CLINICAL STUDY

Post-operative changes in the capsulorhexis aperture: a prospective, randomised comparison between loop and plate haptic silicone intraocular lenses

C.K. PATEL, SUE ORMONDE, PAUL ROSEN, A.J. BRON

Abstract

Purpose **There is disagreement regarding whether the capsulorhexis aperture always decreases or may increase post-operatively. The aim of this study was to settle the controversy concerning loop haptic silicone lenses and to learn more of the dynamics of the capsulorhexis relating to plate haptic lenses.**

Methods **We performed a prospective randomised study comparing the post-operative changes in capsulorhexis aperture in two groups of eyes implanted with either plate or loop haptic silicone intraocular lenses. All the surgery was performed, at a teaching hospital in the United Kingdom, by a single surgeon, using a standard technique of phacoemulsification. Patients were reviewed at 2 weeks and 6 months post-operatively. Digital retroillumination images of the anterior segment were captured. The area of the capsulorhexis aperture was determined by manually detecting its edge on a computer monitor**

Results **Forty-eight cases were randomised. The groups were comparable for demographic variables and mean initial aperture size ($p > 0.05$). There was an 8.4% mean decrease in aperture size for the loop haptics, contrasting with 4.5% expansion for the plate haptics ($p < 0.05$). Sixty-five per cent of patients with the plate haptic underwent enlargement of the aperture, contrasting with 25% for the loop haptic lens ($p < 0.05$).**

Conclusions **Silicone lenses with plate haptics undergo expansion of the capsulorhexis aperture more frequently than those with Prolene loop haptics.**

Key words Capsulorhexis, Cataract, IOL, Phacoemulsification, Phimosis

Phacoemulsification is becoming the preferred method of cataract extraction in many eye units. The capsular contraction syndrome is a well-recognised but rare post-operative complication, which results in intraocular lens (IOL) decentration and axial media opacity.[1]

Recent studies have suggested that subclinical contraction is a universal finding associated with the implantation of three-piece silicone lenses.[2,3] Others, in contrast, have found enlargement of the capsulorhexis aperture to be the dominant response with three-piece lenses.[4,5] Contraction appears to be the dominant response with plate haptic silicone lenses.[4] The purpose of this study was to resolve the controversy concerning the three-piece silicone lens and to provide additional data on plate haptic lenses.

Patients and methods

Patients attending for cataract surgery at the Oxford Eye Hospital, a teaching centre in the United Kingdom, were assessed for the study. Exclusion criteria included previous intraocular surgery, evidence of previous uveitis, and the presence of pseudoexfoliation, high myopia, iridodenesis, diabetes and marked corneal opacity. Patients were included in the study if they gave informed consent.

Prior to surgery the pupils were dilated with g. cyclopentolate 1% and g. phenylephrine 10%. A standard peribulbar anaesthetic was used consisting of a single inferotemporal quadrant injection of 3–5 ml of 2% lignocaine and hyaluronidase. A single surgeon (C.K.P.) performed the surgery. A bi-manual phacotechnique was used through a 3.2 mm temporal corneal incision and paracentesis. Continuous curvilinear capsulorhexis was performed under viscoelastic. Hydrodissection, nucleofractis phacoemulsification and aspiration of cortical lens material were then performed with no specific attempt made to aspirate lens epithelial cells from the capsulorhexis margin. Cases in which the capsulorhexis was incomplete or in which posterior capsule rupture occurred were excluded prior to randomisation. The operating room assistants selected one of two IOLs (Chiron C10UB plate haptic or AMO Phacoflex

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Table 1. *Comparison of the groups receiving loop and plate haptic silicone lenses*

Variable	Loop haptic	Plate haptic	*p* value
No. of cases randomised	23	25	
Mean age in years (SE)	74.4 (2.1)	74.6 (2.3)	0.65
No. of females	15	13	0.44
No. of patients excluded from analysis	7	5	0.40
Mean CA area at 2 weeks (SE) (mm^2)	18.4 (0.79)	18.3 (0.71)	0.70
Mean change in CA area (SE)	−8.5 (3.7%)	+4.2 (2.4)%	0.0068
Proportion of cases undergoing expansion of the CA	25%	65%	0.017

SE, standard error; CA, capsulorhexis aperture.

II, SI30NB loop haptic lens) by opening envelopes containing the randomisation generated using permuted block restriction.

Following IOL insertion and aspiration of viscoelastic, the corneal wound was hydrated. All patients received 2 mg betamethasone and 20 mg of gentamicin subconjunctivally at the conclusion of surgery. Post-operatively g. dexamethasone 0.1% and g. chloramphenicol 0.5% were used four times a day for 2 weeks and reduced thereafter over 2 weeks or as clinically indicated.

The operated eyes were examined at 2 weeks and 6 months following surgery. The pupil was dilated with g. tropicamide 1% and g. phenylephrine 10%. The relations of the capsulorhexis margin were drawn using slit-lamp biomicroscopy to facilitate the interpretation of digital images when measuring the capsulorhexis aperture. Digital retroillumination images of the red reflex were acquired using a computerised system previously developed for cataract analysis (CASE2000).[6]

The images were exported to an Apple Macintosh computer, on which an independent observer determined the area of the capsulorhexis aperture in square millimetres, using the method described by Gonvers *et al.*[4] The 95% confidence intervals (95% CI) for differences in repeat intra-observer measurements were determined in 20 patients prior to the study and indicated excellent repeatability (mean difference, +0.064 mm^2; upper 95% CI, +0.14 mm^2; lower 95% CI, −0.01 mm^2). The measurements for the 2 weeks and 6 month data were carried out on separate occasions with the images numerically coded to avoid bias related to patient identity. The percentage change in aperture between the 2 week and 6 month post-operative visits was determined and used as the main outcome measure.

Where the capsulorhexis margin was adjacent to the optic, the edge of the optic was used to represent the margin of the capsulorhexis. Cases in which there was asymmetric haptic fixation, 'button-hole' IOL malposition[5] or inadequate mydriasis were excluded from analysis.

The chi-squared test was used to compare categorical variables and the Mann-Whitney *U*-test to compare continuous data. A *p* value of less than 0.05 was considered significant.

Results

Fifty-four patients entered the study. Five patients had an incomplete capsulorhexis and one a posterior capsule

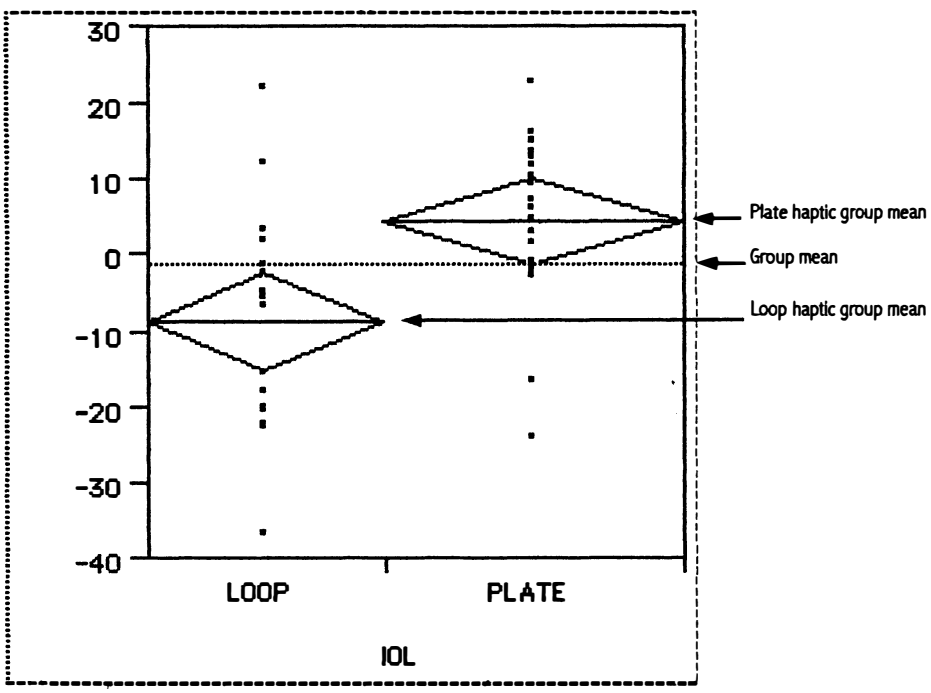

Fig. 1. *Distribution of the percentage changes in capsulorhexis aperture (CA) area between 2 weeks and 6 months following surgery. Tips of the diamonds represent 95% confidence intervals.*

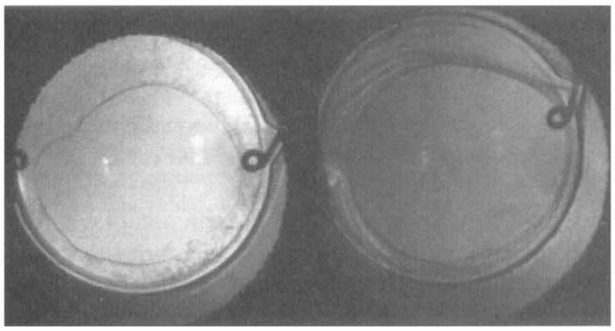

Fig. 2. *Digital retroillumination images obtained at 2 weeks (left) and 6 months (right) post-operatively showing expansion of the capsulorhexis aperture for the SI30NB loop haptic IOL.*

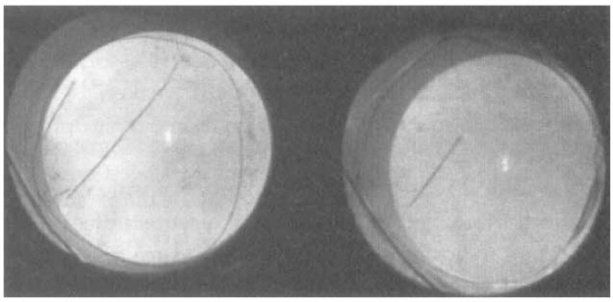

Fig. 3. *Digital retroillumination images obtained at 2 weeks (left) and 6 months (right) post-operatively showing expansion of the capsulorhexis aperture for the C10UB plate haptic IOL.*

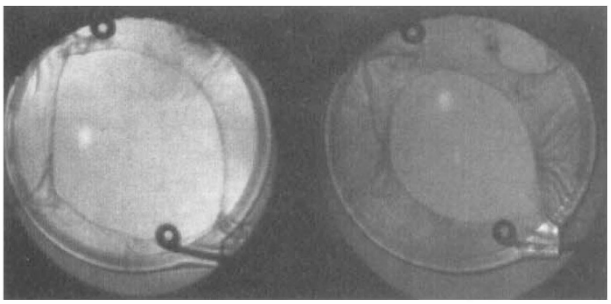

Fig. 4. *Digital retroillumination images obtained at 2 weeks (left) and 6 months (right) post-operatively showing contraction of the capsulorhexis aperture for the S130NB loop haptic IOL.*

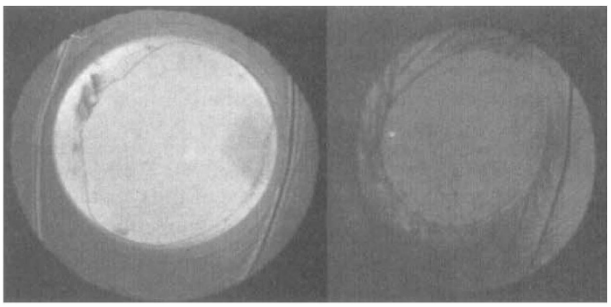

Fig. 5. *Digital retroillumination images obtained at 2 weeks (left) and 6 months (right) post-operatively showing contraction of the capsulorhexis aperture for the C10UB plate haptic IOL.*

rupture, leaving 48 eyes for randomisation. Twenty-three patients received the loop haptic lens and 25 the plate haptic design. There was no statistically significant difference between the groups as regards mean age, sex distribution, the mean capsulorhexis aperture size at 2 weeks following surgery and the number of patients excluded from analysis ($p > 0.05$) (Table 1). Three patients were lost to follow-up in each group; 2 in each group had inadequate mydriasis to image the entire margin of the capsulorhexis; 2 further exclusions in the loop haptic group included 1 patient with asymmetric haptic fixation and 1 with 360 ° capsulorhexis capture ($p > 0.05$).

Expansion and contraction of the capsulorhexis aperture were observed in both groups. Expansion was dominant in the plate haptic group, occurring in 13 of 20 (65%) cases compared with 4 of 16 (25%) for the loop haptic group ($p < 0.05$) (Table 1). The distribution of the change of capsulorhexis aperture for the two groups is shown in Fig. 1. An 8.5% mean contraction of the aperture occurred for the loop haptic group, contrasting with a mean expansion of 4.2% for the plate haptic group ($p < 0.05$). The maximum contraction of the aperture was 36.6% for loop and 24% for plate haptic lenses. The maximum expansion was 22.1% and 21.2% for loop and plate haptic lenses respectively. Examples of these responses are shown in Figs. 2–5.

Discussion

Continuous curvilinear capsulorhexis is the innovation of Gimbel and Neuhan.[7] It has been central to the success of modern, small-incision cataract surgery using phacoemulsification. The advantages it confers during surgery relate principally to maintaining the lens in the bag during fragmentation and aspiration. The endothelium is better protected from the damaging effects of cavitation and high-velocity lens fragments. The anterior uveal structures are less disturbed with a concomitant decrease in blood-aqueous barrier disruption. Posterior capsule rupture and zonular dehiscence are less likely during aspiration of lens matter compared with 'can-opener' capsulotomy because inadvertent aspiration of the anterior capsule is less likely. The post-operative advantages of capsulorhexis include improved implant stability and hence a reduced incidence of malposition and iris capture. Reduced contact of the IOL with the iris leads to less inflammation and theoretically to elimination of the uveitis-glaucoma-hyphaema syndrome. Spikes in intraocular pressure are also said to be less likely following YAG laser capsulotomy because of the segregation of anterior and posterior segment conferred by capsulorhexis.[8]

Post-operative disadvantages of capsulorhexis are few. Secondary glaucoma may occur from the capsular blockage.[9] The capsular contraction syndrome, first described by Davison,[1] is characterised by a large reduction in the size of the anterior capsular opening

resulting in opacification of the visual axis and implant decentration. This syndrome is rare and is associated with conditions in which the zonule is weaker: pseudoexfoliation, high myopia, myotonic dystrophy and uveitis.

Subclinical reduction in the anterior capsule opening has been the subject of a number of recent studies and is important to address because it may reduce fundus visualisation and hence affect the management of diabetic retinopathy and retinal detachment in the pseudophakic eye.

Studies by Zambarakji *et al.*,[3] Hyashi *et al.*[2] and Joo *et al.*[10] have concluded that contraction is a universal post-operative response peaking at 3 months and levelling off at 6 months. In the present study, we have clearly shown that expansion of the capsulorhexis aperture had occurred by 6 months in 4 of 16 patients implanted with a three-piece silicone IOL bearing Prolene haptics (Fig. 2). Zambarakji *et al.*[3] did not find such a response in 35 patients implanted with the same lens. Their group calculated the area of the capsulorhexis aperture by measuring its mean diameter on the slit lamp. The resolution of the measurement scale on a slit lamp is insufficient to provide a sensitive and accurate indication of change in area. In addition error is squared when calculating area from measurements of diameter. Their measurement technique may therefore have been insensitive for picking up real changes in capsulorhexis aperture size. Hyashi *et al.*[2] also did not document expansion of the capsulorhexis aperture in 73 patients implanted with the same three-piece lens. Their study, like ours, used image analysis techniques to determine the absolute capsulorhexis area. It is possible that contraction is more likely in oriental populations, the evidence being that other studies from the Far East have indicated a high incidence of contraction.[11,12] It is also important to note that the mean capsulorhexis area was 26.9 mm^2 in Hyashi *et al.*'s study compared with 18.3 mm^2 in ours. Assuming the capsulorhexis apertures to be circular, the mean diameters would have been 5.9 mm and 4.8 mm in their and our studies respectively. It is surprising that capsulorhexis expansion was not seen in the study by Hyashi's group, given that a previous study[5] has shown expansion to be more likely when the capsulorhexis and implant diameters are similar. Real population-based differences in capsulorhexis dynamics are one explanation. One problem with interpreting Hyashi *et al.*'s data is that they do not comment on the incidence of capsulorhexis capture, which in a previous study of theirs occurred in 20% of cases.[13] Unless one excludes cases of significant capture causing 'button-holing' of the lens, error in measuring the capsulorhexis aperture is likely to increase.

A European study, using a similar measurement technique, agrees with our finding that expansion of the capsulorhexis aperture is possible.[4] In that study, expansion occurred more frequently because the loop haptics were made from PMMA. In contrast to our study, they found contraction of the capsulorhexis aperture to be the dominant response with patients implanted with the plate haptic lens.

The most likely explanation for the variability in the data encountered in the literature is that capsulorhexis dynamics is affected by many factors. Theoretically movement of the capsulorhexis margin occurs when there is resultant force acting on it. The forces that resist centripetal movement of the capsule are the tension in the zonule and the haptic material. Conditions with weak zonules therefore predispose to contraction. Though our study has documented the possibility of expansion of the capsulorhexis aperture with Prolene haptics, the evidence is that contraction is the dominant response with this material, which is more flexible and therefore less able to counteract centripetal forces. PMMA haptics appear to resist contraction better. Our finding differs from that of Gonvers *et al.*[4] with respect to the plate haptic lens. The dominant response in our study was expansion and in theirs it was contraction. The lack of a consistent response may relate to the small sample sizes in both studies. Greater confidence in the results can only be achieved with a larger study.

The post-operative residual lens epithelial response may be an important variable affecting capsulorhexis dynamics. Myofibroblastic metaplasia[14] is known to exert forces on the lens capsule causing it to wrinkle.[15] Such a response is most vigorous at the capsulotomy margin and when this occurs in a round capsulotomy it is likely that centripetal forces will be generated.[16] The fact that the capsulorhexis aperture enlarges when its margin is cut radially with laser,[17] corroborates the presence of such forces. Aspiration of residual lens epithelial cells from the anterior capsule has been associated with reduced contraction of the aperture.[10,18] It is therefore possible, in our study, that variation in clearance of lens epithelial cells under the capsulorhexis margin influenced its dynamics post-operatively.

Frictional force between the anterior capsule and the anterior surface of the optic is the other important determinant of capsulorhexis movement. The lens biomaterial is the variable most likely to affect this factor. Hydrogel lenses are said to be very biocompatible and have, in one study, been associated with marked contraction of the capsulorhexis aperture.[10] One study has reported better stability of the anterior capsule with an acrylic lens.[5] This observation correlates with *in vitro* studies proving that the capsule adheres most with acrylic lenses and least with silicone lenses.[19] The finding of a high incidence of capsulorhexis capture with silicone lenses is an important potential clinical correlate of poor adhesion between silicone and the capsule.[13]

In conclusion, this study has shown that capsulorhexis contraction is not a universal post-operative occurrence even when silicone lenses bear Prolene haptics. The factors affecting capsulorhexis dynamics are multifactorial. If all the factors that promote expansion can be determined it will be easier to manage diabetic retinopathy and retinal detachment in the pseudophakic eye.

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