The influence of implant design on accuracy of postoperative refraction

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Abstract

Purpose To assess the degree of accuracy of postoperative refraction that may be achieved with modern techniques and a new lens of modern design.

Methods Five hundred eyes underwent refraction at one week and one month following phacoemulsification and implantation of the Centerflex™ lens (Rayner Intraocular Lenses Ltd style 570H). Results were compared with the target that had been computerised at the time of surgery, using the Hoffer Q formula for axial lengths less than 22.0 mm, the SRK-T for lengths greater than 24.5 mm and a mean of the two formulae for lengths between 22.0 and 24.5 mm. Statistical analysis used Fisher's exact and one way ANOVA tests.

Results At one month 97% of refractions were within 1.0 D spherical equivalent (SE) of target and 81% within 0.5 SE. The mean absolute error was 0.37 ± 0.39 SD. 75.8% of all eyes achieved 6/12 unaided and 88.6% achieved 6/9 with correction. In only 1.2% the refraction between one week and one month had altered by 0.5 D or more.

Conclusions The Centerflex™ when combined with modern methods of power calculation, can be associated with a high degree of accuracy in postoperative refraction.

Eye (2002) 16, 309–315. DOI: 10.1038/sj/eye/6700043

Keywords: hydrophilic; refraction accuracy; implant stability; biometry

Introduction

One of the key issues for cataract surgeons today is whether or not they can produce a

refractive result that agrees with the preoperative target. Assuming a facility for modern biometry, keratometry and lens power calculation, postoperative stability of the lens implanted is also necessary for an accurate result. In order to assess what may be achieved we have used in a large cohort of patients a hydrophilic implant of modern design, but which also stands up well to the other key issues of biocompatibility, centration, lack of capsular phimosis and lack of unwanted imagery.¹ Results may be compared with the Royal College of Ophthalmologists Cataract Surgery Guidelines which stem from Sweden² that suggest 80% of eyes following surgery should be within 1.0 D of expected refraction and with the American standard of care of having at least 50% within 0.5 D and 90% within 1.0 D of predicted refraction.³

Material and methods

Material

Five hundred and three consecutive eyes were refracted at one week and one month after phacoemulsification through a 3.0-mm clear cornea wound and primary in the bag placement of a Centerflex™ lens implant. The available power range for this implant was 8.0–30.0 D in 0.5-dioptre increments. Wounds were placed in the steepest meridian for any keratometric cylinder above 1.0 D and were otherwise temporal. Paired limbal relaxing incisions were made at the start of surgery where appropriate. The curvilinear capsulorhexis varied between 5.0 and 6.0 mm in diameter. Some capsules exhibited an anterior radial tear at the end of surgery. All were first eye Centerflex™ implantations so that there could be no fudging according to

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Paper read in part at the
Annual Meeting of Royal
College of
Ophthalmologists, 2001

Received: 25 June 2001
Accepted: 29 October
2001

results from the other eye. Three eyes were excluded from the study because of extreme dementia. Other exclusion criteria were at the time of surgery: eyes that had been listed for a different style of implant, for example, a multifocal; eyes for which the required power was outside the Centerflex™ range then available, a complication at surgery for which bag placement was deemed inadvisable; children; and corneal pathology that made keratometry uncertain. Of the five hundred entered into the study 202 eyes were from male and 298 from female patients. The age range was 36–96 years, mean 76.4 years. Two hundred and eighty two operations had been performed by a Consultant (SPBP), six by a Senior House Officer in training and 212 by one of two Associate Specialists (SSS or AVV). Refractions were only performed by the authors SPBP, AVV or SSS, using streak retinoscopy when appropriate and subjective fine tuning with trial lenses.

Implant design

The Centerflex™ (Figure 1) was chosen because of the specially patented haptics which prevent decentration,

Figure 1 Centerflex™ lens (Courtesy Rayner IOL Ltd).

anteroposterior movement or buckling in response to capsular contraction. Hydrophilics that are angulated are known to bow backwards in some cases leading to loss of power and hyperopic surprises. This has been reported for 12.0-mm plate haptic hydrogels⁴ and for the 10.5-mm Stabibag™ hydrophilic from Ioltech.¹ The Centerflex™ is uniplanar, equi convex and has relatively stiff haptics that have a loop span of 12.0 mm but are slotted to accommodate capsular contraction down to a diameter of approximately 10.0 mm after which they are able to resist further forces of contraction before buckling (Figure 2). Yet this lens is injectible through an unenlarged 3.0-mm wound. The lens has square edges, which in the rabbit model can create a capsular bend at the optic edge and delay ingrowth of epithelium.^{5,6} Professor David Apple has confirmed this also with the Centerflex™ (personal communication, 24 March 2001). The relatively low index of refraction (1.46) and reflection coupled with the equiconvex design reduces the chance of debilitating photic imagery after surgery.^{7,8} The lens is made from Rayacryl®, which is a purified copolymer of methylmethacrylate and hydroxethyl methacrylate and has a water content of 26%. It has particular advantages for patients at risk of silicone oil surgery.⁹

Lens power calculation and methodology

Keratometry in all cases was performed using the Nidek KM-500 automated hand held keratometer. This was the preferred instrument in the department having been found to be more consistent than the Alcon hand-held model and the Topcon OM-4 mounted model. Biometry in all cases was performed by one of two orthoptists specialising in the technique and using the contact BVI Axis model (Spectrum Ophthalmics). The two formulae used were the Hoffer Q,¹⁰ which is known to perform better than other formulae for short eyes, and to show similar results to the Sanders Retzlaff Kraff Theoretical (SRK(T)) and Holladay formulae for standard axial lengths,¹¹ and the SRK(T), which has been shown to be superior for very long eyes.^{10–12} Target refraction was defined as the calculated refraction on the print-out for a given power of implant. In general the refraction aim was between –0.1 and –0.8 D, but varying according to individual circumstances. The target refraction was noted at the time of surgery using the Hoffer Q formula for axial lengths less than 22.0 mm, the SRK(T) for lengths greater than 24.5 mm and a mean of the two for lengths between 22.0 and 24.5 mm. The A constant used for the Centerflex™ varied between 117.85 and 117.90 according to progression of the study. The manufacturer's recommendation was 118.0. After an

Figure 2 Compression characteristics (mNewtons) of four intraocular lenses when subjected to varying test diameters. (-----) Softec 1® (hydrophilic open loop from Lenstec Inc). (.....) Akreos Fit® (hydrophilic open loop from Chauvin Opsia SA). (-.-.-) Acrysof® SA30AL (hydrophobic open loop from Alcon Surgical). (——) Centerflex™ 570H (Figure 1). (Courtesy Rayner IOL Ltd Research and Development Laboratory).

initial 20 cases (that were not included in the study) we personalised the A constant at 117.9. The final recommended constant was 117.88. Five hundred consecutive postoperative refractions in spherical equivalents (SE) at one week and at one month were compared with the computerised target noted at the time of surgery. At the end of the study an assessment was made as to how results would have been had a mean of the two formulae been used for short eyes and for long eyes or had the SRK(T) been used for short eyes and the Hoffer Q used for long eyes. Statistical analysis was made using Fisher's exact test and chi-square test.

Results

Four hundred and ninety four (98.8%) of the refractions were stable at one week. In six eyes the refraction was found to have altered by 0.5 D SE or more between one week and one month. There were no cases of capsular phimosis observed at one month. Overall 406 (81.2%) of refractions were within 0.5 D of the target refraction, 485 (97%) were within 1.0 D of target. The mean absolute error was 0.37 (standard deviation 0.39) and Figure 3 shows a scattergram of refraction results in relation to absolute error and little deviation in overall result as the study progressed. Target refractions had been computed using the Hoffer Q formula for axial length less than 22.0 mm (54 eyes), the SRK-T formula for axial length greater than

24.5 mm (46 eyes) and a mean of the two formulae for axial lengths between 22.0 and 24.5 mm (400 eyes). However, Table 1 shows results that might have been achieved had different methods of formulation been used for the short and long eyes.

On detailed consideration of the 54 short eyes, 35 (64.8%) were within 0.5 D of target and 48 (88.9%) were within 1.0 D of target using the Hoffer Q formula. If the SRK-T formula had been used, 25 (46.3%) would have been within 0.5 D of target and 43 (79.6%) would have been within 1.0 D of target. If the mean of the two formulae had been used, 36 (66.7%) would have been within 0.5 D and 45 (83.3%) would have been within 1.0 D of target. These variations were proved to be unrelated to keratometry readings, which ranged between 42.0 and 48.6 D.

On consideration of the 46 long eyes, 26 had axial lengths between 24.5 and 26.0 mm. Of these 20 (76.9%) were within 0.5 D using the SRK-T formula. If the Hoffer Q formula had been used, 20 (76.9%) would have been within 0.5 D and if the mean of the two formulae had been used 21 (80.8%) would have been within 0.5 D of target. Twenty eyes had axial lengths greater than 26.0 mm. Sixteen of these (80%) were within 0.5 D and 19 (95%) were within 1.0 D of target using the SRK-T formula. If the Hoffer Q formula had been used, 12 (60%) would have been within 0.5 D and 17 (85%) within 1.0 D. If the mean of the two formulae had been used, 15 (75%) would have been within 0.5 D and 17 (85%) within 1.0 D of target. Again, these

Figure 3 Scattergram for 500 refractions (spherical equivalent) plotted against absolute error.

Table 1 Clinical refraction at one month compared with target computed at the time of surgery according to axial length and formula used

<i>Axial length</i>	<i>Formula used</i>	<i>No. refracted</i>	$\pm 0.5 D$ <i>of target</i>	<i>P value</i>	$\pm 1.0 D$ <i>of target</i>
<22.0 mm	Hoffer Q	54	35		48
	SRK-T	54	25	0.0809	43
	Mean	54	36	0.0585	45
24.5–26.0 mm	SRK-T	26	20		26
	Hoffer Q	26	20	ns	26
	Mean	26	21	ns	26
>26.0 mm	SRK-T	20	16		19
	Hoffer Q	20	12	0.3008	17
	Mean	20	15	0.3440	17
22.0–24.5 mm	Mean	400	334		392

results were unrelated to keratometry readings, which ranged between 40.13 and 47.25 D.

Excluding the short and long eyes and using the mean of the two formulae, 334 (83.5%) were within 0.5 D and 392 (98%) were within 1.0 D of target. Figures 4 and 5 show the relative refractive results in percentage terms for the short eyes with axial length less than 22.0 mm and the very long eyes with axial length greater than 26.0 mm. However, because of the small numbers, no statistical significance could be shown.

Visual results are shown in Table 2. Three hundred and seventy nine eyes (75.8%) achieved 6/12 or better unaided and 465 (93.0%) with correction. Four hundred and forty three (88.6%) achieved 6/9 or better with

correction. Of the 57 eyes that were seeing less than 6/9, 52 (10.4%) had ocular comorbidity (Table 3) and five developed clinical macular oedema at one month, but which in four eyes had resolved by 4 months.

Discussion

The recognised factors necessary to achieve accurate postoperative refraction include factory accuracy, a dedicated biometrist, tried and tested equipment for keratometry and axial length measurement, and the surgeon factor whereby a repeatable technique is used for consistent and reliable results. All these criteria were met for this study and the surgical technique was similar for all three surgeons.

We believe that a fifth factor is also important and that is the implant design. In order to achieve intraocular stability and hence refractive stability the implant should neither rotate, as may happen with plate haptic lenses,¹³ nor decentre, nor allow anteroposterior movement. Decentration and possible anteroposterior movement results from poor resistance to capsule contraction, which may be asymmetric and is more common if inflammatory events occur postoperatively. Single-piece soft lenses that are angulated will tend to bow backwards if the capsule contracts leading to loss of power and hypermetropic surprise. Three-piece lenses will move postoperatively if capsule contraction leads to crimping of one or other loop. Most lens materials in eyes so predisposed, may be associated with a tendency to capsule fibrosis and capsule phimosis.^{14,15} Ursell *et al* showed that the number of silicone lenses with PMMA haptics and

Figure 4 Percentage of short eyes (axial length less than 22.0 mm) achieving target refraction according to formula used.

Figure 5 Percentage of long eyes (axial length greater than 26.0 mm) achieving target refraction according to formula used.

Table 2 Visual acuity of 500 eyes one month post-operation

	Visual acuity					
	6/12 or better uncorrected	6/5–6/6 corrected	6/9 corrected	6/12 corrected	6/18–6/24 corrected	6/36 or worse corrected
Numbers	379	234	209	22	17	18
%	75.8	46.8	41.8	4.4	3.4	3.6

sing-piece PMMA lenses displaying a degree of capsular movement was approximately three times the number of three-piece Acrysof® acrylic lenses.¹⁶ Other authors have found significant capsule contraction in

association with plate haptic silicones^{17,18} and three-piece silicones.¹⁹

The ability of the unique haptic design of the Centerflex™ to resist capsular contraction is shown by

Table 3 Reasons for visual acuity less than 6/9 at one month (57 eyes)

Age related macular degeneration	Retinitis pigmentosa	Preop treated retinal detachment	Amblyopia	Optic atrophy	Central retinal vein occlusion	Interstitial keratitis	Macular oedema
36	1	2	8	1	3	1	5

in vitro compression force characteristics in Figure 2. In a laboratory setting with a test diameter of less than 10.0 mm (simulating a contracting capsular bag), the lens withstood 7.93 mNewtons before buckling, whereas in comparison the floppy loops of the single-piece Acrysof® (Alcon SA30AL) offered virtually no resistance and withstood only 0.29 mN.

In 494 of the 500 eyes of the study we found the refraction at one week and one month to differ by less than 0.5 D SE. This refraction stability so soon after surgery tends to confirm *in vivo* lens stability and is a suggested reason for the results that have been achieved. Our study purposely included three surgeons and using these techniques results are clearly repeatable. In 81% of eyes the postoperative refraction (SE) was within 0.5 D of target and in 97% within 1.0 D, which may be compared with the Swedish benchmark of 80% within 1.0 D of target.² This was despite 54 eyes being in the notoriously difficult range with axial length of less than 22.0 mm.

Our mean absolute error for all eyes in the study was 0.37 D ($\pm$ 0.39 SD) which compares favourably with that reported by Hoffer for 317 eyes.¹¹ He used a similar surgical technique though an immersion technique for biometry and a plate haptic silicone lens for all eyes. His mean absolute errors were 0.55 ($\pm$ 0.50), 0.43 ($\pm$ 0.51), 0.45 ($\pm$ 0.55), 0.44 ($\pm$ 0.52) using the Holladay 2, Holladay 1, Hoffer Q and SRK(T) formulae respectively.

Best results (Table 1) appear to be obtained from using the Hoffer Q formula for axial length less than 22.0 mm, the SRK(T) for length greater than 26.0 mm and a mean of the two formulae for lengths between 22.0 and 26.0 mm. The results are consistent with the findings of Hoffer who noted the Hoffer Q to be superior for short eyes and the SRK-T superior for long eyes. He also noted that although the Holladay 2 formula was an improvement over Holladay 1 for short eyes, this was neither better than the Hoffer Q for short eyes nor better than the SRK-T for average to medium long eyes.¹¹

Ninety-three per cent of eyes achieved a corrected acuity of 6/12 which may be compared with 86% in the National Cataract Survey.²⁰ We prefer the superior standard of 6/9 and have shown that with phacoemulsification and the Centerflex™, 89% may achieve this as compared with 76% achieving 6/9

following phacoemulsification in the National Cataract Survey.²⁰ When ocular comorbidity (Table 3) is excluded this figure rises to 99%. In practice the results were even better since four of the five cases with clinical macular oedema at one month had resolved by 4 months with improvement of acuity to 6/9 in three and 6/6 in one.

For a more direct comparison with the National Cataract Survey one should however provide results from all first eyes that were operated consecutively by the same surgeons in the same time frame. Thirty-one additional phacoemulsifications were performed but with a different lens style implanted either because of a complication at surgery (six eyes, posterior capsule rupture in four), or because the Centerflex™ was unavailable in the appropriate power (six eyes), or because a different style of implant was judged to be more appropriate (19 eyes, including 12 multifocals and three heparin lenses). Taking these 31 eyes together, 6/12 unaided was achieved in 21 and 6/9 with correction in 26 (83.9%). Comorbidity was a reason for failing to achieve 6/9 in four and a complication of surgery was a reason in one.

In conclusion the results using modern techniques and implant design show what may be achieved on a large cohort of patients in a provincial setting and could be regarded as a useful benchmark for other departments.

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