National Institute for Health and Clinical Excellence

682 – Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

Consultation Comments table

IPAC date: 13th March, 2008

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Specialist Adviser	**1.1**	There should be a clear statement in Para 1.1 regarding the uncorrected poor intermediate visual acuity seen with Multifocal Lenses. This is particularly relevant to computer use, mobile phone use etc.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
2	Specialist Adviser	**1.2**	There is no known increase in the technical difficulty of removing these lenses compared to monofocal.	Section 1.2 is a statement that the lenses are difficult to remove, not that they are more difficult than monofocal lenses.

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3	Specialist Adviser	**1**	I welcome the recommendation that these IOLs are safe and efficacious. However, I believe both the safety and efficacy are understated for reasons detailed in other areas of comments. One very important reason is that there have been 3 generations of these implants, and the older styles should have been excluded from analysis as it is now recognised that they were less efficacious and had more unwanted visual disturbances than modern IOLs. For this reason they are no longer available to use. Another problem is the confusion over nomenclature. These IOLs are sometimes described as bifocal sometimes multifocal (and often a so-called multi-focal IOL is in fact bifocal – i.e. provides only 2 distinct foci). Both descriptions should have been included in literature review. In both types of IOL the primary aim is to give both distance and near vision, but "multifocal" IOLs are supposed to give a third focus at an intermediate distance. Your summary of the procedure includes the statement "…different refractive powers, allowing both near and distant objects to be focused on the retina simultaneously….". Therefore to exclude bifocal IOLs from your analysis is perverse.	Thank you for your comment. The NICE IP programme considers generic procedures rather than particular technologies. The Committee have added a comment to section 2.5.1 to highlight that the technology in this field continues to evolve with the aim of reducing side effects. We agree that there is some confusion in description of these IOLs in the literature. The search for this procedure was generic enough to capture data on both truly multi focal IOLs and also bifocal IOLs. The study by Alio (2004) includes 3 'arms', multifocal, Bifocal, and accommodating lenses. We will re-consider whether any of the bifocal lens studies listed in Appendix A of the overview should be included in the main data extraction table. Please see updated overview for this procedure.

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4	Alcon UK Manufacturer	**1**	The literature behind the Interventional Procedure Consultation Document (IPCD) involves older multifocal (MF) intraocular lens (IOL) technologies that are seldom implanted in 2008. Nevertheless, we largely agree with the provisional recommendations. We concur that patients interested in MF IOLs should be advised of the potential for post-operative halo, glare, and lessened contrast sensitivity (CS). We agree that MF IOLs have no major safety concerns; this statement applies to today's MF technologies too. In sharp contrast to the figures for older technologies in section 2.3.1 of the IPCD, though, published reports for our AcrySof® ReSTOR™ (ReSTOR) say that 80 to 92% of the patients report never wearing any type of spectacles again. (The U.S. FDA label notes 75.7 to 81%.) This compares to a range of 7.5 to 8% reported for monofocal patients. As noted above, the growing body of contemporary published literature on today's MF lenses was not used for the IPCD. We will summarize that literature for our product, ReSTOR, as best we can in the space allowed. We currently (Feb, 2008) are aware of 19 peer review publications reporting ReSTOR experience in humans.	The NICE IP programme considers generic procedures rather than particular technologies. The Committee have added a comment to section 2.5.1 to highlight that the technology in this field continues to evolve with the aim of reducing side effects. Thank you for your comments. Data available at the time on the ReSTOR lens is tabulated in Appedix A. The NICE IP programme considers generic procedures rather than particular technologies.

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5	Specialist Adviser	**2.1**	Indications for the use of bifocal/multifocal IOLs are different from the indications for cataract surgery. The indications for NOT using these implants include patients having no real concern to be spectacle free, not having a history of problems with optical aberrations, not being a professional night-time driver, and having a degree of astigmatism that cannot be corrected by simple surgery. In addition, most people regard a procedure that allows spectacle freedom to be a life-style choice or a cosmetic choice, and therefore if there is both an opportunity cost to the NHS (extra time required for patient selection and counselling) and a financial cost (more expensive implants) perhaps this is not appropriate treatment for the NHS. Could NICE perhaps give some indication of the type of condition that would make these implants appropriate as NHS treatment? As I see it, these would amount to personal issues such as lack of ears or bridge of nose, motility problems (arthritis mainly) that make it difficult for a patient to adjust head posture to use bifocals but also make it difficult to change glasses, or certain occupational issues that make the use of spectacles problematic.	The indications section of the guidance is not indented to be an exhaustive text book account. The scope of this procedure was for multifocal IOL use following cataract surgery, not in phakic eyes.

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6	Alcon UK Manufacturer	**2.1**	Note that MF IOLs are not a recent development as is suggested in section 2.1.2. They have been increasingly used and accepted around the world for some time. The NICE Overview, for example, is partly based on published reports involving a 3M MF IOL developed in the 1980s. Some of the first data on this lens were presented at the Second American International Congress on Cataract, IOL, and Refractive Surgery in 1989 according to one of the references NICE used [Gimbel, et al, 1991]. MF IOLs have been available, and the technologies have been progressively improving, for 20 years.	Thank you for your comment. The Committee has removed 'more recently' from the text of section 2.1.2.
7	Specialist Adviser	**2.2.1**	There are diffractive Multifocal lenses which do not have concentric areas of refractive powers. Also the optics of these lenses does not produce near and distant objects to be focussed on the retina simultaneusly. There is usually a focussed image (distance for example) and a blurred image (near image for example) on the retina.	The Committee has reworded section 2.2.1 to state that these lenses have 'different' (rather than concentric) areas of refractive powers.
8	Specialist Adviser	**2.2**	A description of the procedure should include the pre-surgery work-up, which includes very accurate biometry and patient counselling/selection for this type of technology which inevitably offers a compromise that may not be acceptable to some patients.	This is too much detail for the description of the procedure, which is intended to be brief.

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9	Alcon UK Manufacturer	**2.2**	We agree that the surgical procedure for MF IOL implantation is no different from that for monofocal IOLs. We would point out, though, that the designs of today's MF lenses are not the same. The ReSTOR lens is different from the others in that it has an apodized diffractive-refractive optic. Apodization is a technology borrowed from telescopes. It was applied to ReSTOR IOLs to lessen the occurrence and intensity of glare and halo relative to the other multifocals which have exclusively refractive zonal optics or full diffractive optic designs. All of today's IOLs filter UV light. The latest ReSTOR lenses incorporate an additional feature - a yellow chromophore selected to filter a range of blue light wavelengths thought by some to increase the risk of macular disease in cataract patients.	The NICE IP programme assesses generic procedures rather than specific devices, implants or equipment. The Committee has added a comment to section 2.5.1 to highlight that the technology in this field continues to evolve with the aim of reducing side effects.

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10	Specialist Adviser	**2.3**	The review sampled only papers using the word multifocal, rejecting others because IOL was described as bifocal. I am also aware of papers not assessed because they had neither word in their title (e.g. Kohnen, Allen et al. “European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens.”). A further example that demonstrates this flaw is that the Cochrane Database meta-analysis which is included in your review includes a paper (Allen et al 1996) concerned with a study of one IOL, yet you excluded a further paper from that same study dealing with contrast sensitivity (Haaskjold and Allen 1998) on the basis that this was a bifocal and not multifocal IOL. That Cochrane review also considered results from the very earliest IOLs (which were used in conjunction with older style large-incision surgery) and pooled them with the results from the later generation of IOLs, thus diluting the efficacy. In addition there are sound theoretical reasons to believe that reading vision acuity should be better in true bifocal IOLs compared to ‘multifocal’ and therefore spectacle independence of modern bifocal IOLs is likely to be better than the mean given in this section.	Studies on bifocal lenses were captured in the literature search. The Kohnen study is listed in appendix A, however, larger studies included in table 2 Data from studies using newer lens designs have now been included in the overview and final NICE guidance. The NICE IP programme assesses generic procedures rather than specific devices, implants or equipment. The Committee have added a comment to section 2.5.1 to highlight that the technology in this field continues to evolve with the aim of reducing side effects.

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11	Alcon UK Manufacturer	**2.3**	ReSTOR provides uncorrected near & distance visual acuity (VA) under both photopic and mesopic conditions described by authors as high quality, good, or even excellent. Uncorrected distance VA is comparable to that produced by commonly used monofocals. It provides very good uncorrected near VA; one report indicated 2.5% of ReSTOR patients use reading glasses vs. 92.5% of monofocal patients. Its uncorrected intermediate VA is considered functional (≥20/40). One study found 75% are satisfied with their intermediate vision. ReSTOR patients indicate satisfaction with their near/intermediate/distance vision/function regardless of lighting conditions; 94 to 95% say they would choose it again. ReSTOR significantly improves quality-of-life. Some studies report ReSTOR provides less CS than monofocals. Another report disagreed saying CS under mesopic conditions is comparable to monofocal CD. Another suggested CS improves after 6 months with cortical adaptation to the lens. Yet another indicated CS falls in a normal range. ReSTOR's low height, non-reflective square edge minimizes vision disrupting posterior capsular opacification; corrective Nd:YAG surgery rates are a cumulative 2% per year.	Thank you for your comments. Data from studies using newer lens designs have now been included in the overview and final NICE guidance.

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12	Specialist Adviser	**2.4**	See comments in the efficacy section re incomplete literature review leading in this section to overstatement of for example the contrast sensitivity reduction, or glare/halo problem. I do not recognise the stated high incidence of posterior capsulotomy for capsule opacification, although it is recognised that patients with bi/multifocal IOLs have a lower threshold for needing laser intervention.	Thank you for your comment.

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13	Alcon UK Manufacturer	**2.4**	Roughly 350,000 ReSTOR lenses are implanted today; there are no important safety concerns. Published research on 1,646 patients to date primarily focuses on severe halos or glare. One study comparing ReSTOR to a monofocal reported no severe glare; severe halos were reported by 5% of the patients. An EU study indicated glare and halos are severe in 8.5% and 4.2% of patients, respectively, and defined these rates as clinically acceptable. Other studies assessing these phenomena labeled their frequency and severity as clinically acceptable or said the incidence was low. Properly setting patient expectations is important. Anecdotal surgeon comments tell us glare and halo usually diminish after 6 months with cortical adaptation to the lens. Stereopsis tests of ReSTOR patients show results in a range considered normal, said one author who added the lens does not decrease visual function. Another paper reported stereopsis and reading speed in ReSTOR patients aren't different vs. a monofocal. Three studies noted significantly fewer spherical aberrations compared to monofocals. Finally, one paper suggested ReSTOR has high capsular biocompatibility that could ensure long-term stability.	Thank you for your comments.

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14	Alcon UK Manufacturer	**General**	**Published peer reviewed research reports of AcrySof® ReSTOR™ use in humans.** 1. Akaishi L, Tzelikis PF. Primary piggyback implantation using the ReSTOR intraocular lens: Case series. J Cataract and Refract Surg 2007; 33:791-795. 2. Alfonso JF, Fernandez-Vega L, Baamonde MB, Montes-Mico R. Prospective visual evaluation of apodized diffractive intraocular lenses. J Cataract Refract Surg 2007; 33:1235-1243. 3. Blaylock JF, Si Z, Vickers C. Visual and refactive status at different focal distances after implantation of the ReSTOR multifocal intraocular lens. J Cataract Refract Surg 2006; 32:1464-1473.	Thank you for informing us of this additional evidence, most of which appears in the overview for the procedure: This study is listed in Appendix A This study is listed in Appendix A This study is listed in Appendix A

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			4. Chiam PJT, Chan JH, Aggarwal RK, Kasaby S. ReSTOR intraocular lens implantation in cataract surgery: Quality of vision. J Cataract Refract Surg 2006; 32:1459-1463. 5. Chiam PJT, Chan JH, Haider SI, Karia N, Kasaby H, Aggarwal RK. Functional vision with bilateral ReZoom and ReSTOR intraocular lenses 6 months after cataract surgery. J Cataract Refract Surg 2007; 33:2057-2061. 6. Fernandez-Vega L, Alfonso JF, Rodriquez PP, Montes-Mico R. Clear Lens Extraction with Multifocal Apodized Diffractive Intraocular Lens Implantation. Ophthalmology 2007;114:1491-1498. 7. Kohnen T, Allen D, Boureau C, Dublineau P, Hartmann C, Mehdorn E, Rozot P, Tassinari P. European Multicenter Study of the AcrySof ReSTOR Apodized Diffractive Intraocular Lens. Ophthalmology 2006;113:578-584.	This study is listed in Appendix A This was found in updated literature search and will be included in table 2 of the overview. This does not involve cataract surgery This study is listed in Appendix A

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			8. Lehmann R, Waycaster C, Hileman K. A comparison of patient-reported outcomes from an apodized diffractive intraocular lens and a conventional monofocal intraocular lens. Current Medical Research and Opinion 2006; 22(12):2591-2602. 9. Oliveira F, Muccioli C, Silva LM, Soriano ES, Souza CE, Belfort Jr R. Contrast sensitivity and stereopsis in pseudophakic patients with multifocal intraocular lens. Arq Bras Oftalmol 2005; 68(4):439-443. 10. Pepose JS, Qazi MA, Davies J, Doane JF, Loden JC, Sivalingham V, Mahmoud AM. Visual Performance of Patients with Bilateral vs Combination Crystalens, ReZoom, and ReSTOR Intraocular Lens Implants. Am J Ophthalmol 2007;144:347-357. 11. Rocha KM, Chalita MR, Souza CEB, Soriano ES, Freitas LL, Muccioli C, Belfort Jr R. Postoperative Wavefront Analysis and Contrast Sensitivity of a Multifocal Apodized Diffractive IOL (ReSTOR) and Three Monofocal IOLs. J Refract Surg 2005; 21:S808-S812.	This study has been added to table 2 of the overview. . This study is published in Portuguese (Brazilian study) This study is listed in Appendix A It is not clear if this study involves cataract surgery.

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			12. Sallet G. Refractive Outcome After Bilateral Implantation of an Apodized Diffractive Intraocular Lens. Bull Soc Belge Ophthalmol 2006; 299:67-73. 13. Souza CE, Muccioll C, Soriano ES, Chalita MR, Oliveira F, Freitas LL, Meire LP, Tamaki C, Belfort Jr R. Visual Performance of AcrySof ReSTOR Apodized Diffractive IOL: A Prospective Comparative Trial. Am J Ophthalmol 2006; 141:827-832. 14. Souza CE, Gerente VM, Chalita MR, Soriano ES, Freitas LL, Belfort Jr R. Visual Acuity, Contrast Sensitivity, Reading Speed, and Wavefront Analysis: Pseudophakic Eye With Multifocal IOL (ReSTOR) Versus Fellow Phakic Eye in Non-presbyopic Patients. J Refract Surg 2006; 22:303-305. 15. Toto L, Falconio G, Vecchiarino L, Scorcia V, Nicola MD, Ballone E, Mastropasqua L. Visual performance and biocompatibility of 2 multifocal diffractive IOLs – Six month comparative study. J Cataract Refract Surg 2007; 33:1419-1425.	This study is published in French (Belgian Study) This study is listed in Appendix A It is not clear if this study involves cataract surgery. This study is listed in Appendix A

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			16. Tsorbatzoglou A, Nemeth G, Math J, Berta A. Pseudophakic accommodation and pseudoaccommodation under physiological conditions measured with partial coherence interferometry. J Cataract Refract Surg 2006; 32:1345-1350. 17. Vingolo EM, Grenga PL, Iacobelli L, Grenga R. Visual acuity and contrast sensitivity: AcrySof ReSTOR apodized diffractive versus AcrySof SA60AT monofocal intraocular lenses. J Cataract Refract Surg 2007; 33:1244-1247. **Other published information on AcrySof® ReSTOR™ use in humans** 1. Davison JA. The AcrySof ReSTOR Lens: Pros and Cons. Cataract & Refractive Surgery Today, January, 2006. Page 63. 2. Davison JA, Simpson MJ. History and development of the apodized diffractive intraocular lens. J Cataract Refract Surg 2006; 32:849-858.	The outcomes reported in this study are not clinically useful outcomes. This study is listed in Appendix A This is an editorial review article This is an editorial review article

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			3. Davison JA, Simpson MJ. How does the ReSTOR lens work? Review of Refractive Surgery, October, 2004. Pages 18-20. 4. Lane SS, Morris M, Nordan L, Packer M, Tarantino N, Wallace RB. Multifocal Intraocular Lenses. Ophthalmol Clin N Am 2006; 19:89-105. 5. Tipperman R, Cionni R. Presbyopia-Correcting Intraocular Lenses. Review of Ophthalmology Part 2 of 2 (CME), April, 2007. Pages 1-12. 6. Wallace 3rd RB, Maxwell WA, Dell SJ, Brint SF. Correction of Presbyopia. Cataract & Refractive Surgery Today, March, 2005. Pages 93-98.	This is an editorial review article This is an editorial review article It is not clear if this study involves cataract surgery It is not clear if this study involves cataract surgery