Horizon Scanning report No. 8

Accommodating intraocular lenses for patients with cataract

December 2010

Methods

Agenas is a public body. Its mission is to promote innovations and developments within the Italian national healthcare service and develop a Horizon Scanning (HS) function in the field of healthcare technologies. A full description of the methods used for the production of the present HS report can be found at www.agenas.it

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Limitations

This report is based on information available when the searches were made and does not contain data on subsequent developments or improvements of the evaluated technology. The observations made on effectiveness, safety or cost-effectiveness of the technology evaluated in the report are to be considered temporary.

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Declaration of Conflict of Interest

The authors declare that they will not receive either benefits or harms from the publication of this report. None of the authors have or have held shares, consultancies or personal relationships with any of the producers of the devices assessed in this document.

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Name of the technology/procedure: **Accommodating intraocular lenses for patients with cataract**

Target population

Accommodating intraocular lenses (IOLs) are intended to be used in patients with cataract who elect to treat cataract by IOL implantation and want to reduce spectacle dependence.

Description of the procedure and technology

Accommodating IOLs were developed to treat cataract by mimicking the accommodative abilities of the natural eye. Accommodating IOLs are specially designed to be positioned so that the ciliary muscle will move the lens, changing its effective accommodating power and providing vision for distance, intermediate, and near vision; they are also called pseudoaccommodative IOLs [Ledford JK, 2007].
Accommodating IOLs are implanted by a surgical intervention usually performed with a local anaesthetic and requires phacoemulsification. The accommodating IOL is inserted like a standard IOL through the incision. The aim of the procedure is to allow the eye to focus on near as well as far objects, reducing the need for spectacles [NICE, 2007]. Also multifocal IOLs are developed to address this issue but they are based on the concepts of diffraction. Ideally, the advantages of the accommodating IOLs on the multifocal are linked to the ability to reduce glare and halos, giving a better quality of vision also at the intermediate distances.
The concept at the basis of accommodating IOLs is the optical-shift: the contraction of the ciliary muscle allows the forward shift of the IOL optic to focus on intermediate and near field [Findl O, 2007]. Although this technology has been known for almost two decades [Cumming JS, 1996] the efficacy of the hypothesised mechanism is still under debate [Kohnen T, 2010]. This is probably due to the multifactorial mechanism of accommodation; it involves an active component (the ciliary muscle) and other passive components (the lens, the capsule, the zonule, the uvea and the vitreous) and the effect of “patient motivation” which may play a relevant role [Leydolt C, 2009]. Generally the accommodating IOLs can differ by surface characteristics (e.g. spherical, aspherical), materials (e.g. hydrophilic acrylic, silicone) and other parameters such as mode of action, optic diameter, design of the haptics. At present several products are marketed as “accommodating lens” in Europe while the US market seems to be less diversified due to the different regulation [Devis EA, 2010]. This report focuses on the accommodating IOLs for patients with cataract.

Clinical importance and burden of disease

A cataract is a clouding (opacity) of the lens of the eye that causes a progressive, painless loss of vision impeding the passage of light. As a consequence, vision may be blurred, contrast may be lost, and halos may be visible around lights. Most cataracts are related to ageing, although occasionally children may be born with the condition, or cataract may develop after an injury, inflammation or disease. Risk factors for age-related cataract include diabetes, prolonged exposure to sunlight, tobacco use and alcohol drinking. Diagnosis can be made by looking at the eye with an ophthalmoscope or slit lamp [The Merck Manuals].

Treatment is surgical: the vision can be restored by removing the affected lens and replacing it by an artificial one.
In Italy cataracts affect 8.5% of the population between 70 and 74 years, 12.4% between 75 and 79 and 17.1% of the population over 80 years [Istat]. The Italian NHS providers perform the procedure in day-surgery, inpatients or outpatients. During 2008 (the last year for which data are available using the Ministry of Health's SDO database) the number of admissions was 237,957 (day-hospital/day-surgery and inpatients). This number is underestimated as all the outpatients procedures are not recorded within the SDO database. The SOI (Italian Ophthalmic Society) estimates more than 400,000 procedures (cumulative for procedures performed in day-surgery, inpatients and outpatients by public and private providers).

Products, manufacturers, distributors and approval

We identified 4 IOLs that are classified as "accommodating". These are all available to the European market as they gained the CE mark.
Crystalens AO (Bausch & Lomb, Inc.) is the last evolution of Crystalens (previous generations were AT-45, AT-45SE, Five0, and HD). The main new feature of this device is the aspheric optic that corrects the spherical aberrations. Crystalens AO gained the FDA approval in November 2009 and the CE mark in March 2010.
Synchrony (Visiogen, Inc. part of Abbott Medical Optics, Inc. since 2009) represents a different approach in achieving accommodation: the dual optic design. The device has two optics, an anterior one connected to a posterior one by haptics that work in a "spring-like" manner. Synchrony gained the CE mark in September 2006 but is not yet approved by the FDA (approval has been requested).
Tek-Clear (Tekia, Inc.) is characterised by a full-bag symmetrical haptic design and gained the CE mark in May 2009. FDA approval has not been requested at the time of writing (November 2010).
Tetraflex (Lenstec, Inc.), also known as KH-3500, is the less recent device on the market and it was designed to use the two forces activated during accommodation: vitreous movement and ciliary swelling. Tetraflex gained the CE mark in October 2006 but is not yet approved by the FDA (approval is expected by March 2011). Technical characteristics of all the devices identified are reported in Table 1.

Product name [Manufacturer]	Distributor	CE Mark	RDM	FDA
Crystalens AO [Bausch & Lomb, Inc.]	Bausch & Lomb - IOM SpA	☑	☑	☑
Synchrony [Visiogen, Inc.]	AMO Italy Srl	☑	☑	☐
Tek-Clear [Tekia, Inc.]	NewTech SpA	☑	☑	☐
Tetraflex or KH-3500 [Lenstec, Inc.]	CB Medical Srl	☑	☑	☐

Setting

The implantation procedure is usually performed within the operating room of the department of ophthalmology.

☐ Home	☑ Hospital	☑ Outpatients
☐ Accident and Emergency	☑ Other: Day-hospital / Day-surgery	

Roll out in Italy

Data presented in this paragraph were released by the Italian distributors and refer to the Italian market. Data are as at November 2010. They show the number of implants performed within and of lenses sold to the NHS providers. Number of procedures are cumulative for inpatients, day-surgery, and outpatients.
Marketing of Crystalens AO began in May 2010; 178 implants have been performed (and 247 lenses have been sold). Marketing of Synchrony began in August 2009; 28 implants have been performed (but no lenses have been sold). Marketing of Tek-Clear began in the second semester of 2009; No implants have been performed yet (and no lenses have been sold); 35 lenses have been sold to private providers. Tetraflex (KH-3500) has not been marketed yet in Italy but 130 implants have been performed. Commercialisation will start after FDA approval.

☐ Pre-marketing	☐ On the market for 1-6 months	☐ On the market for 7-12 months
☑ On the market for more than 12 months	☐ Not identified	

Comparators

The main comparators for the accommodating IOLs are the multifocal IOLs. Standard IOLs (i.e. monofocal or bifocal) can't be considered as comparators since they are not designed to improve vision at all distances (near, intermediate and far field).

Effectiveness and safety

The effectiveness of accommodating IOLs is the capability to improve the visual performance and acuity at all distances (far, intermediate and near) without the use of spectacles. We decided to consider those related to visual acuity (VA) and contrast sensitivity as quantitative outcomes (i.e. uncorrected VA; best corrected VA; distance corrected VA; uncorrected near VA; contrast sensitivity) and those related to visual quality as qualitative outcomes (halos, glare, reading speed, spectacle independence).
We carried out a literature search on EuroScan (28th October 2010) and CRD (DARE & HTA) (29th October 2010) databases, published in Italian and English, on the specific accommodating IOLs identified by this report. We wanted to identify Horizon Scanning (HS) reports and Rapid Health Technology Assessments. Five reports on accommodating IOLs were found, but none of them was considered as none assessed the devices identified (they assessed devices no longer on the market).

We looked for evidence by also searching for studies published in English and Italian from January 2004 (two years before the CE marking of the devices herein identified) in the major databases: MedLine, EMBASE and the Cochrane Library (2nd November 2010).
We found 144 studies. After reading the abstract only 13 were considered eligible for an in depth analysis (full text). Four studies met inclusion criteria. These are clinical studies on patients (humans) which underwent cataract surgery, to evaluate at least one of the accommodating IOLs identified in this report, and measure at least one of the outcomes we are interested in. The data extracted and the main results are reported in the Tables 2 to 4.
Although the studies evaluated different accommodating IOLs, all of them but one, showed an improvement in the visual performance of patients as time passed. Nevertheless many studies' limitations affect this conclusion: the small number of clinical studies included (just 4), their design (cases series), the small cohorts of patients enrolled (always less than 50) and the short follow-up (always less than 12 months).
As some devices are very recently marketed, we also searched on the *clinicaltrial.gov* database (30th November 2010). Eight clinical trials were found; one of them (on Tetraflex) is already completed but we did not find any publication reporting the results. Two trials, on Crystalens AO and Synchrony respectively, are in the ongoing phase; four trials are recruiting and one is not yet recruiting (all are on Crystalens AO). A summary of the trials identified is reported in Table 5.
There are no safety concerns related to the new technology since the surgical technique is well established and is the same for standard (monofocal) and multifocal IOLs [NICE, 2007].
However adverse events were observed in the study of Ossma et al. [Ossma IL, 2007] such as mild to moderate anterior capsule opacification (ACO) in 16.6% of the cases and significant posterior capsule opacification (PCO) in 4.2% of the cases at the 6 month visit (Table 4) as well as capsule fibrosis at six months found by Wolffsohn et al. [Wolffsohn JS, 2006].

Potential benefits to patients

Accommodating IOLs are very promising as they may allow patients to see at different distance without using spectacles, providing a better quality of life. Nevertheless not all patients have the same needs and desires; therefore, patient selection is perhaps the most important step for choosing candidates for any accommodating IOL technology. Patient motivation, hobbies, and daily activities at all distances (far, intermediate, and near) are relevant and require careful considerations [Bohorquez VM, 2008].

☐ Mortality reduction or increased survival	☐ Reduction of the morbidity	☑ Improved quality of life (patient/users)
☐ Improved patient monitoring	☐ Other:	☐ Not identified

Cost of the technology/procedure

We contacted the Italian distributors of the devices identified to obtain the following price list (all prices exclusive of VAT):

- Crystalens AO: € 699,00;

- Synchrony: € 650,00;
- Tek-Clear: € 450,00;
- Tetraflex (KH-3500): € 490,00.

Cost of the technology includes one lens that is pre-loaded on a special injector (included in the price).
The main comparator (multifocal IOLs) has a similar range of cost.
Surgical procedure using accommodating IOLs, as well as multifocal IOLs, does not have a specific DRG but is linked to the DRG 039 that is 1.124,75 Euro (TUC for 2009).

☐ Increased costs compared to alternative treatments	☐ Increased costs due to increased demand	☐ Increased costs due to the required investments
☐ New costs	☑ Other: Variations not identified	☐ Not identified

Potential structural and organisational impact

Structural impact

The new technology has no structural impact on the NHS as the surgical procedure associated does not differ from the procedure involving the technologies defined as comparators (i.e. multifocal IOLs).

☐ Increase in requirement of instruments	☐ Always be used	☐ Can be used only under specific circumstances
☐ Decrease in requirement of instruments	☐ Other:	☑ Not identified

Organisational impact

The technology may have a low impact on the organisation. Patient selection and information may play a relevant role as they are related to the pre-operative phase. Questionnaires and other techniques (e.g. routinely performed aberrometry and corneal topography) may have effect on the organisation in terms of dedicated staff, training and other factor (e.g. informed consent to the patient) [Buznego C, 2009].

☐ Increase in the number of procedures	☐ Re-organisation required	☐ Training required for users
☐ Reduction in the number of procedures	☑ Other: Training for the users for the management of the pre-operative phase and patient selection	☐ Not identified

Conclusions

Ideally accommodating IOLs represent an attractive option for patients with cataract that want to gain spectacle independence after cataract surgery with IOL implantation. This technology can be considered emerging and private companies look to this field with great interest.
However this HS report showed lack of knowledge that limits any kind of "positive" judgement. Although accommodating IOLs have been on the EU market for years, clinical studies are very few. Our included studies had very short follow-up periods (from 3 to 12 months), assessed only two devices (Synchrony and Tetraflex) out of the four identified, and were all (but one) non-comparative case series. No definitive conclusions on effectiveness can be drawn from such a limited evidence base. Comparative, larger and long-termed studies are required to prove the performance stability of the devices (especially regarding PCO and capsule fibrosis). Future studies should be also focused on patient's expectation and quality-of-life assessments. Furthermore, as the effectiveness assessment of the technology is closely linked to patient's selection methods (e.g. questionnaires), these methods should be validated within clinical studies.
Even if 4 years have passed, we cannot draw any more definite conclusions than those drawn by the last CADTH horizon scanning report on the accommodating IOLs [Scott A, 2006].
The promise of the accommodating IOLs sound tempting but evidence is scarce; however, devices change rapidly and newer generations take the place of the current ones stopping any evidence generation process. These concerns raise serious thoughts toward the CE marking procedure. In our opinion, this is not evidence generation, this is clinical research, and should be carried out by the proper ways (i.e. with controls).

Future prospects

The technology in this field evolves continuously and fast. Studies with longer follow-up should be published after the end of the registered ongoing clinical trials. New designs and new material for new accommodating IOLs are at the study phases [Buznego C, 2009] as well as new concepts such as lens-refilling procedures are in the experimental phase [Nishi Y, 2009]. For example, we also identified Collamer nanoFLEX lens from STAAR Surgical Company, WIOL-CF intraocular lenses from A.M.I. Care SRO, SmartLens from Medennium, and NuLens from Nulens Ltd. as well as the Optiflex Accommodative IOL by Moss Vision, Inc., characterised by a six haptics design, that seem to have gained the CE mark recently (no distributors were identified for Italy and we had on feedback from the manufacturer).

Table 1: Technical characteristics* of the accommodating intraocular lenses (IOL) identified for the Italian market.

Model	Manufacturer	Market launch	Surface	Material	Mode of action	Optic diameter	Overall diameter	Incision size
Crystalens AO	Bausch & Lomb, Inc.	2009 (US) 2010 (EU)	Aspherical	Silicone	Optic shift	5.00 mm	11.5–12.0 mm	2.8 mm
Synchrony	Visiogen, Inc.	2006 (EU)	Spherical	Silicone	Dual optic	5.50 mm (front) 6.00 mm (back)	9.8 mm	3.75 mm
Tek-Clear	Tekia, Inc.	2009 (EU)	Spherical	Hydrophilic acrylic	Optic shift	5.50 mm	10.0–11.0 mm	3 mm
Tetraflex (KH3500)	Lenstec, Inc.	2006 (EU)	Spherical	Hydrophilic acrylic	Optic shift	5.75 mm	11.5 mm	2.8 mm

Key: US = United States; EU = Europe.

* Technical data were extracted from manufacturer websites, scientific journals or informative materials (e.g. press releases).

Table 2: Visual acuity data from the clinical studies included.

Reference	Patients		Follow-up (mo)	IOL	UCVA	BCVA	DCNVA	UCNVA	Contrast Sensitivity
	Enrolled	Followed							
Dong, 2010	Ps = 44 Eyes = 52	Ps = 42 Eyes = 50	3	Tetraflex	(Dist.) @ 1 mo = 40 eyes 20/40 or better (Dist.) @ 3 mo = 41 eyes 20/40 or better	(Dist.) @ 1 mo = 45 eyes 20/40 or better (Dist.) @ 3 mo = 46 eyes 20/40 or better	(MON) @ 1 mo = 26 eyes J4 or better (MON) @ 3 mo = 33 eyes J4 or better	Not assessed	Not assessed
McLeod, 2006	Ps = 21 Eyes = 26	Ps = 21 Eyes = 24	6	Synchrony	@ 1 mo = logMAR 0.44 (SD, 0.34) @ 6 mo = logMAR 0.23 (SD, 0.18)	@ 1 mo = logMAR 0.11 (SD, 0.13) @ 6 mo = logMAR 0.04 (SD, 0.06)	@ 1 mo = logMAR 0.17 (SD, 0.15) @ 6 mo = logMAR 0.14 (SD, 0.15)	@ 1 mo = logMAR 0.11 (SD, 0.18) @ 6 mo = logMAR 0.08 (SD, 0.12)	Not assessed
Ossma, 2007	Ps = 21 Eyes = 26	Ps = 19 Eyes = 24	6 12 (11 eyes)	Synchrony	(Dist.) @ 3 mo = 15 ps 20/40 or better (Dist.) @ 6 mo = 19 ps 20/40 or better (Dist.) @ 12 mo = 9 ps 20/40 or better	(Dist.) @ 3 mo = 24 ps 20/40 or better (Dist.) @ 6 mo = 24 ps 20/40 or better (Dist.) @ 12 mo = 11 ps 20/40 or better (Near) @ 3 mo = 24 ps J1 or better (Near) @ 6 mo = 24 ps J1 or better (Near) @ 12 mo = 11 ps J1 or better	@ 3 mo = 11 ps J1 or better @ 3 mo = 23 ps J3 or better @ 6 mo = 12 ps J1 or better @ 6 mo = 23 ps J3 or better @ 12 mo = 7 ps J1 or better @ 12 mo = 11 ps J3 or better	@ 3 mo = 16 ps J1 or better @ 3 mo = 23 ps J3 or better @ 6 mo = 17 ps J1 or better @ 6 mo = 24 ps J3 or better @ 12 mo = 7 ps J1 or better @ 12 mo = 10 ps J3 or better	Not assessed
Wolffsohn, 2006	Ps (IG) = 28 Eyes (IG) = 28 Ps (CG) = 20 Eyes (CG) = 20	All enrolled	6	Tetraflex vs Softec1	Not assessed	IG: logMAR 0.06 (SD, 0.13) vs CG: logMAR 0.08 (SD, 0.15) *(p = 0.519)*	Not assessed	Not assessed	IG: +1.57 (SD, 0.27) log units vs CG: +1.58 (SD, 0.15) log units *(p = 0.913)*

Key: mo = months; IOL = intraocular lens; UCVA = uncorrected visual acuity; BCVA = best corrected visual acuity; DCNVA = distance corrected visual acuity; UCNVA = uncorrected near visual acuity; Ps = patients; Dist. = at distance; MON = monocular; SD = standard deviation; IG = index group; CG = control group.

Table 3: Visual quality outcomes from the clinical studies included.

Reference	IOL	Halos	Glare	Reading speed	Spectacle independence	Adverse effects*
Dong, 2010	Tetraflex	Not assessed	Not assessed	Not assessed	Not assessed	None noted
McLeod, 2006	Synchrony	Not assessed	Not assessed	Not assessed	Not assessed	None noted
Ossma, 2007	Synchrony	Not assessed	Not assessed	Not assessed	Not assessed	Mild to moderate ACO in 4 eyes (16.6%) at 6 months. Significant PCO in 1 eye (4.2%) at 6 months.
Wolffsohn, 2006	Tetraflex Vs Softec1	Not assessed	Not assessed	Not assessed	Patients in both groups had a relatively moderate residual distance prescription (range -2.00 D to +1.50 D).	Capsule fibrosis at six months for the Tetraflex group.

Key: IOL = intraocular lens;

* Any adverse effect noted (e.g. ACO, anterior capsule opacification; PCO, posterior capsule opacification).

Table 4: Summary of the studies included and main results reported.

Ref. (country) [study design]	Patients		Mean age (range)	Follow-up (mo.)	IOL	Control	Main findings (by Authors)
	Enrolled	Followed					
Dong, 2010 (China) [case series]	Ps = 44 Eyes = 52	Ps = 42 Eyes = 50	58.2 (47-71)	3	Tetraflex	None	Distance uncorrected visual acuity, best corrected visual acuity and distance-corrected near visual acuity improved as time passed (at 1 month and 3 months).
McLeod, 2006 (USA) [case series]	Ps = 21 Eyes = 26	Ps = 21 Eyes = 24	64.5 (40-78) [followed]	6	Synchrony	None	This pilot study represents a small cohort of patients with limited follow-up. Larger long-term studies are required to reveal the long term stability.
Ossma, 2007 (USA) [case series]	Ps = 21 Eyes = 26	Ps = 19 Eyes = 24	64 (40-79) [enrolled]	6 12 (11 eyes)	Synchrony	None	Best distance corrected near vision better than 0.3 logMAR (20/40 or J3) in 96% of the patients suggests proof of principle. This pilot study represents a small cohort of patients with limited follow-up. Larger long-term studies are required to reveal the long term stability.
Wolffsohn, 2006 (UK) [RCT]	Ps (IG) = 28 Ps (CG) = 20 Eyes (IG) = 28 Eyes (CG) = 20	All enrolled	72.9 (42-88) 71.1 (57-92)	6	Tetraflex (IG)	Softec1 (CG)	Best corrected visual acuity at distance and near were similar in both groups. At six months the Tetraflex group showed a significant reduction in the smallest print size that can be read at near. This study suggest that lens capsule fibrosis occurs with time reducing the benefits over conventional non-accommodating IOL.

Key: Ref. = reference; mo. = months; IOL = intraocular lens tested; Ps = patients; RCT = randomised controlled trial; IG = index group; CG = control group;.

Table 5: Summary of the clinical trials identified.

Trial number: "Official title"	IOL	Purpose	Phase	Arms			Enrolment [patients]	Date (Start – Completion)
				Experimental	*Active comparator*	*Active comparator*		
ACTIVE								
NCT00963560: "A Randomized, Subject-masked Comparison of Visual Function After Bilateral Implantation of Presbyopia-correcting IOLs"	Crystalens AO	"Prospectively evaluating postoperative visual and refractive parameters in a series of subjects bilaterally implanted with Presbyopia-Correcting Intraocular Lenses (IOLs)."	IV	AcrySof ReSTOR Aspheric +3	Crystalens HD	Crystalens AO	132	Aug 2009 – Dec 2010
NCT00425464: "A Prospective Multicenter Clinical Study to Evaluate the Safety and Effectiveness of the Synchrony Dual Optic Intraocular Lens in Patients Undergoing Cataract Extraction"	Synchrony	"To determine if the Synchrony Dual Optic Accommodating Intraocular Lens can be used safely and effectively in post cataract extraction subjects."	III	NR	NR	NR	330	Nov 2005 – NR
RECRUITING								
NCT01122576: "A Three Arm Prospective Clinical Evaluation of Three FDA Approved Intraocular Lenses Designed to Improve Distance, Intermediate and Near Vision Following Lens Extraction"	Crystalens AO	"To evaluate the efficacy and subject satisfaction with three different FDA approved lenses for adults over 40 years of age who desire a reduction in spectacle dependence."	IV	Crystalens AO	Tecnis Multifocal	ReSTOR AOL	78	Jun 2010 – Aug 2011
NCT01225952: "A Three Arm Prospective Clinical Evaluation of Three FDA-approved Intraocular Lenses Designed to Improve Distance, Intermediate and Near Vision Following Lens Extraction"	Crystalens AO	"To compare the contrast sensitivity, high and low contrast visual acuity (VA), glare meter outcomes, and subject satisfaction with three different FDA-approved IOLs in adults at least 40 years of age."	IV	Crystalens AO	ReSTOR 3.0	AMO Tecnis Multifocal	78	Jul 2010 – May 2011

NCT01061281: "Evaluation of the Tecnis™ Multifocal and Crystalens™ Accommodating Intraocular Lenses"	Crystalens AO	"To compare the visual outcomes with bilateral implantation of Tecnis MF and Crystalens™ AO Aberration-free Accommodating intraocular lens (IOLs) 6 months after post cataract surgery."	IV	-	Tecnis MF	Crystalens AO	40	Mar 2010 – Feb 2011
NCT01191229: "Prospective Evaluation of Visual Outcomes With Tecnis One-Piece Multifocal Intraocular Lenses Compared With Patients Previouly Implanted With Crystalens AO"	Crystalens AO	"To collect information about visual outcomes and participant satisfaction with the Tecnis One-Piece Multifocal (MF) IOLs compared with participants previously implanted with Crystalens AO IOLs."	IV	-	Tecnis One-Piece MF IOL	Crystalens AO IOL	50	Jul 2010 – Jul 2011
NOT YET RECRUITING								
NCT01241279: "A Two Arm Prospective, Randomized Double-Masked Clinical Evaluation of Accommodation Measurements After Bilateral Implantation of an Aspheric Accommodating Lens and Monofocal Aspheric Lenses"	Crystalens AO	"To demonstrate the correlation of near vision and changes in higher order aberrations following lens extraction and to characterize the defocus curves of Crystalens® AO™ intraocular lens (IOL) versus the monofocal aspheric SofPort® LI61AO IOL in adults."	IV	Crystalens AO	SoftPort LI61AO	-	24	Nov 2010 – Aug 2011
COMPLETED								
NCT00969371: "Lenstec Tetraflex Accommodating Posterior Chamber Intraocular Lens (IOL) Clinical Investigation"	Tetraflex KH3500	"To evaluate the safety and effectiveness of the Lenstec Tetraflex Accommodating Posterior Chamber Intraocular Lens (IOL) for the protocol inclusion/exclusion criteria."	NR	TetraFlex	Posterior chamber IOL implantation	-	470	Sep 2005 – Jun 2009

Key: NR = not reported.

Evidence searches

Searches of the databases were carried out between 28th October and 30th November, using the following key words to indicate:

- ***the technology of interest:*** IOLs, IOL, intraocular lens, intraocular lenses, accommodation, accommodating, “ocular accommodation”, accommodative, “Crystalens AO”, “Optiflex Accommodative”, Synchrony, Tek-Clear, “Tetraflex KH3500”.
- ***the pathology of reference:*** cataract; “cataract surgery”.

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Glossary

Aberrometry: Measurement of eye tissue imperfections or abnormalities based on the way light passes through the eye which affects the ability of the eye to focus properly.

Accommodation: The process by which the vertebrate eye changes optical power to maintain a clear image (focus) on an object as its distance changes. Accommodation acts like a reflex, but can also be consciously controlled. Mammals, birds and reptiles vary the optical power by changing the form of the elastic lens using the ciliary body (in humans up to 15 diopters).

Aspherical (or aspheric) lens: A lens whose surfaces have a profile that is rotationally symmetric, but is not a portion of a sphere.

Contrast sensitivity: Measure of the ability to discern between luminances of different levels in a static image.

CRD: Centre for Reviews and Dissemination.

DRG: Diagnosis-Related Groups.

FDA: Food and Drug Administration.

Haptics: Flexible supports around the IOL's body that are braced against the capsular bag.

ISS: Istituto Superiore di Sanità (Italian National Health Institute).

Istat: Italian National Institute of Statistics.

Phacoemulsification: Fragmentation of the opacified natural lens by ultrasounds and its removal through a small incision in the cornea.

Pseudoaccommodation (or apparent accommodation): Achievement of functional near vision in an emmetropic or distance-corrected eye without changing the refractive power of the eye.

RDM: Medical device Repertory (http://www.salute.gov.it/dispositivi/paginainternasf.jsp?id=499&menu=repertorio).

SDO: Hospital discharge records database.

Visual acuity (or sharpness of vision): The degree to which a person is able to distinguish and resolve fine detail. The essential requirements are a healthy retina and the ability of the eye to focus incoming light to form a sharp image on the retina. Acuity of distant vision is often expressed as a Snellen score (Snellen chart); acuity of near vision as a Jaeger score (Jaeger test types).

BCVA: best corrected visual acuity.

logMAR: logarithm of minimum angle of resolution; unit for measurement of visual acuity.

TUC: *Tariffa Unica Convenzionale*, Reimbursement fee from the Italian Ministry of Health.

UCVA: un-corrected visual acuity.

DCNVA: distance corrected near visual acuity.

UCNVA: un-corrected near visual acuity.