetz M, Feldmann I, Bucker M, Evaluating and defining the sharpness of intraocular lenses. Microedge structure of commercially available square-edged hydrophilic lenses, *J Cataract Refract Surg*, 2009;35:556–66.
- Hancox J, Spalton DJ, Cleary G, et al., Fellow-eye comparison of posterior capsule opacification with AcrySof SN60AT and AF-1 YA-60BB blue-blocking intraocular lenses, *J Cataract Refract Surg*, 2008;34:1489–94.
- Nanavaty MA, Spalton DJ, Boyce J, et al., Edge profile of commercially available square-edged intraocular lenses, *J Cataract Refract Surg*, 2008;34:677–86.
- Kugelberg M, Wejde G, Jayaram H, Zetterström C, Posterior capsule opacification after implantation of a hydrophilic or a hydrophobic acrylic intraocular lens: one-year follow-up, *J Cataract Refract Surg*, 2006;32:1627–31.
- Kugelberg M, Wejde G, Jayaram H, Zetterström C, Two-year follow-up of posterior capsule opacification after implantation of a hydrophilic or hydrophobic acrylic intraocular lens, *Acta Ophthalmol*, 2008;86(5):533–6.
- Richter-Mueksch S, et al., Uveal and capsular biocompatibility after implantation of sharp-edged hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in eyes with pseudoexfoliation syndrome, *J Cataract Refract Surg*, 2007;33:1414–18.
- Cheng JW, et al., Efficacy of different intraocular lens materials and optic edge designs in preventing posterior capsular opacification: a meta-analysis, *Am J Ophthalmol*, 2007;143:428–36.
- Heatley CJ, Spalton DJ, Kumar A, et al., Comparison of posterior capsule opacification rates between hydrophilic and hydrophobic single-piece acrylic intraocular lenses, *J Cataract Refract Surg*, 2005;31:718–24.