National Institute for Health and Clinical Excellence

706 – Intraocular lens insertion for correction of refractive error, with preservation of the natural lens
Consultation Comments table

IPAC date: 12th December 2008

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Private sector professional Specialist adviser	**1**	Given the evidence on the risk of retinal detachment and endothelial cell loss, it is misleading to conclude that "current evidence…raises no major safety concern". It seems contradictory to say this and raise a major safety concern (increased risk of retinal detachment) in the next sentence. I agree that there is good evidence of short-term efficacy however, retinal detachment and endothelial cell loss are major safety concerns, which should be stated as such. Endothelial cell loss is not currently mentioned in any part of the guidance document or the overview. The provisional recommendations should explain which patients are suitable for this procedure. It is of vital importance that the reader is aware that laser eye surgery offers greater safety than phakic IOLs for lower levels of refractive error. It is controversial to offer phakic IOLs to patients when extra-ocular laser refractive surgery can possibly be performed safely.	Thank you for your comments. Section 1.1 will be changed and endothelial cell loss included as a safety outcome.

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2	Consultee 1 Private sector professional Specialist adviser	**1**	An additional paragraph should mention that there are three different types of phakic IOLs: iris fixated, angle supported, and posterior chamber IOLs, and that the efficacy, safety and associated complications are different for each.	Section 2.2.1 will be changed to acknowledge that different devices can be used for this procedure.
3	Consultee 1 Private sector professional Specialist adviser	**2.1.2**	In section 2.1.2, LASIK and PRK can correct hyperopia as well as myopia, so it would be more accurate to say “treatments for refractive error” instead of “treatments for myopia”. Corneal implants should not be included in this section. Intracorneal ring segments have been made obsolete for the correction of refractive error due to the safety and efficacy of LASIK and PRK. Intracorneal ring segments are currently mainly used for keratoconus. It should be pointed out that LASIK and PRK are more viable treatments than phakic IOLs for the majority of refractive errors. I suggest changing this sentence to read: “Corneal refractive surgery, including photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK), are common and well established surgical treatments for refractive error.”	Thank you for your comment. Section 2.1.2 of the guidance will be changed. The list of current treatments and alternatives is not intended to represent recommendations for treatment, or to be definitive.

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4	Consultee 1 Private sector professional Specialist adviser	**2.3**	The results of each study should specify the type of IOL used: iris fixated, angle supported or posterior chamber as the efficacy might differ with the lens used. Why were so few studies considered if there were over 130 identified? It would be more representative to use findings from several studies for each type of lens rather than only show results from a few studies. Results might differ significantly between studies. Efficacy is represented by 1) the percentage of eyes within 0.50D or 1.00D of the intended refraction, 2) the uncorrected visual acuity post-operatively. Improvement in BSCVA is not guaranteed and patients should not consider this as a primary outcome measure. Changes in BSCVA are usually classified as safety and should be put in the safety section. For section 2.3.2, the uncorrected visual acuity rather than the BSCVA should be quoted. It is redundant to say “0% of eyes had UCVA of 20/20 or better pre-operatively” as all patients were at least -4.25 D short-sighted. It would be more relevant to quote the percentage of eyes within 0.50D of the intended refraction (65% for that paper) as well as how many eyes were 20/20 or better post-operatively.	Thank you for your comments. The details of the intervention used in each study considered by the Committee can be found in table 2 of the overview. The overview was developed in accordance with the IP methods guide. This represents a rapid review of the literature rather than a full structured systematic review. The overview describes the issues of evidence relating to a range of phakic IOL types in the Validity and generalisability of the studies section. BSCVA is reported in most studies as an efficacy outcome (as is UCVA). Where significant loss of BSCVA (usually 2 lines or more) is reported this has been considered a safety outcome.

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5	Consultee 1 Private sector professional Specialist adviser	**2.4**	Sanders has published 5-year follow-up of the Visian ICL showing a 6-7% cataract rate (JRS 200824(6):566-70). The following safety parameters should also be quoted: Endothelial cell loss (1.76% in Malecaze et al, sig. decrease at 1 year in Alio et al, & other papers: JCRS 200834(3):517-9, JRS 200723(9):868-79, Ophth 2008115(3): 464-472, Ophth 200731 and Graefes Arch Clin Exp Ophth 2007245(1):1-7) Explanted or replaced IOL (2% in Stulting et al, 4% in Alio et al) Pupil ovalisation (6% in Alio et al) Uveitis (Ophth 2003110:2153-61) The results of each study should specify the type of IOL used: iris fixated, angle supported or posterior chamber as the safety and complications might differ with the lens used. I strongly object to endophthalmitis being described as “theoretical”. While there are only a few published reports after phakic IOL surgery (JRS 2006 22(4):332-3, JCRS 199925(9):1295-8), the risk is likely to be similar to cataract surgery where the incidence rate varies between 0.05% and 0.33% (JCRS 33:978-88, Ophth 111:699-705, Ophth 106:1869-77). However, no matter how rare, it is a potentially catastrophic complication if it does occur.	Thank you for your comments. The paper by Sanders will be included in appendix A of the overview. Section 2.2.1 will be changed to acknowledge that different devices can be used for this procedure. The description of safety outcomes is only a sample of the most serious or significant. However there are rates available for explantation of phakic IOLs in Stulting (2008) in the overview. Section 2.4.4 is the opinion of the Specialist Advisers.