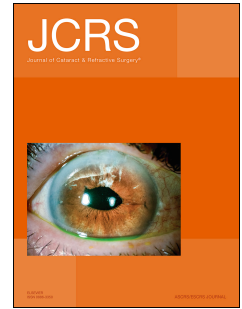


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Edge profile of commercially available square edged intraocular lenses: Part 2

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PURPOSE: To analyze the sharpness of the posterior optic edge and edge thickness of intraocular lenses (IOLs) marketed with a square-edged profile.

SETTING: University of Brighton & Brighton & Sussex University Hospitals NHS trust, Brighton, UK.

DESIGN: Laboratory study

METHODS: Fourteen square-edged 20.0 diopter IOLs analyzed included 9 hydrophobic IOLs [AF-1 (AF-1), AF-1 iSert (AF-1-iS), Clareon (Cl), One-Crystal (Cr), CT-Lucia (CT), Envista (En), One (One), Vivinex iSert (Vi-iS) and RayOne Hydrophobic (R-Phobic)] and 5 hydrophilic [Asphira (As), CT-Asphira (CT-A), Incise (In), Synthesis (Sy) and RayOne hydrophilic (R-philic)]. All the lenses were scanned following a previously published standardized technique using environmental scanning electron microscopy. Posterior optic edges were scanned at a magnification of x500 and x200 to measure radius-of-curvature of the posterior optic edges and optic edge thickness.

RESULTS: The radius-of-curvature of the posterior optic edges ranged from 4.6 to 20.6 μm . Except for In (7.7 μm) all hydrophilic IOLs [Sy (10.6 μm), As (13.7 μm), R-philic (14.0 μm), CT-A (13.7 μm)] had radius-of-curvature >10.0 μm . For hydrophobic IOLs, Cl (7.9 μm), Cr (4.7 μm), Vi-iS (7.6 μm) and CT (4.6 μm) were <10.0 μm [except the En (19.7 μm), One (13.7 μm) AF-1 iS (19.7 μm), AF-1 (19.7 μm) and R-phobic (20.6 μm)]. The Vi-iS (150.5 μm) and In (218.2 μm) were the thinnest IOLs and R-phobic (375.8 μm) and R-philic IOLs (477.1 μm) were thickest in hydrophobic and hydrophilic IOLs respectively.

CONCLUSIONS: Commercially marketed square-edged IOLs still differed in the sharpness of the posterior optic edge. More hydrophobic IOLs have rounder edges than those studied 10 years ago. Variations in edge profile of

hydrophobic IOLs were by far greater compared to the hydrophilic IOLs .

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Introduction

Posterior capsule opacification (PCO) still remains the main complication of cataract surgery. Its development is multifactorial, involving patient factors, surgical technique,¹⁻³ intraocular lens (IOL) design, and IOL biomaterial.⁴⁻⁸ Clinical studies show that IOLs with a square-edged optic profile are associated with less PCO than those with a round-edged profile.⁹⁻¹⁴ Nishi and Nishi¹¹ suggest this is because a square-edged IOL optic produces a sharp bend in the posterior capsule. When migrating lens epithelial cells (LECs) meet this sharp, discontinuous bend, they are subject to contact inhibition and stop proliferating and migrating (the contact inhibition theory).^{6, 7} Bhermi et al.¹⁵ suggest an alternative hypothesis whereby the square edge produces an increased pressure profile at the point on the posterior capsule where the posterior edge is compressed against the posterior capsule; this creates a physical pressure barrier to LEC migration (the capsule compression theory). Tetz and Wildeck,¹⁴ using different edge designs with a poly(methyl methacrylate) (PMMA) block in cell culture, showed that sharper optic edges more effectively prevented the migration of LECs. Most manufacturers produce square-edged IOLs; however, it has become apparent that there are variations in square-edge profiles of different IOLs.¹⁶

Scanning electron microscopy (SEM) has a long track record in IOL evaluation.¹⁷⁻²⁴ With advancing technology, environmental SEM can now scan water-containing materials with high precision without causing any deformation of the specimen. In our previous publication¹⁶ nearly a decade ago, we looked at 17 different 'square-edged' IOLs using a standardized environmental SEM. We found that commercially marketed square-edged

IOLs differed in the sharpness of the posterior optic edge, which may have some bearing on the variation in the PCO performance of different IOLs.

Hydrophobic acrylic and silicone IOLs had sharper posterior optic square edge than most hydrophilic acrylic IOLs.¹⁶

We designed this study, employing the same methodology as our previous study,¹⁶ to look at the posterior optic 'square-edge' sharpness of the newer IOLs marketed as square-edge IOLs since our last publication a decade ago.

Methods

Fourteen IOLs of different design and material were selected from prominent European manufacturers. A 20.0 diopter (D) IOL from each manufacturer was used in the study. The IOLs were mounted and scanned using a Zeiss EVO LS15 environmental scanning electron microscope (ESEM) (Carl Zeiss, Germany) equipped with a variable pressure chamber and Zeiss variable pressure secondary electron (VPSE) detector. Each IOL was processed individually as described in our previous publication.¹⁶

This study included 14 different IOLs, 9 of which were hydrophobic acrylic [Alcon Clareon (Cl), Bausch & Lomb Envista (En), Bausch & Lomb Eye Cee One (One), Bausch & Lomb Eye Cee One Crystal (Cr), Hoya PS AF-1 (AF-1), Hoya PS AF-1 iSert 251 (AF-1-iS), Hoya Vivenex iSert XC1 (Vi-iS), Rayner RayOne Hydrophobic (R-phobic) & Zeiss CT Lucia (CT)] and 5 hydrophilic acrylic IOLs [Bausch & Lomb Incise (In), Cutting Edge Synthesis (Sy), Human Optics Asphira (As), Rayner RayOne hydrophilic (R-philic), Zeiss CT Asphira (CT-A)]. The IOLs were carefully mounted by an experienced

electron microscopist (JS) using a simple microscope on a customized platform with a clamp. Leit-C Plast conductive adhesive paste (Agar scientific - <http://www.agarscientific.com/leit-c-plast.html>) was used in the clamp (Figure 1). The IOL was then slotted in the groove and the adhesive paste so that one end of the IOL optic stood vertically embedded in the adhesive paste within the clamp and the other end protruded beyond the platform edge (Figure 1). Utmost care was taken to identify the anterior and posterior optic edges before the IOLs were mounted so that the posterior optic edge appeared left on the scan (Figure 2). Some IOLs, such as the In, Sy and CT-A required cutting of the haptic for stable mounting to obtain the best scans of the IOL optic edge. To obtain the necessary views, the rim was removed using an ultrasharp 3.0 mm disposable skin biopsy punch (Figure 3).

As per our previous study,¹⁶ a chamber pressure of 93.3 Pa (0.7 torr), an ambient SEM chamber temperature, an accelerating voltage of 15 kV, and magnifications of x500 and x200 were standardized for all IOL scans. Repeated scanning was done until the clearest images were obtained. The mean processing time for each IOL was 25 minutes from when the IOL pack was opened to when the IOL was placed back in the pack.

The IOL was aligned to minimize tilt using a geometric scale (to ensure exact perpendicularity) on the computer monitor screen of the environmental SEM. This microscope allows the user to adjust the tilt and alignment of the object on the platform inside the chamber. The posterior optic edge was then sharply focused, and the resultant image, which included a 200 mm scale marker at x500 magnification, was digitized at a resolution of 2048 dpi x 1760 dpi and saved as an uncompressed image in tiff format. The posterior optic

edge radius of curvature and thickness of the IOL at the optic edge were measured using the principles and techniques described in our previous publication.¹⁶ In brief, the optic edge profile is a line of varying curvature that can mathematically be conceived to be represented by multiple sections of the edge, each with a varying local radius of curvature; thus, the sharpness of the edge profile can be quantified by measuring the local radius of curvature at the point on the posterior edge with the smallest radius of curvature. To measure the local radius of curvature of the optic edge, one assumes that each point on an edge profile is a point of an incomplete circle and 3 adjacent points on the profile define the circle and hence estimate the local radius of curvature. An angle of 45 degrees between the radii is sufficient to produce a robust estimate of the curvature and to define a circle. The edge sharpness was defined as the smallest radius of curvature found at the posterior optic edge.¹⁶ This was standardized for all IOLs. This whole process was repeated at least 3 times, and the mean of the radius of curvature was obtained. For the edge thickness measurement, the midpoint of the curvature of the posterior and anterior edges was plotted on X200 magnification image, and the distance between them was calculated in microns with Photoshop CS (Adobe, USA). At least 3 measurements were done, and the mean of these was calculated.

Data were entered into an Excel spreadsheet (Microsoft). All further evaluation was performed using standard software (Excel, Microsoft Office 2011). Mean, standard deviation and range of the radii of curvature of hydrophobic and hydrophilic IOLs were calculated. Although the sample size was small the normality of the data was confirmed. A P value less than 0.05 was considered significant.

Results

Images of the edge profile of the hydrophobic IOLs are shown Figure 4-12 and hydrophilic IOLs are shown in Figure 13-17. The radii of curvature and the thickness of the optic edge of the 14 IOLs are shown in Table 1. The mean radius of curvature in the hydrophobic acrylic and hydrophilic acrylic groups was $12.6 \pm 7.1\mu$ (range 4.6 to 20.6μ) and $12.0 \pm 4.9\mu$ (range 7.7 to 14.0μ) respectively ($P=0.82$).

All hydrophobic acrylic had a radius of curvature less than 10.0μ , except the En, AF-1 and AF-1-iS and R-phobic (Table 1). All hydrophilic acrylic IOLs had a radius of curvature greater than 10.0μ except the In IOLs (Table 1).

The mean thickness at the optic edge in hydrophobic acrylic and hydrophilic acrylic groups was 250.4 ± 86.8 mm (range 150.5 to 375.8 mm) and 305.6 ± 99.3 mm (range 218.2 to 477.1 mm) respectively ($P=0.33$) (Table 1). The Vi-iS and In were the thinnest IOLs and Ray-phobic and Ray-philic IOLs were thickest in hydrophobic and hydrophilic IOLs respectively. (Table 1)

Discussion

This study found that there are variations in 'square-edge' of the commercially marketed square-edge IOLs with majority of hydrophilic acrylic IOLs with rounder edges. However, some of the hydrophobic acrylic IOLs in our study were also shown to have rounder edge. Since our previous study,¹⁶ approximately 10 years ago, newer IOLs have come into the market but the situation with sharpness of the 'square-edged' hasn't changed.

The sharp optic edge was first postulated by Hoffer²⁵ in the early 1980s as a major inhibitory factor of LEC migration. It has dominated the literature in recent years.^{26, 27} Its key PCO-preventing effect seems largely independent of the IOL material,²⁸ although other studies found a trend toward less PCO with silicone IOLs.²⁹⁻³² and one study even showing better PCO performance with round edge silicone IOLs compared to acrylic IOLs.³³ However, since past 2 decades, there is a trend toward the use of hydrophobic and hydrophilic IOLs only. There is evidence that eyes with hydrophilic acrylic IOLs are more likely to develop visually significant PCO over time.^{5, 7} Whereas some studies suggested that the IOLs with a square posterior optic edge have been associated with better PCO prevention than round-edged IOLs, regardless of the material used in their manufacture.^{27, 34-37} This might be a consequence of the manufacturing process. Hydrophilic acrylic IOLs are lathe cut from dehydrated blocks, which are then rehydrated. This blunts the square edge as the IOL swells and may account for the rounder edge profile.¹⁶

In our previous study¹⁶ we found that IOLs with a radius of curvature of $<10.0 \mu$ appear to have good PCO performance. The AF-1 IOL, with a radius of 19.9μ , has comparatively poor PCO performance.³⁸ This indicates that the minimum edge profile (radius of curvature) of the posterior optic edge should be in the region of 10.0μ , and the IOLs with a greater radius of curvature will have a comparatively poorer PCO performance.¹⁶

We searched the literature for prospective, randomized, comparative studies on PCO between the IOL models analyzed in this study and could only find a prospective, randomized study by Leydolt et al.³⁹ who concluded

that the median PCO scores were comparable between AcrySof IQ and Bausch & Lomb EyeCee One IOLs at 3 years. There are many single armed, non-prospective randomized, non-comparative studies on the IOLs looking at the PCO performances but due to the non-comparative and non-randomized nature of these studies it is not possible to give a comparative evaluation of PCO profiles of the latest IOLs analyzed in this study. Therefore, we encourage all IOL companies to published prospective, randomized, comparative studies looking at PCO.

It was interesting to note that in our study we found some differences in the edge profile calculation and appearance of Bausch & Lomb Eye Cee One and Bausch & Lomb Eye Cee One Crystal lenses (Figure 6, 7 and table 1). Although the difference should only be the yellow tint in the IOL, we found that the quality of finish on the optic edges varied. This is in concurrence with a study by Werner et al.⁴⁰ who also found several differences in edge finishing between the IOLs analyzed, not only between different designs but also between different powers of the same design. In their paper, Werner et al.⁴⁰ obtained pictures of the optic edge at x100, x250 and x1000 magnification. They used the first 2 magnifications to document the overall orientation of the specimen, and the x1000 magnification photographs for the microedge analysis. In our study we used x500 magnification for measurement of the edge sharpness and x200 magnification for edge thickness. Werner et al. used two circles of fixed radii of 40 microns and 60 microns for the edge profile assessment. These reference circles of known radii divided in 4 quadrants by 2 perpendicular lines passing through its center and this was projected onto the photograph. They adjusted the position of the circle so that

the end of both perpendicular lines would touch the lateral and posterior IOL optic edges. The area between the perpendicular radii and the lateral and posterior edge of the IOL was measured in square microns.⁴⁰ Therefore, there was a difference in the methods used by Werner et al.⁴⁰ and by us in this study.

Another interesting issue is the difference between a 'square edge' (Figure 18) and a sharp but not a square edge (Figure 18). In our study CT-A had a sharp edge but not a perfect square edge. Tetz and Wildeck¹⁴ used purpose-made PMMA blocks that were tumble polished for varying lengths of time to give an increasing round edge profile. They found (using a different measurement of edge profile) that the sharpest edges prevented LEC migration. However, there are no studies comparing IOLs with 'sharp but not square edge' (such as CT-A) versus a 'sharp and square edge' IOL (such as In).

It is apparent that the same manufacturer may manufacture IOLs for different companies in the same factory (personal communication with various companies). We found differences in the IOLs square-edge produced by the same manufacturer for different companies. This was interesting. In the past years, IOL manufacturers have marketed aspheric, multifocal, toric, and blue light-filtering IOLs to enhance visual function, fulfill individual needs, and improve the patient's quality of life. Development of IOLs requires consideration of many design and material parameters before the product can be translated to the assembly line and this could be the reason for the difference in edge design quality of various IOLs manufactured by the same manufacturer for different companies.

In summary, even after a decade since we last studied the square edges of the IOLs in the market, the analysis of the newer 'square-edge' IOLs is not dissimilar. The hydrophilic acrylic IOLs still have rounder edges compared to the hydrophobic material and there is huge variation in designs of the IOLs and the thickness of the IOLs. But more hydrophobic acrylic IOLs have rounder edges than in our previous study.

What was known before?

- Commercially marketed square-edged IOLs differed in the sharpness of the posterior optic edge.
- Hydrophobic acrylic and silicone IOLs have sharper posterior optic square edge than most hydrophilic acrylic IOLs.
- Differences in posterior optic edge profile may explain variation in posterior capsule opacification performance with different IOLs and materials.

What this paper adds:

- Commercially marketed square-edged IOLs still differ in the sharpness and thickness of the posterior optic edges
- More hydrophobic acrylic IOLs had rounder edges compared to the same study 10 years ago.
- The quality of edge profile of hydrophobic acrylic IOL had huge variations compared to hydrophilic acrylic IOLs.

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Figures:

Figure 1: Mounting of intraocular lenses

Figure 2: Schematic diagram to show the mounting of IOL with reference to posterior optic edge.

Figure 3: Punching of the intraocular lenses with 3mm skin biopsy punch to get the profile view of the posterior optic edges

Figure 4: Alcon Clareon (Cl),

Figure 5: Bausch & Lomb Envista (En),

Figure 6: Bausch & Lomb EyeCee One (One),

Figure 7: Bausch & Lomb EyeCee One-Crystal (Cr),

Figure 8: Hoya AF-1 (AF-1),

Figure 9: Hoya AF-1 iSert 251 (AF-1-iS),

Figure 10: Hoya Vivinex iSert XC1 (Vi-iS)

Figure 11: Rayner RayOne Hydrophobic (R-Phobic)

Figure 12: Zeiss CT-Lucia (CT)

Figure 13: Bausch & Lomb Incise (In),

Figure 14: Cutting Edge Synthesis (Sy),

Figure 15: Human Optics Asphira (As),

Figure 16: Rayner RayOne hydrophilic (R-philic)

Figure 17: Zeiss CT-Asphira (CT-A).

Figure 18: Variations in 'square' edges.

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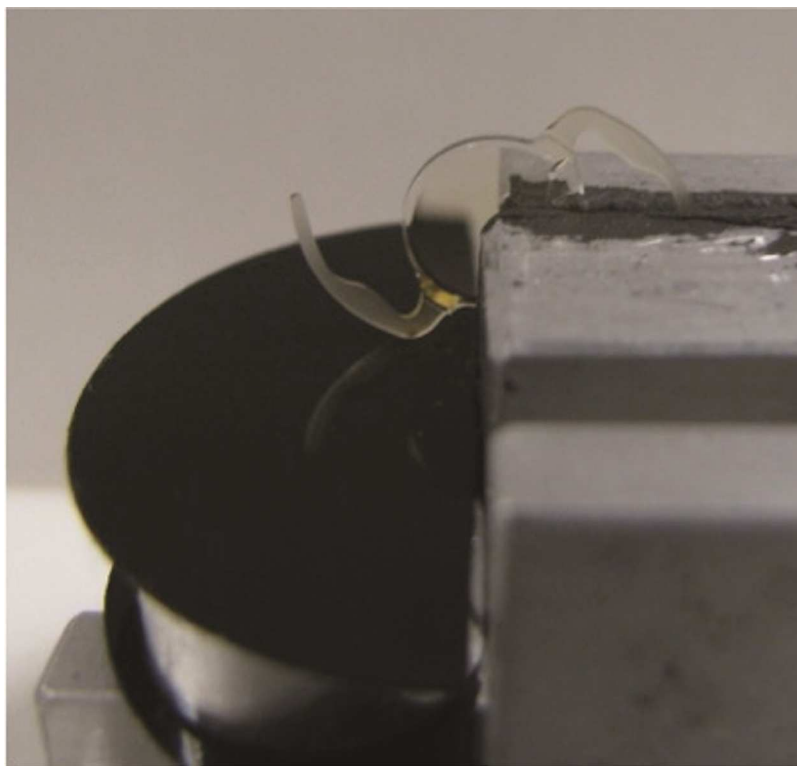
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Table 1. Radii of curvature of posterior optic edge and edge thickness

	2008 Study ¹⁶			Current study		
	Name of the IOL	Radii of curvature (μm)	Edge thickness (μm)	Name of the IOL	Radii of curvature (μm)	Edge thickness (μm)
	Alcon AcrySof [®] SN60WF	8.5	197.7	Alcon Clareon (Cl)	7.9	167.2
Hydrophobic Acrylic IOLs	Alcon AcrySof [®] SN60AT	8.4	198.7	Bausch & Lomb Envista (En)	19.7	250
	Alcon AcrySof [®] MA60AC	9.9	306.8	Bausch & Lomb EyeCee One (One)	8.6	313.3
	AMO Sensar [®] AR40e	8.3	361.1	Bausch & Lomb One Crystal (Cr)	4.7	306.2
	Hoya [®] AF-1(UY)	19.9	259.9	Hoya AF-1 iSert (AF-1-iS)	19.7	174.3
				Hoya PS AF-1 (AF-1)	19.7	172.5
				Hoya Vivenex-iSert (Vi-iS)	7.6	150.5
				Rayner RayOne Hydrophobic (R-phobic)	20.6	375.8
				Zeiss CT-Lucia (CT)	4.6	344.1
Hydrophilic Acrylic IOLs	Rayner [®] C-flex (thickest ridge)	19.6	*	Bausch & Lomb Incise (In)	7.7	218.2
	Rayner [®] Superflex (thinnest ridge)	15.6	379.3	Cutting Edge Synthesis (Sy)	10.6	279.8
	Rayner [®] Superflex (thickest ridge)	10.6	*	Human Optics Asphira (As)	13.7	280.8
	Bausch & Lomb Akreos [®]	15.9	375.1	Rayner RayOne (R-phobic)	14.0	477.1
	Bausch & Lomb Akreos [®] AO MI60	14.3	181.3	Zeiss CT-Asphira 404 (CT-A)	13.7	272.1
	HumanOptics [®] 1CU	8.6	73.8			
	HumanOptics [®] MC 611 MI-B	9.1	189.3			
	Tetraflex [®]	23.1	209.8			

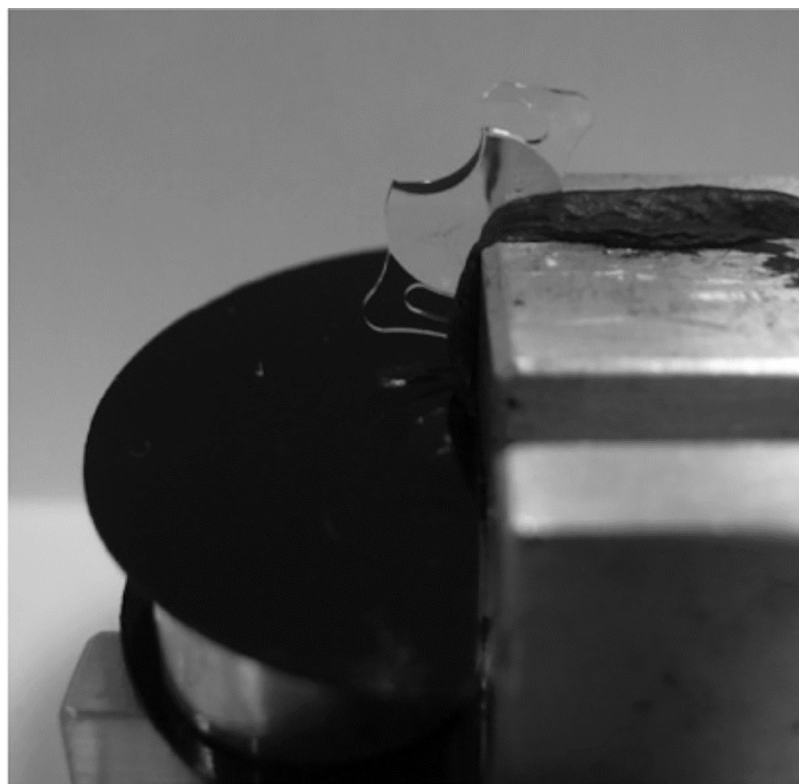


ACCEPTED MANUSCRIPT

Posterior Optic Edge



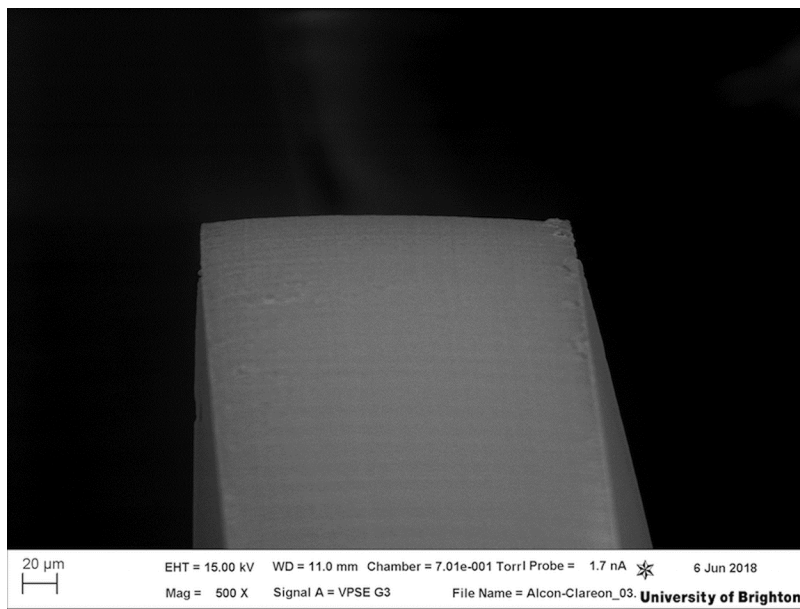
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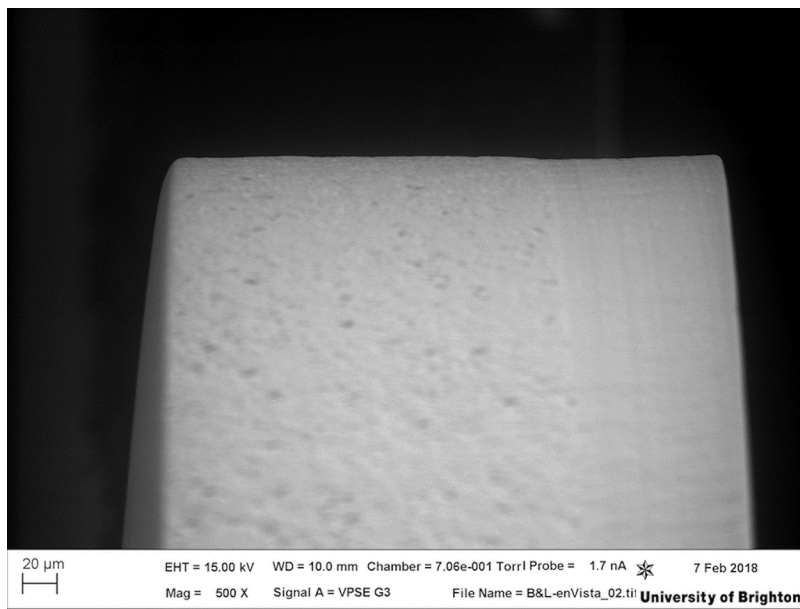


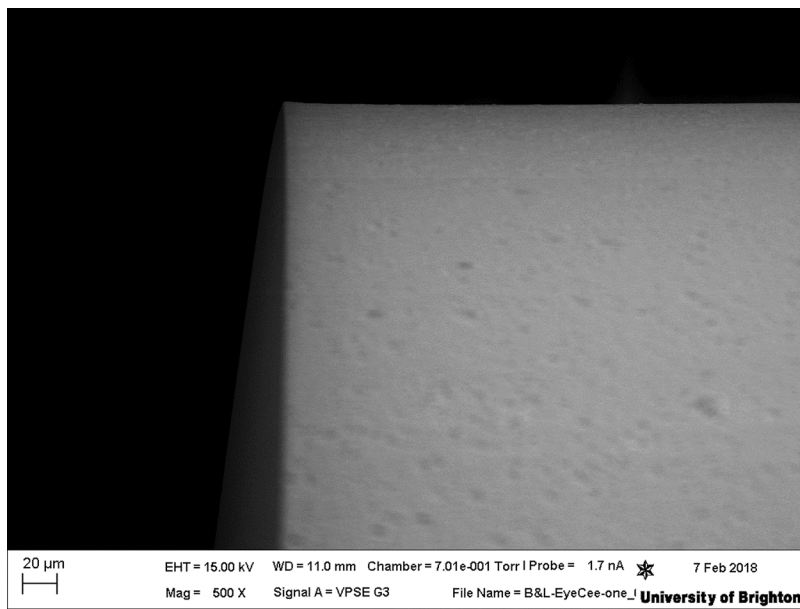
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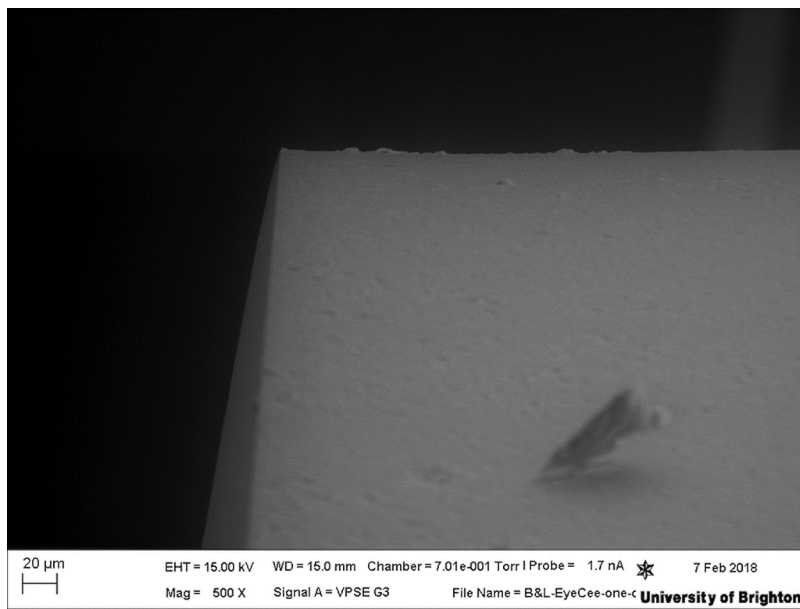


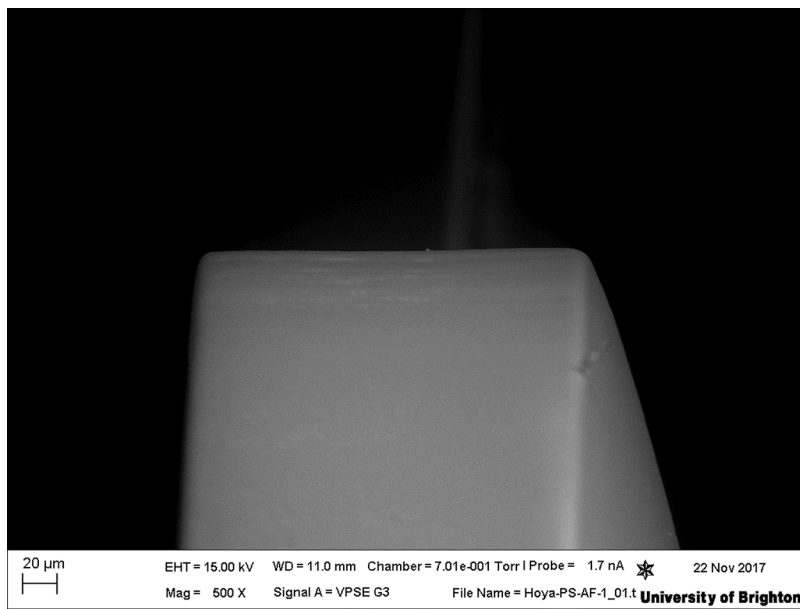
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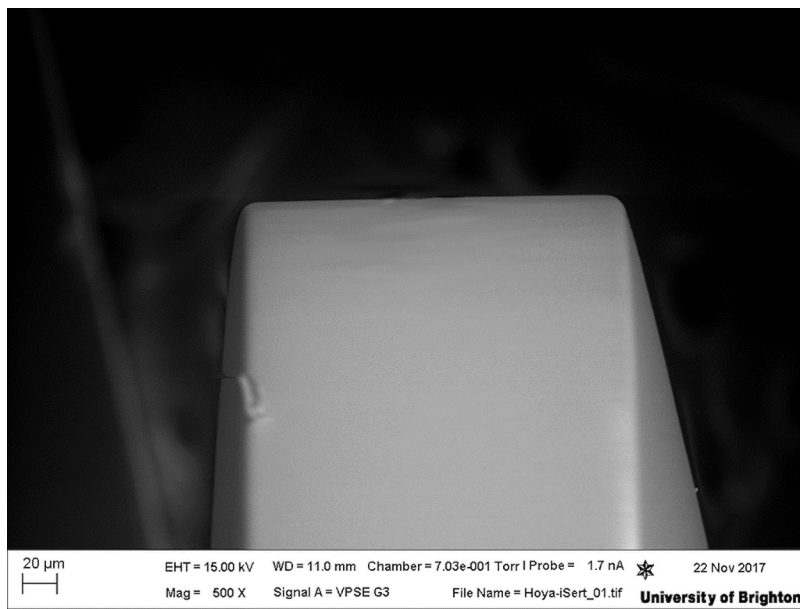


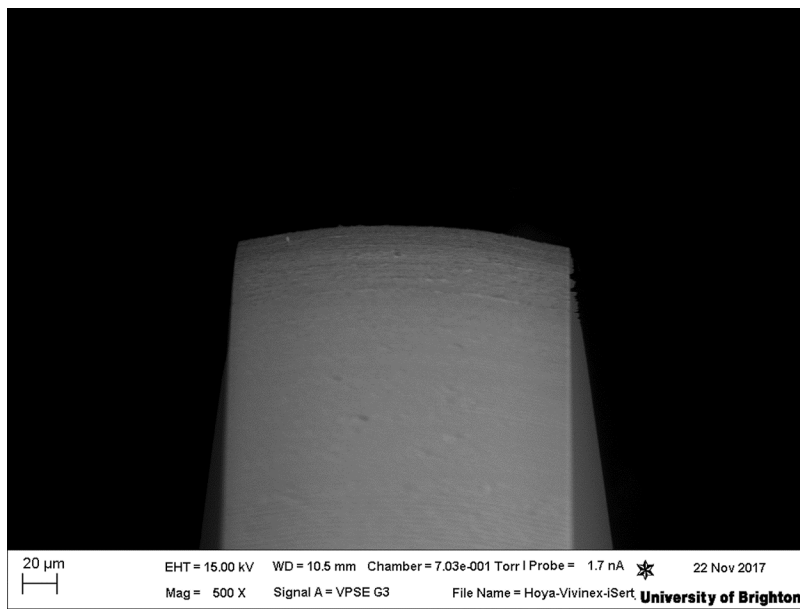


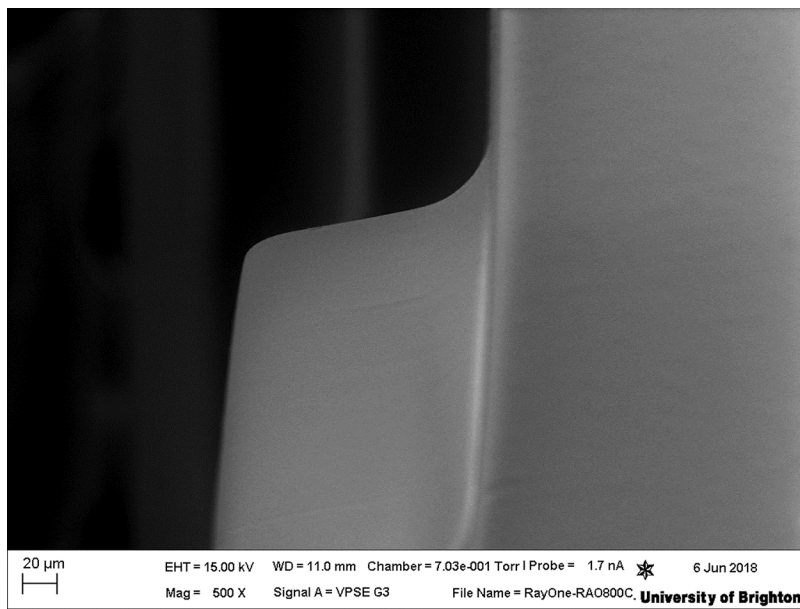


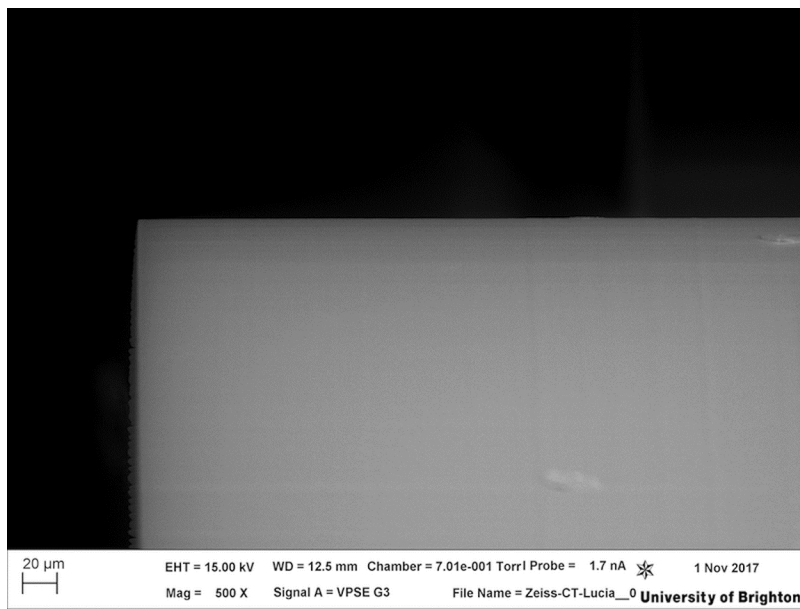


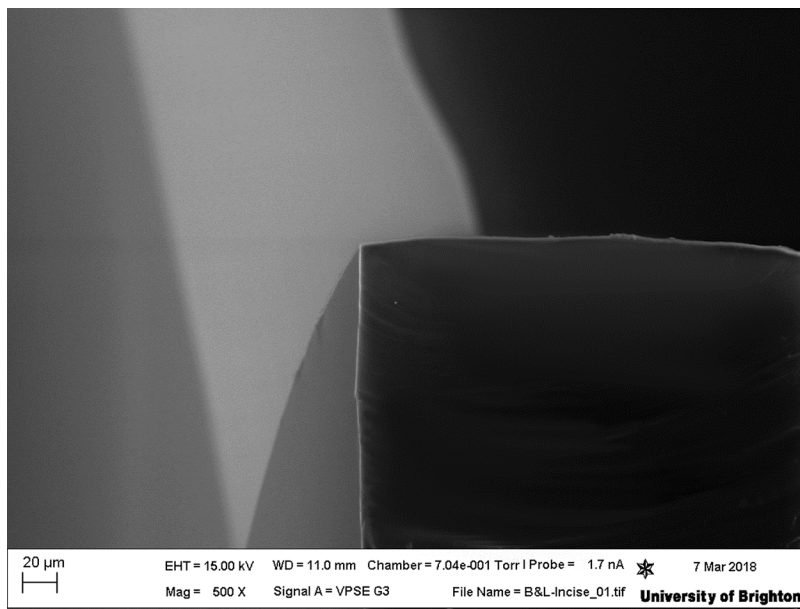


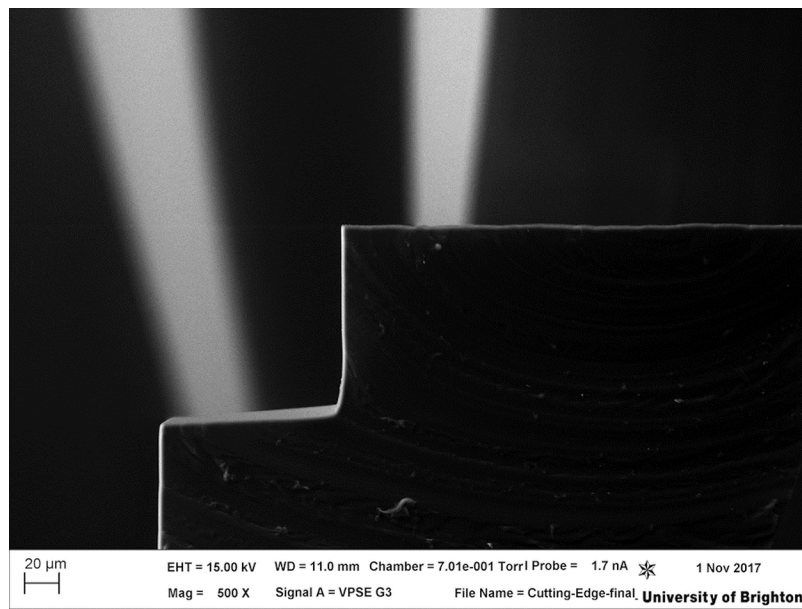


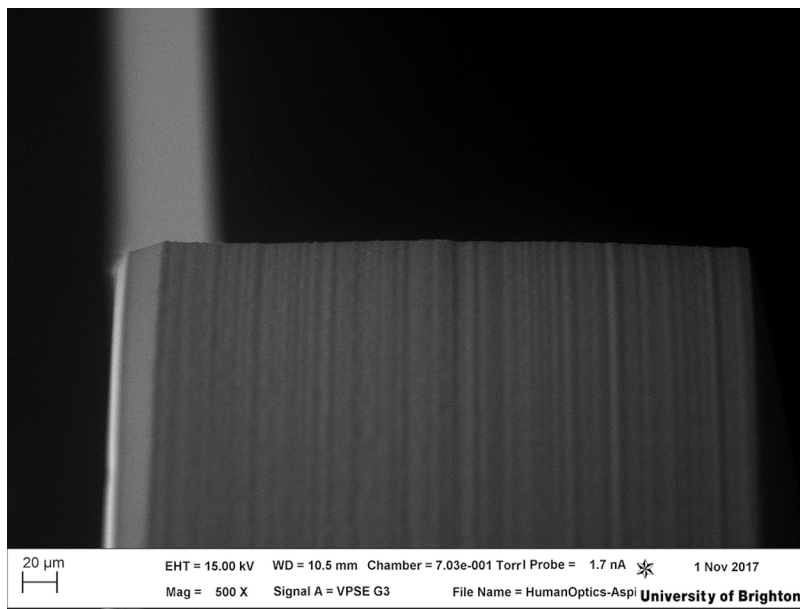


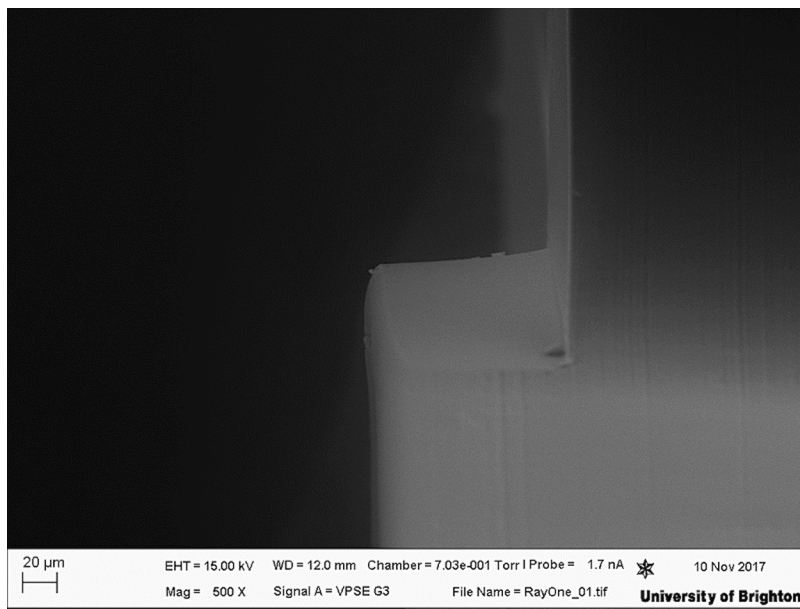


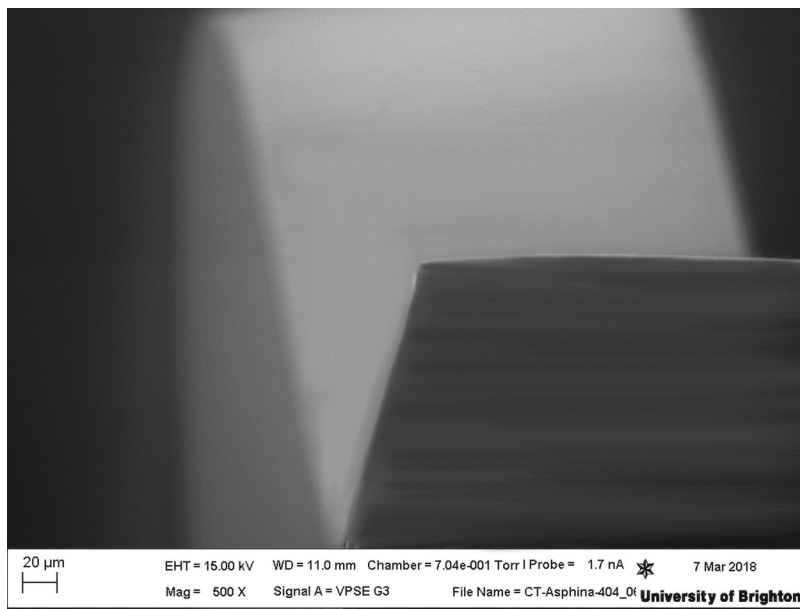












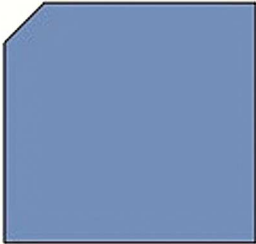
What is a real 'square' edge?



✓



x



x

ACCEPTED MANUSCRIPT

The hydrophilic intraocular lenses (IOLs) still have rounder edges compared to hydrophobic IOLs with huge variations in edge designs and the thickness which may lead to variation in PCO profiles.

ACCEPTED MANUSCRIPT