Intraocular lenses

Single versus three piece acrylic IOLs

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Which haptic design is better?

Since their clinical introduction 10 years ago, hydrophobic acrylic IOLs have gone on to become the most popular foldable IOL category worldwide. According to the annual Leaming surveys of the American Society of Cataract and Refractive Surgery membership, hydrophobic acrylic has been the most preferred IOL material since 1998, and was favoured by 63% of respondents in the 2002 poll.[1] This sustained popularity undoubtedly results from the excellent track record enjoyed by the first hydrophobic acrylic model—the three piece Alcon AcrySof—in terms of safety, biocompatibility, and capsular opacification.[2–6]

While some initially thought that the universally observed reduction in posterior capsule opacification (PCO) with this lens was mainly because of the acrylic material,[7 8] subsequent studies have shown that it is the truncated edge of the IOL that is the primary factor.[9–14] The sharp posterior edge is able to indent the posterior capsule, forming a mechanical barrier to posterior lens epithelial cell (LEC) migration.[9] Nishi *et al* demonstrated in rabbit experiments that if the edge of the AcrySof IOL was rounded the PCO advantage was lost.[10] Furthermore, they demonstrated that any IOL with a squared edge, regardless of material, was able to inhibit LEC migration in rabbits by forming this ''capsular bend.''[11] Abela Formanek *et al* and Auffarth *et al* subsequently confirmed this finding in prospective clinical trials.[12 13] Finally, Buehl and co-authors conducted a prospective trial of 53 patients who each received AMO Sensar hydrophobic acrylic IOLs with or without a square edge in alternate eyes.[14] The eyes receiving the truncated edge model developed less PCO at 1 year. Since the patient variables and the IOLs were otherwise identical, the barrier effect of the IOL edge was clearly more important than the acrylic material in preventing PCO.

The potential optical tradeoffs of a squared IOL edge have also been well documented. Ray tracing studies have shown that the symptoms of arcuate light flashes at night are the result of edge reflections from peripheral sources of light.[15–18] In addition, the high refractive index of the material led to the original AcrySof IOLs having a flattened anterior curvature. This could result in both external and internal reflections and dysphotopsias.[19]

In 2000, Alcon introduced a significantly different design—the single piece AcrySof. Having moulded and floppier haptics permits this IOL to be more easily injected through a small incision. Reduced wound size is particularly important for clear corneal cataract incisions. While the square edge design was maintained, modifications to reduce the aforementioned dysphotopsias were incorporated. The single piece models featured a frosted edge and a steeper anterior curvature—changes that have since been made to the three piece AcrySof models as well. In the brief ensuing period, the single piece AcrySof has become the most popular foldable IOL in the United States, where it accounts for 80% of total AcrySof sales. In Europe, 50% of Alcon's AcrySof sales are the one piece models.

> We must remember that lenses of an identical material, but with different designs cannot be assumed to produce the same clinical results

In this issue of the *BJO* (p 746), Nejima and co-authors address an important and practical clinical question—namely, is the one piece AcrySof equal to the three piece model in terms of centration, tilt, and opacification of the anterior or posterior capsule? Theoretically, these are the parameters that would most likely be affected by changing the haptic design.

Given the enormous popularity and rapid adoption of the single piece AcrySof model, there is surprisingly little in the ophthalmic literature that addresses these questions.

Two rabbit studies of single piece acrylic IOLs from David Apple's group indicated that the truncated edge provided an excellent PCO barrier in spite of the one piece design and the elimination of any haptic angulation.[20 21] This is pertinent because there is no posterior edge present where each thick haptic emerges from the optic. However, Nishi's rabbit studies of the single piece AcrySof raised concerns that PCO will be more likely with this design.[22]

Recent clinical studies have shown that shrink wrapping of the capsular bag around the IOL optic is an important mechanism or prerequisite for creating the LEC blocking capsular bend.[23 24] Naturally, a truncated edge accentuates this capsular indentation. However, even without a sharp IOL edge (for example, AMO SI-40), enough of a capsular bend can form because of this tight ''shrink wrap'' effect. Furthermore, the anterior and posterior capsules first make contact peripherally. This adhesion then progresses centripetally towards the optic, which becomes hermetically sealed.[23] Nishi and Nishi postulate that the bulky size of the single piece haptic may prevent peripheral contact between the anterior and posterior capsule from developing in some cases. Histopathologically, this was observed in rabbit eyes where abundant PCO developed.[22]

In the first clinical comparison of the two AcrySof designs, Wallin and co-authors published a retrospective study of 75 patients.[25] Approximately half had received the single piece AcrySof, and half the original three piece AcrySof. Visual acuity, refractive stability, and centration were similar in the two groups. However, the single piece IOLs were associated with more PCO, less anterior capsule opacification (ACO), and fewer dysphotopsias. YAG capsulotomy was more frequent in the single piece IOL group, but the incidence did not reach statistical significance in this small study. This is the only comparative study so far to evaluate and confirm that the newer design modifications succeed in reducing dysphotopsias.

Da Reitz Pereira and co-authors also reported on a comparison of the two AcrySof IOL designs at the most recent annual meeting of the American Academy of Ophthalmology.[26] Theirs was a retrospective study of 418 eyes, of which 230 received the single piece AcrySof, and 188 received the three piece AcrySof. They found a statistically higher number of patients requiring YAG anterior capsulotomy for anterior capsule contraction syndrome (3% versus 0%), despite the same surgical technique and initial capsulorhexis diameter. Although the incidence of significant capsulophimosis was still low, this study suggests that the reduced tensile strength of the floppy, single piece haptics may not resist capsular contracture as well. This may be an important consideration in eyes at higher risk of capsulophimosis, such as those with psuedoexfoliation, diabetes, or weakened zonules.[27–29]

The study by Nejima and co-authors represents the first prospective, randomised comparison of the single piece and three piece AcrySof IOLs. The

investigators sought to evaluate potential differences in IOL decentration, tilt, ACO, and PCO in 20 bilaterally implanted patients. Implanting the two designs in alternate eyes of the same patient eliminated patient co-variables and selection bias. The use of sophisticated, objective measurements with masked technicians further improved the validity of the results.

While there was no statistically significant difference in PCO measurements, there was a trend towards greater PCO in the single piece AcrySof group. Furthermore, only 16 patients were examined at the final 18 month visit. The authors speculate as to why PCO could be higher with the single piece design, but correctly point out that the sample size and follow up period of their study are clearly insufficient to make a definitive PCO comparison.

In summary, the rabbit studies of Nishi, the retrospective study of Wallin, and the current prospective study of Nejima collectively raise some suspicion that the single piece AcrySof design may not have the same PCO advantage as the traditional three piece AcrySof design, despite the presence of a truncated edge on both models. A larger study population followed prospectively for at least 2–3 years may be necessary to prove whether the designs are equally protective against PCO. As we seek to further improve IOL technology, we must remember that lenses of an identical material, but with different designs cannot be assumed to produce the same clinical results. Now that the single piece design has already overtaken the three piece design in popularity, further comparative studies are warranted to evaluate whether one haptic design is superior to another.

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Health services research

Childhood vision impairment

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Childhood blindness is ranked second only to cataract on the global burden of eye disease

While the number of children with vision loss and blindness is relatively low in comparison with the number of older people with vision loss, the impact as measured in disability adjusted life years (DALY) ranks childhood blindness second only to cataract on the global burden of eye disease and one of the five priority areas of the World Health Organization's ''Vision 2020—the right to sight'' programme.[1] Vision impairment, both low vision and blindness, compromises quality of life. Impaired vision from birth or in early childhood can have a profound impact on an infant's or child's development, restricting participation in social, physical and educational and, later, employment opportunities.

There is wide regional variation in the causes of vision loss and blindness. In both developed and developing countries, the majority of vision loss is either preventable or treatable.[1] Cataract, retinal diseases, and congenital abnormalities are found in all regions. In developing or low income countries where much of the vision loss is related

either to infection or nutrition, corneal scarring is the most common cause of blindness. The prevention of these conditions is largely at primary care level. In high and middle income countries where retinopathy of prematurity and lesions of the central nervous system are common, specialist paediatric ophthalmology services are needed for the prevention and particularly the management of vision loss in children.

The recent study of the incidence and causes of visual impairment and blindness in the United Kingdom found visual impairment was more common than expected and that it occurs in the context of non-ophthalmic impairments.[2] Seventy eight per cent of the children diagnosed with uncorrectable vision loss in the United Kingdom over a 1 year period had impairments in addition to severe vision loss or blindness. The associated disorders were motor, sensory, or cognitive impairments or chronic serious disorders that affected development, education, or independent living. Infants and children with multiple impairments often require not only complex ophthalmic management but also multidisciplinary assessment and follow up, often over long periods of time.

A critical issue in health services research related to infants and children is that of timely, necessary, and appropriate referrals for early childhood intervention services. Follow up with parents can ascertain if referrals were accepted and acted on. Thus, in middle to high income countries such as the United Kingdom, health services research for children with impaired vision needs to include specialist paediatric ophthalmic services, other paediatric health care, habilitation, and education services. Evaluation of the effectiveness of the new community link team in the Great Ormond Street Hospital department of ophthalmology will provide useful information on the referrals and networking between the often large number of health, habilitation, and educational professionals involved with children with vision impairment, and especially those with multiple impairments.

> The existence of bias in a study sample can lead to gaps in our knowledge of patterns of use of eye care and vision services

Health services information for adults is often included in population based studies of the prevalence and causes of eye disease in adults.[3] There are few similar large scale population based studies of children. Those that have been conducted though[4] do not help our understanding of the eye care services used by infants, children, and their families in countries such as the United Kingdom. It is clinic based surveys of families, such as that of Rahi and colleagues (p 782), which will provide much needed information.

A retrospective survey was sent to parents of children with newly diagnosed eye disease at a city hospital. To assess the barriers to participation and possible bias in health services research, the characteristics of participants were compared with those who did not participate. Sociodemographic data were extracted from hospital records, as was family history and degree of vision loss, non-ophthalmic disorders, and parents' main language. The study found that those who were more likely to participate had no other vision impaired family members, were white British, spoke English as their main language, and were from higher socioeconomic groups.

Identification as a member of an ethnic group does not indicate the language spoken or the acculturation of the child or parents. Both the language spoken and cultural beliefs about vision impairment and disability are likely to affect a family's experience and use of eye health services.

Most research is conducted only in the predominant community language, in this case English, thus possibly hindering participation by people who cannot read or speak English. The article discusses the difficulty of developing valid questionnaires in the languages required—it is not just a matter of translating the questions. The study group used one of its members, a Hindi speaker, to follow up people from south Asian countries. Based on their experience, they believe it might not be that the language spoken was a major barrier

Consideration of language spoken though is an important issue. A recent study in the United Kingdom found that the incidence of vision impairment was significantly higher in ethnic minorities than in ''white'' population. The odds of being vision impaired ranged from five times higher in south Asian groups, and over twice an elevated risk for ''black'' and other groups.

Cultural beliefs can influence a family's reaction to and acceptance of a child with a disability. Blame for a vision disorder may be directed at one or both parents. Utilisation of traditional, alternative, or mainstream hospital and medical services can be related to practices in the country of birth of the parents. For this reason, representation of ethnic minorities in health service research is important to gain an understanding of services used.

One of the purposes of Rahi *et al*'s study was the experience of health services. A study in a mental health service related language spoken in patients' country of birth to the length of time spent in clinic appointments.[5] People from English speaking countries had significantly greater duration of face to face clinic visits than did people from countries where English is not the main language. Reasons for the difference in duration such as need for and availability of interpreters were not available in the data collected in that study. While in a different area of health, this issue is one that needs to be explored as ophthalmologists and hospitals are one of parents' important sources of information about their child's vision disorder.[6]

In another study of families of children at the same hospital, 25% of appointments were not kept during the study period. While there are no details of non-attendees, this again is likely to limit the scope of participants. The demographic details of the families such as socioeconomic groups were not reported. The cost of appointments is given as a reason for not attending appointments. This is the case even in public hospitals where there is no charge for the appointment. It is the cost of travel and foregone wages that preclude many people from attending apparently ''free'' appointments.

The study by Rahi and colleagues demonstrates the challenges of the inclusion of all potential groups of participants when conducting health services research in ethnically and socioeconomically diverse communities. The existence of bias in a study sample can lead to gaps in our knowledge of patterns of use of eye care and vision services.

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