

National Institute for Health and Clinical Excellence

363 – Implantation of accommodating intraocular lenses during cataract surgery

Comments table

IPAC date: 14 December 2006

Consultee organisation	Section no.	Comment no.	Comments	Response
Individual respondent – clinician	1 – Provisional recommendations	1	Accommodative lens have been shown to correct distance visual acuity as well as any standard monofocal lens. It is incorrect to say that this is a short term effect. I agree there is inadequate evidence that they achieve accommodation (defined as a dynamic change in the optical power of the eye) but there is solid clinical evidence in the form of an FDA study and other clinical studies (RCTs) that they provide better focal range than a standard monofocal lens. In other words they provide an improved focal range compared to a standard lens. The introduction to this consultation incorrectly states that a standard intraocular lens has no focusing ability and that the accommodative lens is intended to allow focus for distance and near. All standard Intraocular lens have an inherent focusing ability and can provide good vision at one set distance (near, intermediate or distance) while an accommodative lens is designed to improve on this focal range and provide distance, intermediate and near vision. The data is clearly supportive of distance and intermediate vision (6 meters to 40 cm) but not consistently supportive of distance, intermediate and near vision.	<p>Please respond to all comments</p> <p>Thank you for your comment. Only two small studies reported results after a follow-up greater than 12 months. Section 1.3 states that publication of long-term results would be useful and that the procedure will be reviewed in due course.</p> <p>It was agreed that the lay box in the overview would be amended. The lay box does not form part of published guidance.</p>

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United Kingdom & Ireland Controlled Release Society	1 – Provisional recommendations	2	Agree	Noted, thank you.
Individual respondent – clinician	2.1 – Indications	3	These lenses are also indicated in patients who are presbyopic and wish for good distance and intermediate vision without glasses.	Thank you. This guidance relates only to the treatment of cataract and not to the correction of presbyopia (as stated in section 2.5.1).
United Kingdom & Ireland Controlled Release Society	2.1 – Indications	4	Agree but a commonly used alternative strategy is to correct the dominant eye for distance (emmetropia) and leave the non dominant eye slightly myopic to give increased depth of focus and better near vision. there are also developments in corneal laser surgery to give near vision but these are probably outside the scope of this report, nevertheless cataract and corneal surgery might in future be combined for correction of near vision	The Committee agreed to insert the following sentence in section 2.1.2: ‘These can be either multifocal lenses, which allow simultaneous near and distance vision to be obtained by the construction of the lens itself, or accommodative lenses which move position within the eye in a similar manner to the human lens.’

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Alcon Laboratories (UK) Ltd	2.1 – Indications	5	In the report a new generation of intraocular lenses were discussed and this group was divided into accommodative and multifocal lenses. The review then went on to provide a comprehensive detailed account on accommodative lenses with very little reference to the mechanism and performance of multifocal intraocular lenses. As such, we believe that it is important that the two lens groups are better differentiated or both are discussed in full in the review. To summarise accommodative lenses work by moving within the eye. When situated further back they have a weaker effective power thus providing clear distance vision. Upon reading the patients ciliary body contracts and this theoretically causes the lens to move forward. The result is an increase in the effective power and clear near vision. Multifocal lenses work optically using either refraction or diffraction or a combination of the two to provide both distance and near vision simultaneously.	<p>Please respond to all comments</p> <p>The guidance relates to the efficacy and safety of accommodative lenses and it is intended to give only brief descriptions of alternative treatments.</p> <p>The Committee agreed to insert the following sentence in section 2.1.2: ‘These can be either multifocal lenses, which allow simultaneous near and distance vision to be obtained by the construction of the lens itself, or accommodative lenses which move position within the eye in a similar manner to the human lens.’</p>
Individual respondent – clinician	2.2 – Outline of the procedure	6	This is too simplistic. The preoperative workup for these lenses is very different and needs much more accurate biometry, topography, astigmatic correction planning as well as careful preop counselling of the patient to identify their visual needs and expectations. The aim of the procedure is not to eliminate glasses but to reduce or minimise the use of spectacles after surgery.	The Committee changed the last sentence of section 2.2.1 to: ‘The aim of the procedure is to allow the eye to focus on near as well as distant objects, to reduce the need for spectacles.’
United Kingdom & Ireland Controlled Release Society	2.2 – Outline of the procedure	7	Agree	Noted, thank you.

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Individual respondent – clinician	2.3 – Efficacy	8	This section should include data from the above studies on spectacle usage for different distances and over all spectacle dependence. The point should also be made that the intermediate distance vision is much better with these lenses. This is computer distance vision. So the data in the FDA study should be relevant hereto demonstrate clinical efficacy.	Please respond to all comments The data presented in the efficacy section are from randomised controlled trials. Data from the FDA trial are presented in the overview in table 2 (Cumming et al. 2006).
United Kingdom & Ireland Controlled Release Society	2.3 – Efficacy	9	these results are controversial and depend very much on how accommodation was assessed, whether this was by psychophysical tests and how carefully these were performed. I don't think the studies were double blind, ideally one needs objective data that the lenses work rather than psychophysical tests which can be very biased. Clinical experience shows that about 20% of patients with bilateral monofocal IOLs in both eyes have good reading ability. Results will be very dependent on which IOL is studied	The Committee agreed to add the following sentence to the beginning of section 2.3: 'Only one randomised controlled trial reported that both the patient and the examiner were blind to which lens had been implanted.'

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Alcon Laboratories (UK) Ltd	2.3 – Efficacy	10	We believe that the primary advantage of using an accommodative intraocular lens over a monofocal lens is in its potential to provide patients with both clear distance and clear near vision thus resulting in spectacle independence. We would like to highlight the potential advantage newer generation multifocal lenses have over accommodative lenses in this respect. One of the newer additions to the multifocal lenses now available reports significantly higher levels of spectacle independence in the region of 85% ¹ and as such could provide a significantly higher level of patient satisfaction. In addition this lens is made of a material with a wealth of evidence revealing extremely low rates of PCO ^{2,3} . It could be argued that a lens that provides superior spectacle independence and significantly less secondary complications as seen with Nd:YAG would prove a more effective cost option to both patients and the NHS. 1. Hollick et al. Ophthalmology. 1999. 106. 49-55 2. Davison JA. J Cataract Refract Surg. 2004. 30. 1492-1500 3. Chiam et al. J Cataract Refract Surg. 2006. 32. 1459-1463	Please respond to all comments Noted, thank you. Evaluation of the cost effectiveness of procedures is not within the remit of the interventional procedures programme.
Individual respondent – clinician	2.4 – Safety	11	The other modality to improve the focal range of an eye is Multifocal lenses. Accommodative lenses are inherently safer than multifocal lenses as they do not have haloes and glare common with multifocals and better image contrast and quality of vision.	This was reported in one study, described in section 2.4.4.
United Kingdom & Ireland Controlled Release Society	2.4 – Safety	12	PCO and these complications are very much dependent on IOL design and possibly material and one cannot make generalised assumptions for these IOLs. Complications in 245 are all possible and need monitoring, they also occur with monofocal IOLS !	Noted, thank you.

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United Kingdom & Ireland Controlled Release Society	2.5.1 – Other comments	13	clear lens extraction for treatment of refractive errors and presbyopia has a vocal minority of advocates especially in the USA and Europe less so in the UK	Noted, thank you.
United Kingdom & Ireland Controlled Release Society	3.1 – Further information	14	this is a very new field and there are no recognised gold standard criteria for audit so you must not be proscriptive	Noted, thank you.