Alberta Heritage Foundation
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Intraocular lenses for uncomplicated senile cataracts

Christa Harstall and Wendy L. Schneider

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This Health Technology Assessment Report has been prepared on the basis of available information of which the Foundation is aware from public literature and expert opinion and attempts to be current to the date of publication. It has been externally reviewed. Additional information and comments relative to the Report are welcome and should be sent to:

Director, Health Technology Assessment
Alberta Heritage Foundation for Medical Research
1500, 10104 – 103 Avenue
Edmonton
Alberta T5J 4A7
CANADA

Tel: 780-423-5727, Fax: 780-429-3509

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SUMMARY

- Cataract surgery with implantation of an intraocular lens (IOL) is a successful technology for treatment of uncomplicated senile cataract.
- The results from a meta-analysis indicated that cataract surgery gives excellent results for visual acuity in approximately 95% of eyes without pre-existing ocular co-morbidity.
- The surgical techniques for removal of senile uncomplicated cateracts continue to evolve. The advent of small incision cataract surgery and the development of phacoemulsification stimulated the search for new IOL materials that allow for the folding of the lens prior to insertion. Surveys indicate trend to increasing use of foldable IOLs.
- The three main types of IOL in terms of the material used for optics are PMMA, silicone, and foldable acrylic. In Canada, PMMA IOLs have been used since the early 1970's, silicone IOLs for approximately ten years, and the first hydrogel IOLs received pre-market clearance about two years ago.
- Some degree of foreign body reaction occurs in all eyes after cataract surgery with IOL implantation, regardless of the IOL material. Cellular proliferation on the surface of an IOL is an indication of the biocompatibility of the lens' material.
- Posterior capsular opacification (PCO) is the most common cause of visual morbidity following cataract surgery with the insertion of a posterior chamber IOL. A meta-analysis found that rates of visually significant PCO incidence in patients undergoing standard cataract surgery were 11.8% for one year, 20.7% for three years, and 28.4% at five years after surgery.
- The association of lens material, design and configuration to the risk of PCO needs further research.
- The most convenient method for treating PCO is Nd:YAG laser capsulotomy. The incidence of damage to IOLs by Nd:YAG laser has been reported to vary from 4% to 40%.
- Significant modifications of PMMA IOL design have occurred as a result of the developments in surgical methods. PMMA remains a popular material for IOL optics and is still the gold standard against which other materials are compared.
- Only a few studies have compared all three optical lens types. Most of these have methodological limitations and small numbers of subjects.

- At present, there is limited information on which to base decisions regarding the choice of IOL. A large number of IOL products are available, and their safety and effectiveness are functions of a complex interaction between the lens and the surgical procedure. Moreover, there are several different haptic designs and materials available.
- On the basis of the relatively weak scientific evidence that is currently available, foldable acrylic IOLs appear to offer greater short-medium term benefits than other optical lens types in terms of biocompatibility and risk of PCO.
- There is a requirement for standardized definitions and methods of measuring such outcomes as PCO and biocompatibility related to cell densities of the IOL surface. Nd:YAG capsulotomy rate is not an appropriate measure of PCO.
- Best corrected visual acuity may not be an appropriate outcome measure. The use of VF-14, which measures functional impairment, provides information not conveyed through measures of visual acuity.
- Further, good quality studies are required to better define the comparative safety and effectiveness of different types of IOL. These should include measures of improvement in functional status and of quality of life.

GLOSSARY [50]

Anterior Chamber: the space in front of the iris and behind the cornea.

Astigmatism: the refraction of a ray of light is spread over a diffuse area rather than being sharply focused on the retina. It is due to differences in curvature in various meridians of the cornea and lens of the eye.

Capsule: transparent, structureless membrane that surrounds and encloses the lens of the eye.

Capsulorhexis: the making of a continuous circular tear in the anterior capsule during cataract surgery to allow expression or pharcoemulsification of the nucleus of the lens.

Capsulotomy: the cutting of the capsule of the crystalline lens.

Contrast Sensitivity: the ability to perceive differences between an object and its background.

Cornea: the outer, transparent, dome-like structure that covers the iris, pupil, and anterior chamber; principal part of the eye's focusing system.

Endophthalmitis: an inflammation of the inside of the eye that may or may not occur in both the posterior or anterior chamber and/or vitreous.

Intraocular lens (IOL): an artificial lens that is implanted into the eyes of patients who have had their cataracts surgically removed and which is designed to restore the lost focusing power of the removed natural lens.

Intraocular Pressure (IOP): pressure of the fluid inside the eye; normal IOP varies among individuals.

Iris: the colored ring of tissue suspended behind the cornea and immediately in front of the lens; a diaphragm that regulates the amount of light entering the eye by adjusting the size of the pupil.

Kerotometry: determination of corneal curvature at two points about 3mm apart on the central cornea (results are reported as radius of curvature in mm or refracting power in Diopters).

Lens: the transparent, double convex (outward curve on both sides) structure suspended between the aqueous and vitreous; helps to focus light on the retina.

Macula: the small, sensitive area of the central retina; provides vision for fine work and reading.

***Nd:YAG capsulotomy**:* the most commonly used technique for treating posterior capsular opacification, usually referred to as YAG capsulotomy. With this technique, an Nd:YAG laser is used to make a hole in the central part of the lens to improve vision. Nd=neodymium. YAG= yttrium aluminum garnet.

Optic disc/optic nerve head: the circular area (disc) where the optic nerve connects to the retina.

Optic nerve: the bundle of over one million nerve fibers that carry visual messages from the retina to the brain.

Phacoemulsification (PE): a surgical technique that is a modification of the extracapsular cataract extraction procedure. The nucleus of the cataract is fragmented by a probe oscillating at ultrasonic frequency. Nuclear fragments are simultaneously aspirated from the eye. An intraocular lens is then implanted in the eye.

Posterior capsular opacification (PCO): an opacification, or clouding, of the posterior lens capsule left into the eye following modern cataract surgery.

Posterior chamber: the space between the back of the iris and the front face of the vitreous and lens; filled with aqueous fluid.

Pupil: the adjustable opening at the center of the iris that allows varying amounts of light to enter the eye.

Retina: the light-sensitive layer of tissue that lines the back of the eyeball; sends visual messages through the optic nerve to the brain.

Retinal pigment epithelium: the pigment cell layer that nourishes the retinal cells; located just outside the retina and attached to the choroid.

Sclera: the tough, white, outer layer (coat) of the eyeball; with the cornea it protects the entire eyeball.

***Senile cataract**:* an opacification of the natural lens that is formed for no other reason than the aging process.

***Snellen visual acuity test**:* a standard method of measuring visual acuity used during vision tests. Snellen's chart, bearing rows of letters of standard, decreasing size, is set at a predetermined distance from the patient. One eye is covered and the patient reads as far down the chart as possible. The procedure is repeated for the second eye.

Uvea, uveal tract: the middle coat of the eyeball; consisting of the choroid in the back of the eye and the ciliary body and iris in the front of the eye.

Visual acuity (VA): the ability to distinguish details and shapes of objects; also called *central vision*.

Visual field: the entire area that can be seen when the eye is forward, including peripheral vision.

Vitreous: the transparent, colorless mass of gel that lies behind the lens and in front of the retina.

Zonules: the fibers that hold the lens suspended in position and enable it to change shape during accommodation.

Sources: Brunette, Personal Communication
National Institute of Health Intraocular lenses and cataract surgery www.nei.nih.gov/publications/glossary/htm 1998
Taber's Cyclopedic Medical Dictionary. 17th Education, Philadelphia, F.A., Davis Company, 1993

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INTRODUCTION

Cataracts are one of the leading causes of blindness in North America. Cataract surgery is now the most frequently performed surgical procedure in the USA population [65]. More than one million procedures are being performed on Medicare beneficiaries per year at a cost to the Medicare program of more than $3.5 billion [65]. About 50% of Americans between the ages of 65 and 74 years have cataracts [3]. Cataracts are found to be visually significant in 14% of men and 24% of women aged 65 to 74 years and in 30% of men and 46% of women aged 75 years and older [2, 34].

Over the last 15 years, it has been demonstrated that patients experienced improvements in both functional status and quality of life as a result of cataract surgery [74]. Improvements in surgical techniques have made cataract surgery an increasingly safe procedure [1]. These improved outcomes have led ophthalmologists to recommend cataract surgery at better visual acuity levels than previously [32, 55, 78].

In Canada, as in other countries, cataract surgery is on the rise mainly due to an aging population. For example, a report by the Health Services Utilization and Research Commission states that cataract surgery volumes in Saskatchewan grew by more than 250 per cent over an 11-year period, from 1983-84 to 1993-94 and that the province had the second highest rate of cataract extractions in Canada in 1993 [25]. In Manitoba, the public system performed 53% more cataract procedures in 1997 than in 1991 and cataract procedures increased by 290% over the same time period for cataract procedures done in private clinics [70]. Advances in anesthesia procedures, pre- and post-operative care, surgical techniques and the variety of intraocular lenses (IOLs) available have made the removal of cataract with concurrent intraocular lens placement available to many who would otherwise not be eligible for surgery [10, 26, 33, 41].

The IOL is a highly successful technology which is known to be effective and which has transformed the management of cataracts. Advances in this field have been made possible through developments both in surgical procedures and in the design and manufacture of IOLs.

This report has been prepared because of the interest by the Consumers' Association of Canada and the Health Ministry in the increasing use of newer types of IOLs and in their comparative advantage. The focus of the report is on the safety, efficacy and effectiveness of the three types of intraocular lenses (PMMA, silicone, and foldable acrylic).

Multifocal lenses for uncomplicated, age-onset (senile) cataracts have not been considered here although Health Canada has recently approved the use of

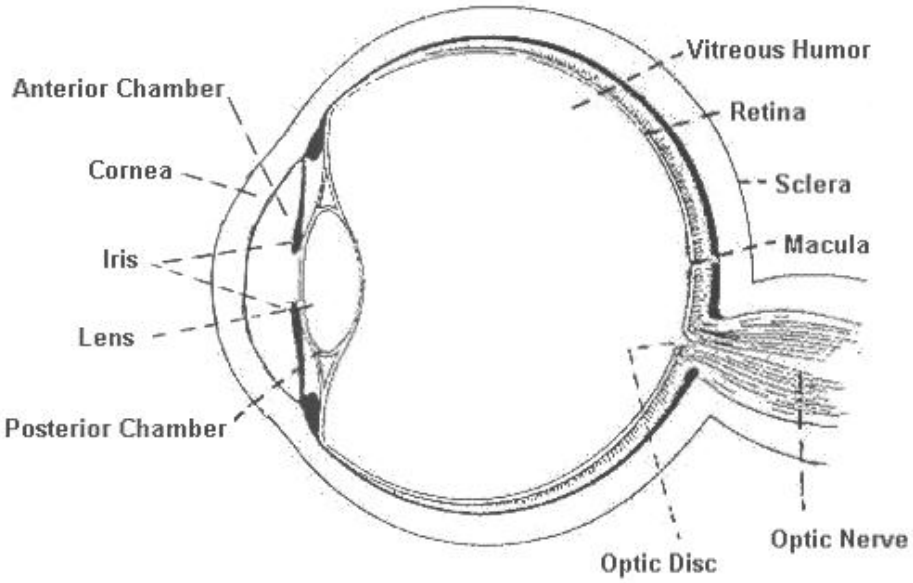
multifocal IOLs. Multifocal IOLs have the potential to surpass monofocal IOLs. Some ophthalmology clinics in Canada are inserting multifocal IOLs (Brunette, personal communication).

The assessment has drawn on a systematic literature search of electronic databases using selected exclusion/inclusion criteria. Details of the methodology are provided in Appendix A.

BACKGROUND

Components of the eye are shown in Figure 1. A normal healthy lens, composed of mostly water and protein, is clear and transparent allowing light to pass unimpeded to strike the retina [4]. The lens is held in place by an elastic capsule and suspensory ligaments. It is located just behind the iris.

Figure 1: Diagram of the eye



Proteins in the lens may clump together resulting in the lsos of transparency. A cataract is an opacity or cloudy area in the lens that can block or scatter light. Once a cataract has developed it grows larger over time and clouds more of the lens, eventually causing severe visual impairment. Studies have indicated that over a one year time period 20% of cataracts get progressively worse and that 65% worsen over a five year time span [53].

The etiology of cataract formation is not fully understood but most cataracts are age related [3]. As yet there are no medical treatments available to prevent the formation and progression of a cataract in a healthy adult eye [2, 3, 19].

Cataract surgery is considered in an otherwise healthy eye when the medical, optical and environmental measures are no longer adequate for the individual's visual requirements [3]. Cataract surgery involves the opening of the front capsule and removal of the lens. Once the lens is removed it needs to be replaced or substituted. The choices are an IOL, a contact lens, or cataract glasses.

Ridley performed the first IOL implantation in England in 1949 using a lens made from the acrylic polymer poly methyl methacrylate (PMMA) [36]. PMMA remains a popular material for IOL optics and is still the gold standard against which other materials are compared [36].

Cataract surgery for the removal of uncomplicated senile cataracts has been evolving over a number of years. Intracapsular cataract extraction (ICCE), which involves removal of the entire lens including the capsule, was the method of surgery fifteen years ago [53]. Following ICCE, the insertion of an anterior chamber IOL is an option. The predominant method of cataract extraction has changed dramatically. An estimated 95% of the procedures for the one million cataracts now being removed annually in the USA by extracapsular cataract extraction (ECCE) [64].

With ECCE only the lens is removed, leaving the capsule intact, and a posterior chamber IOL may be inserted in the capsular bag. This change from ICCE to ECCE in most developed countries has occurred despite the fact that ECCE requires an operating microscope, usually takes more surgical time than ICCE, and may require additional surgery to address opacification of the posterior capsule [50].

The advantages and benefits of using a posterior chamber IOL have driven the change from ICCE to ECCE. These include the reduced risk of such serious complications such as retinal detachment, cystoid macular edema, and vitreous loss [4, 37, 64]. Posterior chamber IOLs are the focus of this assessment. Evaluation of the different surgical methods and intraoperative techniques, types of anesthesia, viscoelastic substances and post surgical treatments are outside the scope of this report.

SURGICAL PROCEDURES

Types of surgical ECCE procedures

There are two basic techniques for removing the human crystalline lens nucleus using the ECCE procedure [50]. The anterior capsule is opened in what is termed as capsulotomy. In the case of standard ECCE the "can opener" capsulotomy was the technique used most frequently.[19, 53]. The nucleus is expressed with gentle pressure inferiorly such that the lens is partially dislocated in its entirety into the anterior chamber and out of the eye through the incision in the cornea [15]. The remaining cortex is aspirated, the IOL is implanted, and the wound or incision is sutured [15].

During the 1980s and, particularly the 1990s, phacoemulsification (PE) surgery became increasingly popular [52]. In 1997 PE was the technique preferred by 90% of members of the American Society of Cataract and Refractive Surgery [64]. One of the fundamental steps in PE involves the fashioning of a well positioned and adequately sized continuous curvilinear capsulorhexis (CCC) [15, 16, 84]. PE breaks up the nucleus with an ultrasound probe inserted through the incision and removes the nucleus and lens cortex by manual or automated aspiration [50]. This method requires a smaller incision than standard ECCE and fewer if any sutures.

The choice of technique (either standard ECCE or PE) does not seem to influence the postoperative visual acuity [70]. In 1992 an International Cataract Surgery Outcome Study was set up to assess the impact of variation in the management of cataract and surgical technique across health care systems in Manitoba, the United States, Barcelona, and Denmark [55]. Mean best-corrected post-operative visual acuity on a Snellen chart was the measure of outcome. The crude visual outcome measurements varied significantly across all health systems. However, the risk of poorer visual outcome was not significantly different across the health systems for patients with no ocular morbidity after controlling for differences in pre-operative visual acuity, age, and general health status. This indicates that patient-related factors, rather than differences in medical management, affects visual acuity after cataract surgery.

There are also different phacoemulsification techniques. Dick et al. published a study in 1996, which evaluated post-operatively (2 to 5 days; 6 months; 1 year), the effect of mean PE time (116 ∀ 45 sec) and mean ultrasound power (23.7 ∀ 8.5%) using endothelial cell counts as a measure [12]. They found a direct linear relation between endothelial cell loss (ECO), ultrasound time, and power. Their sample size was small with fewer than 60 patients. Kohlhaas et al. [35] conducted a study using the "reversed tip and snip" phacoemulsification technique on half of the patients and the "divide and conquer" technique on the other patient group. Using ECO as the measure of outcome, length of operation and phaco

energy per second was not signficant between groups. However, the phaco time was significantly shorter in the "reversed tip and snip" group. This group also showed significantly less ECL.

Systematic reviews on effectiveness of surgical procedures

Powe et al. performed a meta analysis of the ophthalmologic literature (1975 to April 1991) on clinical outcomes, defined as visual acuity (VA) and complications, and on differences in outcomes according to technique of cataract extraction with IOL implantation [64]. This meta analysis was a source document for the development of guidelines by the Agency for Health Care Policy and Research (AHCPR) [2]. Powe et al. concluded that cataract surgery yielded excellent VA results (20/40 or better) in approximately 95% of eyes without pre existing ocular comorbidity and is a relatively safe procedure whether performed with PE or manual expression of the crystalline lens.

The NHS Centre for Reviews and Dissemination published a systematic review in 1996 on the evidence of effectiveness of treatment for people with cataract [53]. They found that PE is increasingly believed to be more effective than standard extracapsular surgery. At the time of their review no completed randomized controlled clinical trials (RCTs) directly comparing visual acuity and health outcomes, complications or costs were identified.

Complications

Ng and colleagues noted that individual surgeons switching from standardized ECCE to PE should expect an increase in surgical complication rates during the learning curve [52]. Surgical complications include anterior and posterior capsule tears, vitreous loss, lens matter dislocation into the vitreous cavity, zonulysis, luxation of the lens in the vitreous, and corneal endothelial trauma. Their study demonstrated a decrease in the incidence of complications as an individual surgeon accrued experience. Complication rates dropped to a low baseline level after 150 cases.

Schein and colleagues [70] compared adverse outcomes in patients of ophthalmologists who performed different volumes of surgery. Differences in patient adverse outcomes were noted for those ophthalmologists who carried out more than 200 but less than 400 procedures a year and those who performed between 51 - 200 annually. There was no significant difference in adverse outcomes at found months after surgery between the two groups of patients, nor was there any difference in visual improvement. However, a significant association was found between surgical volume and reported posterior capsular opacification and Nd:YAG laser discission within four months after surgery. It was suggested that surgeons with higher caseloads may have had a lower reporting thresthold for this complication.

Norregaard et al. [54] expanded the study of Schein and colleagues by including ophthalmic clinics from Manitoba, Denmark and Barcelona. They examined intraoperative clinical practice and rates of adverse events after cataract surgery across the four health care systems. The USA (6%) had a significantly lower rate of intraoperative adverse events compared to the range of 11-13% for Manitoba, Denmark and Barcelona. Post-operative events were significantly higher in the USA (19%) and Manitoba (20%) compared to Denmark (7.9%) and Barcelona (5%). These variations could not be explained by patient characteristics or surgical techniques. PE was performed in two-thirds of the extractions in the USA and Manitoba, but only in one-third in Denmark and 3% in Barcelona.

Issues for consideration with any surgical cataract procedure are incision length, location, configuration and depth; and the complex phenomena of wound healing [57]. The incision is considered to be the most important step of the operation since it affects ocular integrity and corneal stability [38].

The configuration of the incision has some affect. For example, a frown-shaped incision is said to be more stable than either an arcuate or a chord incision [57]. Most surgically induced astigmatism (SIA) is due to changes in corneal curvature [4]. A small incision is preferred as it is believed to reduce incidence, severity, and duration of post-operative astigmatism [4].

The interest in PE is due to the opportunity to perform cataract surgery with a small incision size, with or without sutures. The advantages of smaller incisions (3.2 to 4.0mm versus 5.0 to 5.5mm), are decreased SIA, fewer post-operative complications and possibly less inflammation, and faster rehabilitation [31, 36, 48, 63, 76]. Advantages such as these have encouraged cataract surgeons to use foldable IOLs. PMMA lenses require larger incision size, as they are inflexible [31, 36, 80].

Posterior capsule opacification

The change in technique from ICCE to ECCE has been accompanied by a new and significant problem, posterior capsular opacification (PCO) [58, 69]. PCO or "secondary cataract" is the most common cause of visual morbidity for patients who have undergone uncomplicated ECCE [8, 53, 58, 69].

PCO, opacification of the posterior capsule, the part of the lens left "intact" or "in place" after ECCE, causes clinically significant visual impairment in approximately half of patients within two to five years of the procedure [4, 9, 81]. The proliferation of remnant lens epithelial cells across the posterior lens capsule appears to be the primary underlying cause of the opacification [9]. Currently, there is no way to predict the extent to which patients who have primary cataract surgery will develop PCO [9]. In general, the older the patient, the lower the frequency of capsular opacification [4].

The surgical procedure used (standard ECCE or PE) does not seem to influence the occurrence of PCO [70]. The meta analysis by Powe and colleagues was unable to show a statistically significant difference between standard ECCE and PE in the proportion of eyes with PCO [64]. The proportion of eyes with PCO varied from 0.67 to 38.5% for PE compared to 0.8 to 47.6% for standard ECCE.

A meta-analysis of MEDLINE literature indexed between 1979 and 1996 found that the overall pooled rates of visually significant PCO incidence in patients undergoing standard ECCE or PE were 11.8% at one year, 20.7% at three years, and 28.4% at five years after surgery [69]. No specific risk factors were identified. More precise estimates of incidence and identification of risk factors will depend, in the opinion of the authors, on the development of a standardized measurement of PCO and more rigorous research design in future studies.

The most convenient method for treating PCO is Nd:YAG laser capsulotomy. The Nd:YAG laser produces breakdown of optical tissues through the application of light in the infra-red range [4]. A "window" of cleared vision is created and the opened capsule usually folds back out of the visual axis. In almost all cases this creates a permanent cure. Surgical capsulotomy is an alternative option [8].

Even though Nd:YAG laser capsulotomy has replaced, in most cases, the invasive needling procedure, it is not without complications [58]. Post-operative elevation of intraocular pressure, acute inflammation, intraocular lens dislocation, damage to the IOL, cystoid macular edema, disruption of the anterior vitreous face, and increased incidence of retinal detachments have been reported [4, 58, 69]. A USA study of 14,000 Medicare patient records suggest that patients who underwent Nd:YAG laser treatment had four times the risk of a detached retina, which can lead to permanent blindness [72].

The incidence of damage to IOLs by Nd:YAG laser has been reported to vary from 4% to 40% [51]. Newland et al. note that IOL damage may have many causes. One of the important variables is the type of optic polymer used in the IOL [51]. In their study of three optic polymers (Acrylic MA60BM, PMMA MC60BM, Silicone AQ1016) they found that the silicone polymer exhibited statistically significantly more damage than the other materials at all energy levels. The issue of effect of the IOL damage on functional vision was not addressed.

Incision size, SIA, and wound management issues

Small incision cataract surgery with foldable intraocular lens implantation is designed to offer rapid visual restoration, physical recovery and optical stability by minimizing changes in corneal curvature [47]. The incision size is dictated by the surgical procedure and the type and style of the intraocular lens. There is an

increased interest by cataract surgeons in both the rapidity with which stable levels of post surgical VA are obtained for their patients and the level of uncorrected VA in regard to assessing the relative merits of small versus large incision cataract surgery [64].

Over the last few years use of the 5mm incision decreased and use of the 3mm incision increased, both significantly [33, 42, 61, 77]. A larger incision size has been correlated with increased post-operative blood aqueous barrier damage [81]. It has been postulated that this increases the protein content and cells in the anterior chamber, which may lead to increased cases of post operative inflammation [66].

Forces acting on the incision wound after cataract surgery may be either with or against the rule [57]. Forces that relax the wound result in against the rule (ATR) shift and forces that tighten the wound result in with the rule (WTR) astigmatic shifts. The incision is the major cause of astigmatic shifts. Suture technique can have either effect [76]. Sutures may also stabilize the wound during healing depending on number, length, depth, and tightness of the sutires [57].

Decision on the location of the incision (scleral or corneal, superior, temporal or oblique) may be further impacted if preoperative astigmatism is present [67]. Roman and colleagues concluded that superior corneal incision produced significant SIA, leading to increased postoperative astigmatism and poor uncorrected visual acuity [67].

In a randomised, multicentre study Steinert and colleagues [76] used three common analytical methods to measure changes in keratometric cylinder: simple substraction, the axis induced cylinder method of Cravy, and Vector analysis method by Jaffe and Clayman. These methods were used to calculate induced astigmatic changes. The differences between the results as calculated by each of the methods are noteworthy. The Jaffe and Clayman method gives a higher mean value than the other two methods. Therefore, outcome results will vary depending on the choice of method for calculating SIA. Astigmatism associated with surgery is a controversial issue. Powe et al. exluded astigmatism as a measure of clinical outcome in their meta-analysis [64].

INTRAOCULAR LENSES

The advent of small incision cataract surgery and the development of PE by Kelman in the late 1960s stimulated the search for new IOL materials [29, 31, 36, 59, 80]. Optics produced from materials such as silicone elastomers, nonhydrogel acrylics (commonly referred to as acrylics) and hydrogel acrylics (commonly referred to as hydrogels) are now available [31, 39, 80]. Hydrogel acrylics, such as poly hydroxyethylmethacrylate (PolyHema), have a water content varying from 18% to 38% [39].

The decision on what type of lens to use is usually based on surgeon preference and training [56]. Results from surveys indicate an increasing trend for the use of foldable IOLs in cataract and refractive surgery by American, German, and Japanese surgeons [36]. However, PMMA is still the most frequently used material for artificial IOLs.

Significant modifications of PMMA design have occurred as a result of the introduction of PE and small incision surgery. Modifications include decreasing the total diameter and optical size and reducing the optic/haptic angulation to near planar to accommodate the new developments in cataract surgery [13].

Mechanical/technical considerations

An IOL basically consists of two components: the haptic and the optic. The haptic of a posterior chamber IOL fixes the IOL in the capsular sac. Haptics come in different configurations (plate, disc, C or J loop) and may be made from materials that are different from that used for the optic. For example, a silicone lens may have a PMMA loop. Manufacturers have modified the angulation of the loops to position the lens optic at the greatest possible distance from the anterior segment structures, thereby decreasing the contact between them and the posterior capsule [13].

Because of the different materials available for the manufacturing of IOLs and the various possible designs, IOLs differ in their refractive indices, water content, surface properties, clarity, and mechanical strength [36]. With the large number of IOL models available, controversy remains about the ideal lens to implant in regards to safety, effectiveness and costs [71, 80].

IOLs are usually examined by the manufacturer for optic and haptic surface quality, edge finish, haptic/optic junction, and, specific for foldable IOLs, post folding consequences [59]. Mechanical trauma due to rough, irregularly finished edges, and haptic/optic junctions can cause damage to delicate intraocular tissues, which may then be associated with such complications as uveitis-glaucoma-hyphema syndrome, corneoretinal inflammatory syndrome, chronic inflammation, pigmentary dispersion, or glaucoma [39, 59]. Irregular sites

on the lens allow for the deposition and accumulation of inflammatory cells. Although important in the past, manufacturing defects such as these have been essentially eliminated (Koch, personal communication).

There are different folding methods and also different techniques for inserting foldable lenses such as cartridge injectors or forceps [56, 63, 72]. Post folding consequences, in particular referring to silicone lenses, are due to folding procedures place significant strain on the lens which may result in tearing, cracking, or indentation [59, 72]. The earlier silicone lenses were more difficult to fold because of their low refractive index and relatively high optical thickness [71]. Silicone lenses are generally not easy to handle when wet because they are slippery [71].

Foldable acrylics have a higher refractive index (1.55) than silicone lenses (1.47), fold more easily and can be handled when wet. However, acrylic is temperature sensitive and if the lens becomes too warm it may become sticky and unfolding can be difficult [71]. Hydrogel lenses, with a refractive index of 1.47, may fold and unfold faster than acrylic lenses and are more controllable than silicone lenses, but they must be kept hydrated until implantation because of their water content [71].

Biocompatibility

Several investigators have demonstrated the importance of surface properties for IOL safety, particularly for the lens' long term biocompatibility [39]. Some degree of foreign body reaction occurs in all eyes after cataract surgery with IOL implantation, regardless of the IOL material. This leads to a dynamic interaction between the device and the host tissue.

Biocompatibility, as defined by Hollick et al., is the ability of a material to perform a specific application with an appropriate host response [29]. However, no material is completely inert within the body. Even though PMMA is considered not to be biologically degradable and the degree of foreign body reaction is relatively low, clinical and histological studies have shown that PMMA is not as biologically inert as originally thought [66]. There has been recent work to reduce cellular reactivity to PMMA. Research is continuing to find ways in which to modify the len's surface.

Two basic surface modifications have been studied: heparin and surface passification [66]. Heparin modification should reduce the molecular interaction between the PMMA lens surface and the biologic environment of cells. Surface passivation makes the lens' surface infitinely smooth and thereby it resists cell adhesion [66].

Surface qualities of IOLs have been shown to influence post-operative inflammation and long term acceptance of the IOL [39]. Cellular proliferation on

the surface of an IOL is an indication of the biocompatibility of the lens material. The presence of cellular deposits on the surface of IOLs is a manifestation of the breakdown of the blood-aqueous barrier produced by surgery; cellular response on the anterior surface of the IOL; and cellular infiltration of the posterior capsule [29, 66].

Ravalico and colleagues suggest that several factors influence cellular reaction: preexisting or predisposing condition such as chronic uveitis, diabetes mellitus or glaucoma; nature and quality of the surgical procedure; and post-operative inflammatory reaction and therapy [66]. However, the clinical significance of biocompatibility of IOL materials is unclear (Koch, personal communication).

Decentration and tilt

The two major complications of the earliest foldable IOLs implanted in the capsular sac or bag were decentration and tilt [83]. Factors affecting an IOL's position after surgery can be grouped into three categories: the normal anatomical configuration of the crystalline lens and capsule; the surgeon's operative technique; and the IOL type and design [83]. Slight decentration and tilt exists even after the ideal operative technique and implantation [22]. The most common cause of decentration and tilt is that the IOL is not completely captured within the capsular bag [4, 83]. Lens decentration and tilting are the most common reason for silicone IOL explantation [80, 83].

The method of performing anterior capsulotomy (by either the "can opener" or CCC technique) is an important factor that affects IOL centration [83]. CCC has been found to be surgically safer and associated with significantly fewer radial tears of the anterior capsule since the absence of jagged edges confers elasticity [80, 83, 84]. Following surgery, the relationship of the anterior capsule to the IOL is dynamic [80]. The most commonly reported complication of CCC is the reduction in the equatorial diameter of the capsular bag, fibrosis of the anterior capsule and shrinkage of its opening [17, 23, 84].

Severe contraction of the capsulorhexis opening may lead to capsular phymosis syndrome [80, 84]. In this instance the capsule opacifies and the reduction in the area of the anterior capsule opening is sufficient to obscure the optical axis and the patient may require laser treatment [23]. Marked capsular shrinkage may also decentre the optic by asymmetric bay contractive [80, 84]. Contraction of the capsulorhexis opening as well as the rate of PCO appear to be related to the size, shape, and symmetry of the contact between the IOL and the CCC [80].

From a technical aspect, appropriate capsular fixation of IOLs provides the best and most consistent centration [83]. Several studies have concluded that the design and material composition of the haptic influence centration and tilt [14, 17, 22]. Fruscella and colleagues conducted a prospective study to evaluate

post-operative decentration with respect to the loop material and the IOL fixation technique [14]. They observed more decentration with IOLs that had polypropylene loops than those with PMMA loops. It was suggested that this may be due to the fact that IOLs with more rigid loops and a firmer structural memory can better offset any eventual contraction and hence better resist decentration.

Another study looked at haptic design (loop versus plate) and found that it had an effect on the change in size of the CCC [17]. The plate haptic IOL group demonstrated a significant construction of the CCC compared to the loop haptic group. However, another study conducted by Hayashi et al. found no difference in decentration and tilt regardless of the haptic loop material, as long as the IOL was implanted accurately in the capsular bag [22]. Appropriate in the bag placement seems to be the most important aspect influencing decentration and tilt, not the haptic design or material.

Regulatory status

The U.S. Food and Drugs Administration (FDA) first approved silicone IOLs in 1990 and foldable acrylic as a lens material in December, 1994 [71].

Health Canada (Lapner, personal communication) advised that Canadian experience with regulation of IOLs is comparable to that in the U.S. which is reported in the medical literature [73].

In Canada, PMMA IOLs have been implanted after cataract surgery since the early 1970's. The Canadian Medical Devices Regulations were promulgated in the early 1980's so that the original IOLs were 'grandfathered'. Silicone IOLs have been available in Canada for approximately ten years, and the first hydrogel IOLs received pre-market clearance in Canada two years ago (Lapner, personal communication).

Details of the IOLs used in the studies of efficacy/effectiveness are provided in Appendix B. It is interesting to note how few of the IOLs included in the studies located for this assessment are available in Canada (5/14 PMMA lenses, 4/9 silicone lenses and 2/3 soft acrylate lenses). Considering this assessment included studies from 1991 onwards, this demonstrates how fast these IOLs are becoming obsolete as newer versions replace older product designs. There is a wide range of costs per lens, from $50 to $694, with an average cost of about $300 per lens.

COMPARATIVE STUDIES OF EFFICACY/EFFECTIVENESS

Nineteen studies that compared lenses are summarized in Appendix C. Authors of four of the studies [23, 58, 63, 81] published extensions of their earlier work. These are also included as separate studies [20, 22, 28, 29, 60, 80] in the Appendix. Highlights of these comparative studies are presented in Table 1.

Five studies focused on the differences in ***decentration and tilt*** among the lenses. All of these studies compared PMMA and silicone lenses except that of Hayashi et al. [22] which compared all three optical lens types. There were no statistically significant differences among the three lens types. Ursell and colleagues [80] measured the amount of anterior capsule movement with the PMMA, AcrySof®, and silicone lenses. They found that capsule movement was greatest within the first three months following surgery and was statistically significantly less for AcrySof® compared to PMMA and silicone IOLs.

Three studies provided results of ***cell density measurements on lens' surfaces*** using specular microscopy. Ravalico et al. [66] considered five groups of patients, one with a standard PMMA lens, two groups with surface modified PMMA lenses, one group with the hydrogel lens and the fifth group with the silicone lens. Thirty days after surgery, epithelioid cells were observed on 80% of the conventional PMMA IOLs, 20% of surface modified PMMA IOLs, and no cells were seen on silicone and hydrogel lenses. Their results were statistically significant even though there were only ten patients in each of the five groups.

Hollick and colleagues [29] reported maximum small and giant cell grades over a two year period and found that the silicone (90%) lens had significantly more small cells than the PMMA (50%) and AcrySof® (53%) lenses. In relation to the maximum giant cell grades over two years the AcrySof® lens had no giant cells while giant cells were detected on both the PMMA (40%) and silicone (33%) lenses. From a clinical perspective, giant cell counts are the most important. The authors note, however, that a third group of cells, the lens epithelial cells (LECs) which remain after surgery, are those that migrate onto the anterior lens surface and the posterior capsule. On the anterior lens surface LECs form a fibrotic capsulorhexis rim. On the posterior capsule LECs may lead to PCO. The authors conclude that AcrySof® IOLs have a higher degree of biocompatibility.

Three studies reported on ***changes in the CCC size*** and used different measuring systems or analyses. One study [17] found that the haptic design had an effect on change in size of the CCC. The study by Hayashi et al. [23] found that the percentage of area reduction with the silicone lens was significantly larger than that for the PMMA and foldable acrylic lens. In their study both the silicone lens and the foldable acrylic lens had loop haptics made from PMMA.

Eight studies compared ***PCO rates and visual acuity***. Ursell and colleagues [81] used the standard ECCE method while the other three studies [20, 58, 63] performed ECCE using PE. Two studies did not indicate if a pre-operative visual acuity test was performed. Olson and colleagues [57, 58] noted a statistically significant increased PCO score with the PMMA lens and a statistically significant benefit in uncorrected visual acuity with the silicone lens. Another study by Oshika and colleagues [60] noted that the cumulative rate of PCO was higher for the silicone lens group over a three year period compared to the PMMA lens group. The noted differences were not statistically significant.

Ursell et al. [81] did not find a statistically significant difference among the three lenses (PMMA, silicone, AcrySof®) in corrected Snellen visual acuity at two years. They did note a significant beneficial decrease in PCO with the AcrySof® lens compared to PMMA and silicone. A three year follow-up study by Hollick and colleagues again showed a statistically significant decrease in percent PCO and Nd:YAG capsulotomy rates for the foldable acrylic. Hayashi et al. [19] noted a statistically significant increase in the mean PCO value for the PMMA lens groups compared to the silicone and foldable acrylic lens groups at two years. They concluded that the greater degre of PCO with the PMMA IOL is attributable to the optic material.

Ursell and colleagues [28] observed that the mechanism by which IOL material influences PCO is unknown. Mechanical changes in IOL design or the optic and haptic materials may influence PCO. All three lens types in their study were of similar size and biconvex design. The AcrySof® lens has a thinner optic than the PMMA and silicone lenses due to its higher refractive index and more defined squarer edge profile. It is theorized that the anterior capsule is more stable on the anterior surface of an AcrySof® IOL than on silicone and PMMA IOLs resulting in greater IOL-capsule adhesion for the AcrySof® IOL and thereby decreasing the risk for PCO.

It is difficult to compare the results from these studies for several reasons. The surgical techniques differed somewhat; the inserted IOLs were of a variety of types, designs and configurations; and there was no standardization in the methods for measuring the outcomes of relevance. For illustration, dissimilarities included the surgical technique and use or non-use of sutures; incision depth, location and configuration; techniques for folding and inserting flexible IOLs; unique methods for measurement of outcome of interest and different measurement systems or analyses to determine the same outcome. Moreover, it is not clear to what extent statistically significant outcomes are clinically significant.

Table 1: Summary of comparative studies

Author/ study design	Total samples	# of groups and lens type	Outcome of interest	Statistically significant (SS) study conclusion
Martin & Sanders [46] 1992 Randomized comparative	112	N = 58 silicone N = 54 PMMA 1 year FU results not provided consistently	Corrected and uncorrected VA **Flare and cell measurement** Cell density	Day 1 – SS enefit for silicone lens grp for best corrected VA, flare and cell measurements, mean keratometric cylinder. 3 months – SS benefit for silicome lens grp for best uncorrected VA and mean keratometric and refractive cylinders
Olson, Crandall [58], 1998 Randomized comparative	119	N = 60 silicone N = 59 PMMA All results reported at 3 years of follow up on N = **84**	**PCO** measured by opacity meter, laser capsulotomy rate and slit lamp evaluation	Silicone lens group (8.6%) had SS less PCO than PMMA group (10.4%) by lens opacity meter. Laser capsulotomy rates no SS difference. Slit lamp PCO scoring for silicone lens group (0.88) was less than PMMA group (1.79)
Olson. Crandall [57] 1998 See [58] Randomized "best case review"	111	N = 55 silicone Results reported at 3 years of follow up N = **26** N = 56 PMMA Results reported at 3 years of follow up N = **29**	**Snellen Uncorrected visual acuity** (LogMAR), pre and post	Silicone lens group SS difference in favor of the silicone lens group (0.14 versus 0.26 for the PMMA group)
Holweger, Marefat [30] 1997 Randomized comparative	200	N = 100 silicone N = 50 PMMA radial suture N = 50 PMMA X suture	**Corneal endothelial cell count** (Cooper Vision HR 750) Corneal topography (Computed Anatomy TMS-1, 25-ring cone), pre and post	Follow up of 6 to 9 months did not show any SS results in corneal endothelial cell count & grading of IOL centration
Oshika et al. [63] 1994 Multicentre randomized comparitive	200	N = 93 silicone sample fluctuated follow up of **66 to 75** N = 89 PMMA sample fluctuated from **65 to 74** during follow up visits	Snellen **visual acuity** and **keratometry**, pre and post	Uncorrected visual acuity SS better in silicone lens group than the PMMA lens group at day 1, 2 weeks and 1 month At 1 week, 3 and 6 months no SS results between the groups for uncorrected visual acuity

Table 1: Summary of comparative studies (cont'd)

Author/ study design	Total samples	# of groups and lens type	Outcome of interest	Statistically significant (SS) study conclusion
Oshika et al. [60] 1998 See [61]	200	N = 99 silicone sample fluctuated from **46 to 98** N = 98 PMMA sample fluctuated from **43 to 96**	Cumulative rate of PCO (%)	Rate of PCO was higher for silicone lens group for each FU period over a 3 year FU but difference was not SS
Zambarak et al. [84] 1997 Prospective comparison	64	N = 29 PMMA N = 35 silicone	Slit lamp change in **anterior capsule area or CCC change**	Change in capsular area for PMMA lens group for period 1 (day 1 to 6 weeks) –16.14% and for period 2 (6 week and 6 months) –2.4% was SS. Change in capsular area for silicone lens group for period 1 –19.9% and for period 2 –7.5% was SS Difference in % change between the 2 groups was SS better for PMMA lens
Wang et al. [83] 1998 Prospective comparative	70	N = **24** PMMA N = **17** silicone	Scheimpfllug photography using EAS-1000 (Nidek) **Tilt/decentration**	No differences were found in the amount of tilt and decentration between PMMA lens and the silicone lens over the 6 month period
Gonvers et al. [17] 1997 Prospective comparative	85	N = 29 silicone (PMMA haptic) N = 26 PMMA N = 27 silicone	**Inflammation of anterior chamber** measured pre and post with Kowa flarecell meter **CCC measured** using Zeiss slitlamp & Agfa Studioscan®	The CCC mean decrease or constriction in the silicone lens without the PMMA haptic group was SS. No SS change in CCC between PMMA lens and the two silicone lens groups The PMMA group had a SS increase in inflammatory response compared to the silicone lens with the PMMA haptic.
Kohnen et al. [38] 1995 Randomized comparative	60	N = 20 plate haptic silicone N = 20 silicone disc N = 20 PMMA	Computerized videokeratography (EyeSys Laboratories Inc.) **Surgical Induced Astigmatism**	SIA was significantly lower in the plate haptic silicone lens group with a 3.5mm incision than in the disc silicone (4.0mm) and PMMA (5.0mm) lenses groups.
Jacobi et al. [31] 1995 Retrospective "Best" post op case series	42	N = 15 PMMA N = 15 silicone plate N = 12 silicone disc	**Contrast sensitivity** under photopic light using Vistech wall chart with 3 orientations Contrast sensitivity and **glare disability** under mesopic light using Mesotest	No SS difference among the three lenses groups in contrast sensitivity and glare disability over the 6 month follow up.

Table 1: Summary of comparative studies (cont'd)

Author/ study design	Total samples	# of groups and lens type	Outcome of interest	Statistically significant (SS) study conclusion
Ravalico et al. [66] 1997 Randomized comparative	50	N =10 PMMA N =10 surface passivated PMMA N =10 heparin surface modified PMMA N =10 poly-HEMA hydrogel N =10 silicone	Slit-lamp to identify specific areas of **high-density cells** examined by Konan specular microscopy & photographs. Snellen post op **visual acuity**	SS results at all periods of follow up 7,30, 90 and 180 days. Surface passivated and heparin surface modified PMMA showed less cell deposits than conventional PMMA. Silicone and foldable acrylic compared to conventional PMMA had less cellular reactivity. Mean best corrected VA not SS.
Hayashi et al. [23] 1997 Randomized Comparative	225	N =74 PMMA N =73 silicone N =78 foldable acrylic	Anterior Eye Segment Analysis System (EAS-1000) **Change in anterior capsule area or CCC change**	Mean percent of area reduction of anterior capsule opening in PMMA lens group and foldable acrylic group were SS less than in the silicone lens group at 1,3 & 6 months.
Hayashi et al. [22] 1997 See [23]	225	N =74 PMMA N =73 silicone N =78 foldable acrylic	Anterior Eye Segment Analysis System (EAS-1000) **Tilt/decentration**	No SS difference in decentration and tilt among the three lens types over the 12 months of follow up.
Hayashi et al. [20] 1998 See [23]	212	N = 69 PMMA N = 70 Silicone N = 73 foldable acrylic	Anterior Eye Segment Analysis System (EAS-1000) Arial densitometry Scheimpflug videophotography **PCO**	Mean PCO value in PMMA group SS increased than the silicone lens and foldable acrylic lens groups at 2 years. No SS difference between silicone lens group and foldable acrylic lens group.
Ursell et al. [81] 1998 Randomized Comparative	90	N =30 PMMA N =30 silicone N =30 foldable acrylic	Standardized retroillumination images of posterior capsule using Zeiss 120 slit lamp **PCO**	SS results in % PCO among all three groups at two years. SS less % PCO in the foldable acrylic lens group than the PMMA and silicone lens groups.
Ursell et al. [80] 1997 See [81] Randomized comparative	90	N =30 PMMA N =30 silicone N =30 foldable acrylic	Standardized digitized retroillumination imaging to measure **anterior capsule movement;**	Capsule movement similar for PMMA and silicone lens groups but SS less for the foldable acrylic lens group over the four time period (7 to 30 days; 30 to 90 days; 90 to 180 days; 180 to 360 days).

Table 1: Summary of comparative studies (cont'd)

Author/ study design	Total samples	# of groups and lens type	Outcome of interest	Statistically significant (SS) study conclusion
Hollick et al. [29] 1998 See [81] Randomized comparative	90	N =30 PMMA N =30 silicone N =30 foldable acrylic	Specular microscopy of anterior IOL surface using Zeiss slit lamp **Cell density**	Silicone lens group had SS more grade 1 small cell response than PMMA lens group and foldable acrylic lens group over 2 years. Foldable acrylic lens group had SS less grade 1 giant cell response than PMMA lens group and foldable silicone lens group over 2 years.
Hollick et al. [28] 1999 See [81]	64	N = 23 PMMA N = 22 Silicone N = 19 foldable acrylic	Standardized retroillumination images of posterior capsule. 15 LogMAR visual acuity with Early Treatment Diabetic Retinopathy Study Chart Contrast and sensitivity with Pelli Robson Chart	Foldable acrylic lens group had SS reduction in % of PCO and Nd:YAG capsolutomy rades. Compared to PMMA and silicone lens groups.

Quality of comparative studies

Although SIA is mentioned in Table 1, this outcome measure will not be compared or discussed due to the controversy regarding the reporting and interpretation of this outcome [38, 58, 63]. Different analytic methods are used to calculate induced astigmatic changes. Furthermore, most studies do not identify those individuals with pre-operative astigmatism. Since pre-operative astigmatism may impact severity of SIA, interpretation of reported outcomes may be biased.

Few studies were found that compared all three optical lens types. Seven randomized controlled studies, three of which compared all three optical lens types, were located. Most of the RCTs were not well designed and had relatively small numbers in each group ranging from 10 to about 70 individuals.

Studies with randomized design included in Table 1 either randomized patients according to incision size (which then determined the lens to be implanted) or by the sealed envelope method. The largest randomized comparative study of the three optical lens types, by Hayashi et al. [22, 23], enrolled 225 patients who were assigned by the sealed envelop method. Most studies also controlled for surgical disparities by having only one or, in some cases, two surgeons perform all of the procedures.

Most researchers did not attempt to blind the evaluators, identify the number of evaluators, their qualifications, or their affiliation with the study. It is understood that even when the evaluator was blinded to the type of IOL implanted, it was possible to recognize the style of IOL from the microscopic examination or other measurement systems utilized. However, the evaluator could be someone who has no interest in the outcome of the study or was blinded to its purpose. Use of only one evaluator might be considered to improve consistency of measuring outcomes.

Heterogeneity within the study groups was an issue. Many studies did not account for losses to follow up and did not present group-specific results. Within the study groups there were large age ranges and length of follow up within some of the case series studied varied by six months or more. As well, there was no consistency in how cases were counted. Sometimes the number of eyes were provided and at others the number of patients.

Number of cases lost to follow up in the older age group is an issue and attempts should have been made to explain these losses or to compare this group to those that completed the study. Many of the studies did not include the "lost to follow up" cases in reporting their results, hence introducing bias by not measuring outcome based on the number intended to treat. As noted by Jacobi and colleagues [31] some researchers choose to include "best cases" only for optimum

surgical outcome, thus limiting the generalizability of the results to the general population of uncomplicated senile cataracts.

Others have emphasized [64] the lack of standard protocols for the performance of measurements and lack of consistency in the measurement systems used to evaluate the clinical outcome. Evaluation of outcomes for the three types of optical lenses may vary due to the evaluative capability of the measurement systems. For instance, the surface cytology is easiest to see on the AcrySof® lenses because of their high refractive index and is most difficult to see on silicone IOLs which have the lowest refractive index of the three IOL types [29].

The American Academy of Ophthalmology suggest that the simple Snellen acuity, although not a definitive measure of visual dysfunction, is the most universally used index of visual functioning and a technique that is reasonably standardized [3]. Most studies use this measurement system but there are inconsistencies. Some researchers do not provide pre and post examination results. In some instances either the best corrected visual acuity or best-uncorrected visual acuity are presented, rather than both. Furthermore, only in a few instances were study groups divided by their visual acuity scores and then compared using other outcome parameters [63].

Olson and Crandall [57] noted that the incidence of visually significant PCO varies dramatically from study to study, for a host of reasons. Since PCO can occur from months to years after surgery, it has been found that the proportion of patients who experience this complication increases with length of follow up [44, 53, 58, 66, 79].

There is a need for standardized definitions and clinically significant quantitative ranges for such outcomes as PCO and biocompatibility related to cell densities at the IOL surface. As noted by Schaumberg and colleagues [69] there was no standardized definition for PCO and relying on capsulotomy rates fails to distinguish the different degrees of opacification. Hayashi et al. point out that numerous studies use subjective measures of PCO [21]. They suggest that Scheimpflug videophotography system would be a measurement system of choice since it is correlated with visual acuity and they have shown it to have excellent reproducibility.

Summary of findings from comparative studies

Eleven studies compared lenses composed of either PMMA or silicone optics. Four of these studies used the same set of patients but split their outcome measures and reported them separately [57, 58, 60, 63]. There was no statistically significant difference identified between the two optics in relation to decentration and tilt at six to nine months after surgery [30, 83, 84]. Earlier (one week, two weeks, and one month) uncorrected VA was significantly better with

silicone optics but no statistically significant difference was seen between the two lenses at three to six months [63]. A smaller study [57] with long term follow-up on less than 100 cases found a significant benefit for the silicone optic at three years for uncorrected VA. Percentage of PCO at three years, as measured by lens opacity meter, was 8.6% for patients with the silicone optic and 10.4% for patients with the PMMA optic. This was a statistically significant result. The authors do not state whether this is a clinically significant result. Oshika et al. [60] did not find a statistical significant difference in the cumulative rate of PCO between the two optics at three years. For this study, the occurrence of PCO was defined as a loss of more than two Snellen lines and requiring Nd:YAG capsulotomy.

Eight studies compared all three optical lenses, but in essence there were only three studies since Hayaski et al. and Ursell et al. have reported on the outcomes of the same patient groups over time. There was no statistical significant difference in decentration or tilt among the three lens types [22]. The largest study of 225 patients found that the mean percentage of area reduction of the anterior capsule opening at six months was significantly less for the PMMA and foldable acrylic lenses than for the silicone lens. Cell density was significantly greater for the PMMA lens than for the foldable acrylic lens [29, 66]. The percentage of PCO at three years was significantly less for the foldable acrylic lens compared to PMMA and silicone lenses [28].

Uusitalo and Tarkkanen point out that most studies focus on surgical details and changes in the eye's functional state than on quality of life [82]. Patient satisfaction is dependent on the magnitude of functional changes and the change in vision-related daily life activities. The VF–14 is a 14-item instrument designed to measure functional impairment caused by cataract surgery. Its validity, reproducibility, and responsiveness have been demonstrated [7] . The change in patient's scores of their self-reported trouble and satisfaction with vision were better correlated with change in VF-14 score than with the change in visual acuity [74]. Furthermore, Steinberg et al. showed a lack of correlation between pre-operative VA in the operated eye and the functional improvement experienced by the patient after surgery [74]. No comparative studies presented in this report used any measure for visual function such as the VF-14 or measures of quality of life.

In summary, decentration and tilt does not seem to be an issue for any of the IOLs evaluated in this series of studies. The PCO value and capsolutomy rate was reduced in patients with the soft acrylic lens over a follow-up period of two to three years when compared to those for patients with PMMA or silicone lenses.

STUDIES OF SAFETY AND EFFICACY ON IOLS WITH THE SAME OPTIC MATERIAL

Details of eight studies conducted on IOLs with the same optic material are given in Appendix D. In some cases there was more than one lens with the same optic material but with different designs or configurations. Most of the studies reported percentage of PCO and visual acuity; one [24] focused on decentration and tilt and one on post-operative inflammation. Overall, they provide an indication of acceptable results for various specific types of IOL with, in some cases, relatively long term follow up. Further comments on some of these studies are as follows.

The paper by Steinert et al. [75] summarizes follow-up data for the AMO PhacoFlex® silicone IOL (one year data from two groups and three-year data from a core-/modified-core group). For two of the groups the surgical techniques were not outlined and patient demographics and methods of recruitment were not described. The authors state that there is no objective standardized method of determining the degree or level of PCO. The study used rates of Nd:YAG capsulotomy to relate to PCO incidence for the PhacoFlex® foldable silicone lens. However, the shortcoming with using this method is that it only identifies severe, vision-inhibiting PCO. PCO occurrence as a factor in judging one IOL's suitability over another may be misleading.

Milazzo et al. [49] in a prospective study of foldable silicone IOLs found that they did not have a higher rate of complications than has been reported for PMMA IOLs. The same surgeon performed all of the procedures. Approximately half of the lenses were implanted in the bag and half in the sulcus and more than one type of silicone IOL was used. These variations make it difficult to interpret the overall outcome.

Oshika et al. [62] in their non-randomized, prospective clinical series looked at clinical safety and efficacy of a soft acrylic IOL. Weaknesses in this study were inconsistent surgical procedures, and dissimilar surgical expertise. As well, the surgical procedure changed part way through the study.

Linnola and Holst [44] evaluated the safety and performance of CeeOn® foldable silicone lens. After 12 months of follow up they concluded that there was good visual outcome and excellent centration. However, the choice of instruments for folding and implantation of the IOL are important.

Brown et al. [6] assessed the early postoperative efficacy and safety of the Staar Collamer® foldable IOL in small incision cataract surgery. Six investigators reported data on 107 patients of 125 who were enrolled. The same surgeon

performed all surgeries, with the exception of two cases. The four to six month follow-up visual acuity compared favourably to those reported for other lenses.

Sanchez and Artaria [68] in their prospective, medium-term study of acrylic IOLs found the clinical results to be comparable to those of other foldable lenses. One surgeon performed all of the surgeries using the same technique and the same IOL throughout the study period. The limitation is the wide age range of the patients, and the ocular co morbidities in their series do not allow their results to be applied to individuals with senile cataract surgery/lens implantation.

Hayashi et al. [24] examined the difference in the extent of decentration and tilt between one piece and three piece PMMA IOLs using a randomised study design. Three ophthalmic technicians who were not informed of the purpose of the study carried out all measurements. There was a statistically significant difference in decentration with less decentration with the one piece PMMA lens.

In summary, while the study designs were weak, all IOLs considered in these studies are deemed to be safe and provide adequate viasual actuity following cataract removal and implantation.

PRACTICE PATTERNS

In the Canadian setting the appropriateness of cataract surgery has been judged using some of the criteria from the Clinical Practice Guideline, *Management of Cataract In Adults,* published by the AHCPR [2]. In the majority of senile cataract cases the surgery is considered a non-emergency procedure. A complete diagnosis is required before cataract surgery is considered as an option. The reasons for this are to ensure that a cataract exists and to determine if the cataract is impairing vision to such an extent as to require surgery.

The decision to operate on cataracts should come from the patient regardless of the measured visual acuity. Cataract surgery is indicated when a patient believes that functional disability caused by the cataract is troublesome enough to risk removal [74].

Considerations should include what the ophthalmologist has recommended and subjective, objective, and educational criteria. Subjective criteria would include the inability to carry out needed or desired activities. An example of an objective criterion is visual acuity as determined by the Snellen test. All risks and benefits of cataract surgery with lens implantation should be explained to the patient [2].

The AHCPR Guideline points out contraindications for surgery when:

- the patient does not desire surgery;
- glasses or visual aids provide satisfactory functional vision;
- the patient's lifestyle is not compromised; or
- the patient is medically unfit.

Practice patterns in several developed countries in regards to age-related cataract extraction with intraocular lens implantation are summarized in Appendix E. The trends are similar in these countries. There is a changeover from standard ECCE to PE. As well, the use of smaller incisions with foldable lens implantation is on the rise.

In Canada, the most popular surgical procedure is cataract extraction using PE with implantation of the IOL in the posterior chamber. Phacoemulsification is either the most frequently used surgical procedure for removal of cataracts or is rapidly becoming so [5, 77].

Bellan et al. conducted a national survey of 528 Canadian ophthalmologists and studied their routine practices associated with cataract surgery. The purpose of the survey was to document patterns and variations in preoperative testing, surgical technique, anesthesia, and postoperative care in the year 1992. Information from cataract surgeons addressed routine practice patterns

pertaining to cataract surgery for patients aged 65 years or more, with no ocular or medical problems other than cataract. Results were compared with the AHCPR Clinical Practice Guideline [2, 5]. Overall the self-reported practices of Canadian surgeons with relation to pre-operative testing and post-operative follow-up appear to be consistent with the AHCPR guidelines.

The reported median number of cataract procedures per surgeon for 1992 was 150. Surgical procedures varied in that 52% of surgeons were classified as performing predominantly ECCE, 46% predominantly PE and 2% predominantly ICCE. The number of post-operative visits were inversely related to volume of surgery. Mean numbers of post-operative visits was greater for surgeons who used standard ECCE (4.7 visits) than those who used PE (3.75 visits). Overall, 94% of respondents reported personally examining their patients on the first day after surgery. The timing of the second post-operative visit was not found to vary significantly in relation to principal surgical technique or volume of surgery.

Across surgeons a mean of 17.9% of patients were estimated to undergo Nd:YAG laser capsulotomy within the first year after cataract extraction, presumably for posterior capsule opacification. Most surgeons estimated their rate of laser capsulotomy as less than 40% of cases but there were some significant outliers with rates over 60%.

Limitations of the survey identified by the authors are that self-reported patterns of care may not accurately reflect actual practice patterns, and that responses may be affected by recall and social desirability bias. Data obtained in 1993 may not reflect current practice patterns, but will provide an important reference point for future comparisons of Canadian practice [5].

DISCUSSION

While the IOL has long been established as an effective technology, the relative advantages of different types and brands of lenses are not easy to determine. There are many combinations of optic and haptic materials and different designs of lenses. A large number of IOL products have reached the market place and new designs continue to appear. In only a few cases have good quality reports been published on their safety and efficacy/effectiveness. It seems unlikely that comprehensive trials will ever be undertaken on each individual product, some of which may have quite short market lives.

The difficulty in obtaining a clear indication of the comparative safety and efficacy of different types of IOL is compounded by the fact that the clinical performance of the technology will reflect the interaction between the lens and the surgical procedure. Lens implantation is a complex intervention.

In Canada, trends in the use of different types of IOL have been influenced by the availability of new products and the decisions of individual ophthalmologists in relation to their practice routines.

There is a keen interest by ophthalmologists in using a small incision size because of the concept that a smaller incision means quicker restoration of visual acuity. Available data show that current types of cataract surgery with IOL implantation give excellent results for visual acuity in 95% of patients where there is no ocular co-morbidity. Cataract surgery/IOL implantation is also a relatively safe procedure.

A disadvantage with current surgical approaches is the occurrence of PCO ('secondary cataract') in a substantial proportion of patients (over 28% after five years post-surgery). The common method of treating PCO is laser capsulotomy. This is effective, but represents an additional procedure with consequent costs and outcomes. There are wide variations in rates and timing of Nd:YAG laser surgery. This may be due to the lack of standardized measurement systems and clinical relevant PCO values. Nd:YAG laser surgery is not without complication and risk. Complications can result in additional health costs.

At present, there is only limited information on the comparative performance of different types of IOL. The focus of the present assessment has been on studies with a follow up time of six months or more. Only a small number of studies were identified and the results from these are inconclusive for several reasons. In particular, the quality of the research methodology is limited and sample sizes are small. Also, it is not always clear whether reported statistically significant differences between lenses and techniques are clinically significant.

Surgical cataract procedures continue to evolve and IOLs of all three optical lens types continue to be modified. A further factor is the learning curve for specialists as the procedure for senile cataract surgery with IOL implantation changes. The proliferation of available lenses in relation to design and configuration presents a daunting task for the ophthalmologist in choosing the IOL that is most effective and efficient [27].

Research in all aspects of cataract surgery and IOLs is continuing on all fronts. Recently Clarke et al. [9] published their research results on MDX-RA, an investigational immunotoxin designed to limit epithelial cell growth to prevent post surgical PCO. The development of multifocal IOLs can be expected to lead to additional products and treatment options.

Outcomes for the three optical types of IOLs differ depending on whether there is interest in the short term benefits (usually within one to three weeks) or the longer term benefits. Optical advantages of small incision surgery may be clinically important for the first few months after surgery, but they become less evident over time. The proportion of eyes with PCO was higher in studies of longer duration [64, 69]. Powe and colleagues [64] noted a trend for visual acuity to be inversely associated with patient age, duration of follow up, and sample size.

The results from the studies reviewed in this assessment should only be generalized to lenses listed in Appendix B. If the choice were to be made on lens optics alone, the foldable acrylic IOLs seem to have the best performance, based on the relatively weak scientific evidence available to date. When compared to PMMA and silicone IOLs, foldable acrylic IOLs appear more beneficial in the short term (three years) in relation to biocompatibility, PCO, decentration and tilt, and anterior capsular stability. Available outcome measures are quite limited in that they offer little or no insight into changes to functional status or quality of life measures, from the perspective of the patient.

Overall, there appears to be little good quality information to guide ophthalmologists, consumers, and funders in their choice of the most appropriate type of IOL. The choice of IOL seems to depend mostly on the surgeon's preference, training, expertise and availability (coverage by the Health Ministry and purchasing choices by Regional Health Authorities). There seems a clear need for good quality studies to better define the comparative performance of the different versions of this important technology. It would be desirable for future studies to focus on linking their outcome measures to clinically important parameters, to functional status improvements, and to quality of life measures.

APPENDIX A: METHODOLOGY

Search Strategy

Databases were searched using key words/Subject Headings and included: Medline, Embase, HealthStar, DARE, HTA (York), ECRI IHTA, Science Citation Index, and Current Contents, Bioengineering Abstracts, Cochrane Controlled Trials, Advanced Polymers Abstracts.

Search terms used alone or in combination were: 'Lenses, Intraocular/', 'Lens Implantation, Intraocular/', 'Lens Implant/', 'intraocular len$', 'iol', 'polymethyl methacrylate', 'pmma len$', 'silicone len$', 'foldable len$', 'acrysoft', 'Cataract Extraction/', 'Cataract/su', 'Phacoemulsification/', 'exp Post-operative Complications/', 'Intraoperative Complications/', 'exp Complication/', 'exp Consumer Product Safety/', 'efficacy', 'effectiveness', 'exp Cost and Cost Analysis/', 'cost', 'Economic Aspect/', 'Practice Guidelines/', 'Physicians Practice Patterns/', and 'exp Health Surveys/' (**Source:** Lisa Tsojvold, Alberta Heritage Foundation for Medical Research Librarian).

Abstracts from the literature search were analyzed for relevance to cataract surgery with lens implantation. Studies were selected that had the following criteria:

- Meta-analyses, multi-centre RCTs, single-centre RCTs, and prospective comparative studies including cohort and case control studies and reviews. Guidelines and surveys of physicians practice patterns were also included but not analyzed.
- Literature search was limited to human subjects and the timelines 1991 to current.
- English language was the predominant choice, however, English abstracts of papers in other languages were perused for information.
- Further relevant articles were found by examination of the references listed in the retrieved papers.

Appraisal Criteria and Quality Analysis

Study inclusion criteria

- Uncomplicated senile cataract surgery with no ocular co-morbidity
- Number of subjects per study was not less than 40
- The follow-up was not less than 6 months in duration
- Patient age demographics provided
- Patients older than 45 years with an average group age >55 years

- Sample size of more than 10 per group; overall sample size of more than 40 patients or eyes
- Human clinical studies

Study exclusion criteria

- Multifocal lenses
- Explantation of lenses
- Cadaver or postmortem studies
- Studies with follow up of less than 6 months
- Comparative studies that do not use PMMA as a gold standard
- Studies that do not provide lens model numbers or adequate information to identify lens

Quality analysis (methodological considerations)

- Were outcomes assessed in a standardized fashion?
- Was the duration of the follow up similar within a group?
- Did a single person assess the outcomes or was the level of agreement among multiple assessors established?
- Was the clinical significance of outcomes defined?
- Was attrition of patients mentioned and adequately assessed?
- Were both pre-operative and post-operative VA examined?

Studies selected for this assessment controlled for pre-existing conditions by including only patients with uncomplicated senile cataracts to compare the biocompatibility of the different lenses. Biocompatibility was compared by such measures as endothelial cell counts, cell mass densities, Nd:YAG laser capsolotomy rates, fibrosis on the anterior capsule, and PCO incidence.

Definitions

Efficacy

- refers to the performance of a technology under 'ideal' conditions or conditions of best practice

Effectiveness

- refers to the performance of a technology under 'routine' conditions; for example when it has become widely distributed in a health care system.

APPENDIX B: CHARACTERISTICS OF SOME IOLS EVALUATED IN THE STUDIES

Table 2: PMMA Lenses

Manufacturer	Model	Average cost per lens	Available in Canada Y(yes) N (no)
Allergan	PC-43NB		N
Ioptex	UPB330VS		
Kabi Pharmacia	812C		
Pharmacia	CeeOn 812A		
Pharmacia	720		
Pharmacia	725		
Pharmacia	815		
Pharmacia	812A	$50-$150	Y
Pharmacia	720A		
Pharmacia	809C		
Pharmacia	740P		
Pharmacia	809P	$50-$150	Y
Storz	650CUV		N
Storz	359	$299	Y
Alcon	CZ70BD	$325	Y
Alcon	MC60BM		N
Alcon	MZ60BD	$325	Y
Iolab	P256D		N
Iolab	U106D		N
Iolab	PL56E		N
Iolab	P256E		N
Iolab	G157R		N
Iolab	P756B		N
Menicon Co. Ltd. (Japan)	UV25T		
Menicon Co. Ltd. (Japan)	UV22		

Table 3: Silicone Lenses

Manufacturer	Model	Average cost per lens	Available in Canada Y(yes) N (no)
Pharmacia	CeeOn 920		
Allergan	AMO SI-30NB	$125	Y
Allergan	AMO SI-18B PhacoFlex		N
Allergan	AMO SI-20		N
Allergan	AMO SI-19		N
Allergan	SI-40 NB	$200	Y
Allergan	Phacoflex II		
Chiron	32-10B		N
Chiron	C10		
Chiron	32-c10xx		N
Iovision	127		
Staar	AA 4203	N/A	Y
Iolab	LI 41U	$694	Y
Adatomed	90D		

Table 4: Soft Acrylate Lenses

Manufacturer	Model	Average cost per lens	Available in Canada Y(yes) N (no)
Alcon	AcrySof MA30BA	$400	Y
Alcon	MA60BM	$400	Y
Alcon	IOGEL 1130		N
Mentor ORC	MemoryLens U940A		
IOPTEX/ALLERGAN	ACR360		
STARR COLLAMER®	CC-4203VF foldable lens		

APPENDIX C: COMPARATIVE STUDIES OF DIFFERENT TYPES OF IOLS

Abbreviations:

ATW:	Against the Wound
BCVA:	Best corrected visual acuity
CCC:	Continuous Curvilinear Capsulorhexis
CECL:	Corneal endothelial cell loss
cpd:	Cycles per degree
CS:	Contrast sensitivity
D:	Diopter
FU:	Follow up
Gr:	Group
HCF:	Haptic centrifugal force
HEMA:	Hydroxyethyl methacrylate
LogMAR:	Logarithm of the minimum angle of resolution
MD:	Macular degeneration
MMA:	Methyl methacrylate
Mo:	Month
NSS:	Not statistically significant
Opt:	Optic
PCO:	Posterior capsular opacification
PE:	Phacoemulsification
PMMA:	Polymethyl methacrylate
Post op:	Post-operative
Pre op:	Pre-operative
Pt:	Patient
Si:	Silicone
SIA:	Surgically induced astigmatism
SS:	Statistically significant
VA:	Visual actuity
Wk:	Week
WTW:	With the wound
Y:	Year

Table 5: Comparative studies of different types of IOLs

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Olson. Crandall * 1998 [57] See [58] Randomized best case review	Exclusion criteria: <45 y, any corneal pathology including astigmatism >2 diopters, Fuch's dystrophy; diabetic retinopathy; macular pathology; veitis; glaucoma; amblyopia Grp 1 = mean age 74.3 y, N = 55 at ~ 3yr n = 38 Grp2= mean age 73.9 y, N = 56 at ~ 3yr n = 42	Lens types see [58] Scleral incision at superior vertical meridian (12 o'clock), either 3.2 or 5.5 mm in length depending on computerized randomized schedule at time of surgery. Used anterior capsulorhexis of 4.5mm, PE, divide & conquer technique.	Pre op LogMAR VA: Grp1 0.65 Grp2 0.64 Day 1 post op slit lamp examination & applanation tonometry; Day 1 & 8; 1, 3 & 6 mos. & 3 y Blinded keratometry & logMAR VA, best corrected & uncorrected. 3 y best corrected brightness acuity & contrast sensitivity	Pt. with decreased VA of 0.2 LogMAR or more not included LogMAR VA without correction at 3 ys, SS difference in favor of Grp1 n=26 (0.14 +/-0.16) Grp2 n=29 (0.26+/-0.24) LogMAR VA with correction no SS difference at any time period.	Astigmatism (Cravy method) ATW & WTW SS difference between two grps through to 3 y. For ATW & WTW shift. absolute astigmatism shifts >0.5 diopters SS for all time periods except day 1 & 30 post op. Absolute astigmatism shifts >1 Diopters SS for all time periods except 30 days post op. MD n=14; PCO n=5; diabetic macular edema n=1; macular hole n=1; branch retinal vein occlusion n=1; punctate keratitis dry eye n=1; retinal detachment n=2; cystoid macular edema n=1	3 y. post op pts with Si IOLs had less astigmatism (-.18 vs -.88 SS), fewer pt. ATW astigmatism >1 diopter (8% vs 31% SS), better uncorrected VA (.14 vs .26 logMAR SS)	*Pt who had decreased VA of 0.2 LogMAR or more where not identified to belong to any particular group * Evaluations were masked but conducted by more than one technician * Wide SD intervals * About 50% of individuals lost to follow up
Olson, Crandall 1998 [58] Randomized comparative	Grp 1 Si, mean age 74.5 y N = 60 Grp 2 PMMA mean age 73.3 y N = 59	Grp 1 AMO SI-30 Grp 2 5.5 mm biconvex, round all PMMA See [57] for surgical procedure	Pre op LogMAR VA: Grp 1 0.63 Grp 2 0.63 FU: PCO lens opacity meter (LOM) 3 & 6 mo., 1 & 3 yr.; slit lamp evaluation (scoring from 0 no opacity to 4+ dense opacity) at final examination. Nd:YAG performed if VA 20/30 or worse, pt preference	All results reported on N = 84 at 3 yr. Grp 1: LOM (blinded) 8.6%; YAG caps. 24%; PCO score(not blinded) 0.88 Grp 2: LOM 10.4% (SS compared to grp1); YAG caps. 33% (not SS compared to grp1); PCO score 1.79 (SS compared to grp 1)		*no surgical complications *no complications for YAG caps. *suggest that PCO was less in AMO SI-30 compared to PMMA	*Method of randomization refer to (56) *Individual data for the FU periods were not provided *Patients (~30%) lost to FU *results were not reported according to number of patients or eyes in each grp

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Holweger, Marefat 1997 [30] Randomized comparative	200 eyes (185 pt) Inclusion criteria: preop endothelial cell count of 1700 cells/mm 2 min., IOL in the bag Grp1: Si N=100 eyes, mean age 77 (41 to 93 yr) Grp2a: PMMA one radial suture N=50, mean age 76 (58 to 95 yr.) Grp2b: PMMA X suture, N=50 mean age 80(50 to 94 yr.)	Grp1: silicone foldable plate haptic (Chiron 32-c10xx)) 3.5 mm limbal groove Grp2: PMMA one piece C loop (Ioptex UPB330VS) 5.0 mm limbal groove CCC; endocapsular PE; Randomized by sealed envelope.	FU 6 to 9 mo Preop corneal endothelial cell count (Cooper Vision HR 750) and Pre op corneal topography (Computed Anatomy TMS-1, 25-ring cone) Post op corneal endothelial cell count & grading of IOL centration	Little change in corneal indices: Grp1 +.051; Grp2a +.130; Grp2b -.137 Mean endothelial cell loss: Grp1 3.38%; Grp2a 4.11%; Grp2b 1.96% Polar K Grp1 -.123; Grp2a -.172, Grp2b .151 IOL was centered or almost centered in most eyes.		Stable corneas regardless of the IOL type, suture length, and closure method used. Endothelial cell count decreased in all groups. Minimal amount of IOL decentration in all groups.	*Did not mention who conducted FU evaluations. *Mentioned FU rate for each group (88.67% Grp1, 88% Grp2a, 90% Grp2b) but did not account for those lost to FU. *large age variation among grps, no mentions if grps were SS different
Oshika et al. 1998 [63] Multicentre randomized comparative	N=200 eyes (180 pt.) randomized into 2 incision groups at each of the 7 sites Excluded pt. who missed >2 FU visits & those with surgical or preexisting complications Grp1 = mean age 70.5+/- 9.3yr. Si optic N=93 eyes Grp 2 = mean age 71.2 +/- 10.2yr. PMMA optic N=89 eyes	Grp1 SI-30NB Allergen folded & inserted using either forceps & Fine block folding or Ernest – MacDonald folding forceps and Livernois holding forceps Grp 2 PC-43 NB Allergen Corneoscleral incision, CCC & PE No sutures	Snellen VA and keratometry at all sites pre op & post op. Pts in each grp subdivided by VA of >=20/40 & >=20/50 for analysis FU 1day, 1 wk., 1,3 & 6 mo. Pre & post op evaluations: Flare intensity & cell count (laser flare cell meter) 4 sites Glare disability & photographic analysis of decentration 2 sites Specular microscopic of corneal endothelium 5 sites Corneal topography (topographic Modelling System) 1 site; EyeSys Corneal Analysis 2 sites Fluorophotometric evaluation 1 site	Uncorrected VA SS better in grp1 at : **day 1**(82.7% versus 55.4% for >=20/40 and 36% versus 25.7% for >=20/25) **2 wks** (89.4% versus 66.2% for >=20/40 and 48.5% to 36.9% for >=20/25) **1 mo** (87.3% versus 86% for >=20/40 and 43.7% versus 31.4% for >=20/25) Corrected VA SS better for grp1 at day 1 & 1 wk. At 3 and 6 mos no SS between the grps for uncorrected & corrected VA Post op flare at day1 SS lower in grp1, after 1 wk no SS Independent masked rating of corneal topography 66% in grp2 & 50% in grp1 had wound related flattening SS Decentration & rate of CECL no SS between grps. Indices of blood-aqueous layer, fluorophotometry, no SS YAG laser 2 pts in grp1 & 1 pt in grp2	At all post op visits for both the Cravy & Jaffe / Clayman analyses grp2 had SS larger ATR changes & SS larger induced cylinders. Transient cystoid macular edema 2pts in grp1 & 1 pt in grp2	Clinical results for both lenses were satisfactory. The pts with silicone lenses had significantly earlier recovery of visual function and better preservation of corneal shape.	*method of randomization not mentioned *Pre and post op evaluations varied between sites *no mention of pre op VA values and comparison within grps to post op values *measurement systems varied between sites *number of sites participating in post evaluations varied

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Oshika et al. 1998 [60] See [61]	See [61] Grp 1: Sample fluctuated from 98 to 46 Grp 2: Sample fluctuated from 96 to 43	See [61]	See [61] FU 1 day, 1 & 2 wk, 1, 3 & 6 mo., 1, 2 & 3 y ND;YAG laser when two line loss of Snellen VA (rate of PCO)	Cumulative rate of PCO (%) no SS: Grp 1: y1 – 8.6 y2 – 14.8 y3 – 23.5 Grp 2: y1 – 5.7 y2 – 10.3 y3 – 18.4	Grp 2 significantly larger ATR changes than grp 1 from day 1 to 3 y	See [61]	*No mention if patients lost to FU were similar to those who completed the study. *Did not account for losses
Ravalico et al. 1997 [66] Randomized comparative	Grp1 N=10 PMMA Grp 2 N=10 surface passivated PMMA Grp 3 N=10 heparin surface modified PMMA Grp 4 N=10 poly-HEMA hydrogel Grp 5 N=10 Si Exclusion: uveitis, active corneal disease, glaucoma, diabetic retinopathy, intraoperative complications. Average age 67.8 yr (+/- 7.6) no SS among grps	Grp 1 AMO PC-43NB Allergen Grp 2 Ioptex UPB 330 VS Grp 3 Kabi Pharmacia 812 C Grp 4 Alcon IOGEL 1103 Grp 5 AMO SI-30NB, Allergen All 1 piece PMMA with PMMA haptic 5.5mm optic for PMMA, HSM PMMA & 6.0 mm optic for SP PMMA,poly HEMA,Si One surgeon performed all surgeries CCC & bimanual PE, all lenses implanted in unfolded state	Post op FU slit-lamp to identify specific areas of high-density cells examined by Konan specular microscopy & photographs. Snellen post op visual acuity Evaluator masked with respect to type of IOL FU at 2, 7, 30, 90,180 days,	Mean best corrected VA was comparable among all grps at all time periods NSS. **Day 7 & 30:** cell density SS Grp 1 >50/mm² Grp 2,3 & 4 10 - 50/mm² Grp 5 <10/mm² **Day 90:** Cell density SS Grp 1 10-50/mm² Grp 2 <10/mm² Grp 3 80% <10mm² Grp 4 70% <10/mm² Grp 5 60% <10/mm² **Day 180:** cell density decreased in all grps but SS		Conventional PMMA material exhibited the most cellular adhesion. Within 6 months of surgery surface passivated PMMA & heparin surface PMMA showed less cell deposits suggesting surface modification to be effective in improving PMMA tolerance. Silicone and poly-HEMA few signs of cellular reaction suggesting high tolerance.	*Very small numbers in each of the groups. *Method of randomization not mentioned. *No pre op VA evaluations
Zambarak et al. 1997 [84] Prospective comparison	Exclusion criteria: diabetes, glaucoma, pseudoexfoliation, ocular inflammation, any other form of ocular co-morbidity. Grp 1 PMMA N=29 av age 75 (57 to 89yrs) Grp 2 Si N=35 av age 76 (61 to 91 yrs)	PMMA one piece, CZ Alcon, optic 5x6 mm, 5 degrees Silicone optic/polypropylene haptic, 3 piece, Allergen, optic 6x6 mm, 10 degrees Sutureless surgery through corneal tunnel using PE Performed by 2 surgeons	Post op the diameters were measured along the 45°& 135 ° meridians using slit lamp for time period 1 (day 1 to 6 wk) & time period 2 (6 wk to 6 mo) FU 1day,6 wk,6 mo	Grp 1 period 1 –16.14 % SS; period 2 – 2.4% SS Grp 2 period 1 –19.9% SS; period 2 – 7.5% SS Difference in % change between the 2 grps SS No patient developed clinical significant change requiring Nd:YAG laser anterior capsulotomy No disabling decentration or lens dislocation		Due to small numbers no conclusions can be made in the incidence of clinically significant capsular phymosis. Recommend the use of rigid one piece PMMA lens with firm haptic	*No attempt at blinding for FU evaluations *no mention of number of evaluators *no mention if grps were similar

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Wang et al. 1998 [83] Prospective comparative	Exclusion criteria: Uveitus, glaucoma, trauma, high myopia & previous IOL surgery N= 70 eyes (29 patients did not complete FU) Grp 1 PMMA N=24 mean age 64.2 +/- 16.1 yrs Grp 2 Si N=17 mean age 70.4 +/- 8.5 yrs NSS between grp differences in age, sex, axial length	One surgeon performed all surgeries using CCC 5 to 6 mm, PE of nucleus and aspiration of cortex. Scleral incisions were frown shaped length 5.5mm for PMMA & 3.2mm for Silicone Grp 1 I piece biconvex CeeOn 812A, Pharmacia, 5.5mm optic, C loop haptic Grp 2 3 piece biconvex AMO SI-30NB Allergan, 6.6mm optic, C loop polypropylene haptic	Anterior segment analysis system Scheimpfllug photography using EAS-1000 (Nidek) FU 1 wk; 1,2,3,4, 5 & 6 mos	Degree of tilt & amount of decentration NSS Anterior chamber depth SS difference, Grp 1 mean difference 0.24 mm larger than grp 2		No differences were found in the amount of tilt and decentration between PMMA lens and the silicone lens over the length of study FU	*Reasons for loss to FU not provided. * number of evaluators not identified
Gonvers et al. 1997 [17] Prospective comparative	Exclusion criteria: pts >75yrs.; pseudofoliation; myopia with axial length >25mm; diabetes; active or quiescent uveitus; history of ocular surgery N= 85 eyes (78 pts) Grp 1 N= 29 eyes Si optic; PMMA haptic Grp 2 N=26 eyes PMMA Grp 3 N=27 eyes Si	Grp 1 three piece silicone optic; PMMA haptic; Iovision 127 folded lengthwise implanted through 3.5mm temporal incision into clear cornea Grp 2 one piece PMMA 5.5mm diameter optic 5.5x4.0 mm Pharmacia 812A sclerocorneal tunnel Grp 3 plate haptic silicone Staar AA4203 folded implanted by injection through 3.5mm temporal incision into clear cornea CCC with PE using divide & conquer no sutures, performed by one surgeon	Inflammation of anterior chamber measured pre op with Kowa flarecell meter, post op 1,7,30 & 180 days CCC measured using Zeiss slitlamp & Agfa Studioscan® all final measurements made using NIH-Image®Software, 1 day & 6 mo post surgery Three eyes from grp 2 excluded CCC could not be visualized. FU CCC change 6 mo; 1,7,30,180 days flare evaluation	Grp 1 mean enlargement +0.57 +/- 1.15mm² SD (+3.5%) not SS Grp 2 mean decrease –0.57 +/- 2.16mm² SD (-4.3%) not SS Grp 3 mean decrease -2.55 +/- 3.51mm² SD (-14.4%) SS No SS change in CCC between grp 2 PMMA optic & grps 1,3 Si optic but SS between grp 3 plate haptic & grps 1,2 loop haptic Grp 2 greatest inflammatory response & grp 1 least, SS		Initial CCC size not predictive of constriction. Optic material not determining factor in modification of CCC size. Haptic design did have an effect on change in size of CCC. Post op inflammation significantly increased with PMMA optic. Fibrosis of the anterior capsule more pronounced in eyes with plate haptic IOLs than with one piece PMMA or 3 piece Si / PMMA	*Break down of age for each gp not provided therefore groups may not be comparable *Not all results for integrated flare (photons ms-1) presented. *Number of evaluators not mentioned

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Hayashi et al. 1997 [23] Randomized comparative	Exclusion criteria: cataracts not due to age related changes, previous ocular surgery or inflammation, pseudoexfoliation, retinal morbidity, diabetes mellitus, pupil diameter <6 mm after dilation Grp 1 PMMA N=74 (6 lost to FU) age 67.3 +/- 8.3yr Grp 2 Si N=73 (7 lost to FU) age 68.9 +/- 7yr Grp 3 foldable acrylic N=78 (2 lost to FU) age 67.3 +/- 9.6 yr No SS differences between grps.	Grp 1 one piece PMMA MZ60BD Alcon 6mm optic Grp 2 three piece Silicone SI-30NB Allergen 6mm optic PMMA loops Grp 3 three piece soft acrylic MA60BM Alcon 6mm optic PMMA loops All surgeries performed by one surgeon. CCC ~ 5.5mm diameter, PE. All pts randomly assigned by sealed envelope method.	FU 1wk, 1,2 & 6 mo Anterior Eye Segment Analysis System (EAS-1000) All measurements performed by 3 ophthalmic technicians not informed of purpose of the study	Mean percent of area reduction of anterior capsule opening in group 1(5.8%+/-8, 11.3%+/-17.7, 8.1%+/-18.9) & 3 (5.0%+/-8.6, 10.2%+/-12.9, 7.7%+/-12.9)were SS less than in gp2 (12%+/-10.4, 19.7%+/-15.2, 18.1%+/-16.112%, 19.7%, 18.1%) at 1,3 & 6 mos. respectively Mean area changes of anterior capsule showed no SS 1 wk post op. Mean areas were SS larger in grps 1 & 3 than in grp 2 at 1,3 & 6 mos.		Area of anterior capsule opening decreased for up to 3 mo post op. After 3 mo no further progress in area reduction. Percentage of area reduction for Si IOL was significantly larger than for PMMA & soft acrylic IOLs.	*standard deviations had a large variation so that they overlapped within each follow up period.
Hayashi et al. 1997 [22] See [23] Cohort	Same as [23] Continuation of study [23]	Same as [23]	FU 1wk, 1,3,6,9, 12 mos Same as [23]	No SS differences in the post op changes in the length of IOLs decentration in any of the 3 grps. No SS differences in post op changes in degree of tilt in IOLs of the 3 grps		Performing proper CCC & in the bag IOL fixation neither the decentration nor tilt of the IOL significantly increased up to 12 mo post op	
Hayashi et al. 1998 [20] See [22, 23] Cohort	Exclusion criteria same as [23] Continuation of study [23] Grp 1: PMMA N=69 (11 lost to FU) age 67.9± 9.6 Grp 2: Si N=70 (10 lost to FU) age 70.2± 8.1 Grp 3: foldable acrylic N=73 (7 lost to FU) age 68.4± 9.3 No SS difference between groups	Same as [23]	FU ~ 2 yrs. Same as [23] VA determined using decimal charts; misiscule decline in corrected VA from best post op VA either for PCO measurement or Nd:YAG laser capsulotomy PCO measured using axial densitometry of Scheimpflug videophotography	Nd:YAG before PCO measurement: Grp 1: N=21 Grp 2: N = 4 Grp 3: N = 2 Greater Nd:YAG rate than grps 2 and 3. PCO measurement + CCT (computer-compatible type steps): Grp 1: N = 48; CCT 26.3 ± 12.2 Grp 2: N = 66; CCT 12.0 ± 8.3 Grp 3: N = 71; CCT 16.0 ± 10.3 VA loss in PMMA grp was SS greater than in grps 2 and 3		PCO measurement showed good correlation with patient's VA Degree of PCO with PMMA IOL was more extensive than with either the silicone or foldable acrylic IOL	*did not account for those lost to FU criteria for *determining Nd:YAG capsulotomy not proviced *wide ranges of CCT; clinical signficant range not providec *correlation between PCO measurement and Nd:YAG not mentioned

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Ursell et al. 1997 [80] See [28, 29, 81] Randomized comparative	Same as [29]	Same as [81]	FU four time comparisons: 7 to 30 days 30 to 90 days 90 to 180 days 180 to 360 days Standardized digitized retroillumination imaging to measure anterior capsule movement; observations by two independent observers. Pts who missed > than 2 FU images excluded	Capsule movement was greatest within first 3 mos & then decreased Capsule movement similar for grps 1 & 2 but SS less in grp 3 **7 to 30 days** Grp 1 16/26 IOLs Grp 2 16/25 IOLs Grp 3 6/27 IOLs **30 to 90 days** Grp 1 14/26 IOLs Grp 2 14/29 IOLs Grp 3 3/28 IOLs **90 to 180 days** Grp 1 6/26 IOLs Grp 2 10/29 IOLs Grp 3 2/27 IOLs **180 to 360 days** Grp 1 2/25 IOLs Grp 2 4/25 IOLs Grp 3 2/26 IOLs		The AcrySof® lens produced significantly less anterior capsule movement in the first year following surgery.	
Ursell et al. 1998 [81] Randomized comparative	Inclusion criteria: senile cataract in otherwise normal eye Exclusion: <55yrs; diabetes mellitus, glaucoma, uveitus, significant posterior segment pathology, cataract surgery in contralateral eye in previous 4 mo, unable to give consent N= 90 eyes (81 pts) prospectively randomized using numbers into one of three grps Grp 1 PMMA Grp 2 Si Grp 3 AcrySof®	Grp 1 PMMA MC60BM Alcon 10 degree angulation Grp 2 Silicone LI41U Iolab 5 degree angulation Grp 3 AcrySof® MA60BM Alcon PMMA haptics 10 degree angulation All lenses had 6 mm optics & inserted unfolded standardized ECCE with 10 mm superior corneal section; nucleus hydroexpressed through 5.5 to 6.5 mm CCC; sutured with continuous 10-0 nylon Performed by one surgeon.	Standardized retroillumination images of posterior capsule using Zeiss 120 slit lamp **FU 180 days** Grp 1 n=25 images Grp 2 n=24 images Grp 3 n=21 images **FU 360 days** Grp 1 n=21 images Grp 2 n=23 images Grp 3 n=25 images **FU 720 days** Grp 1 n=24 images Grp 2 n=21 images Grp 3 n=16 images	Corrected Snellen VA at 2 yrs 20/40 or better NSS: Grp 1 88% (22/25) Grp 2 81% (17/21) Grp 3 94% (15/16) Significant difference in % of PCO among three groups at 2 yrs. Grp 1 median 43.65% (3.9 to 67) Grp 2 median 33.5 % (4.7 to 75.6) Grp 3 median 11.75% (2.6 to 52) Difference between grp 1 & 2 NSS; SS between grp3 and grps 1 & 2		Results show a significant and beneficial decrease in PCO with AcrySof® IOL compared with the PMMA and silicone IOLs	*The number of patients or eyes allocated to each group was not mentioned. *Provided the number images at each FU. Numbers varied within each group. The largest loss (9/25) in grp 3 of 36%. *The number of observers was not provided *Losses to FU not accounted. *Pre op VA not measured. *Results not based on total number of pts randomized to each grp. *Overlapping ranges with large intervals

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Hollick et al. 1998 [29] See [81] Randomized comparative	Exclusion criteria: <55yrs; diabetes mellitus, glaucoma, uveitus, significant posterior segment pathology, cataract surgery in contralateral eye in previous 4 mo, unable to give consent N= 90eyes (81 pts) Grp 1 N=PMMA 30 Grp 2 N=Si 30 Grp 3 N=foldable acrylic 30 No difference in age or sex distribution. Average age 73 yrs (55 to 89 yrs)	Same as [81]	FU 1,7,30,180, 360,& 720 days NP: Assessed pre op by same person, specular microscopy of anterior IOL surface using Zeiss slit lamp	Degree of small cell response SS association between IOL type & maximum small grade over 2 yrs: Grp 1 27% grade 1 & 23% grade 2 or more Grp 2 60% grade 1 & 30% grade 2 or more; SS more than grp 1&3 Grp 3 40% grade 1 & 23% grade 2 or more Maximum giant cell grade; SS association between IOL type & maximum giant cell grade over 2 yrs: Grp 1 30% grade 1 & 10% grade 2 or more Grp 2 20% grade 1 & 13% grade 2 or more Grp 3 none SS less than grp 1 & 2		AcrySof® IOLs have a high degree of biocompatibility.	*Results not presented for each individual groups or numbers of patients included in analysis *results not presented in time period intervals but maximum cell grades over 2yrs *no mention of pts lost to FU
Hollick et al. 1999 [28] See [81]	Grp 1: PMMA N = 23 Grp 2: Si N = 22 Grp 3: Foldable acrylic N = 19 Follow up rate 71% (accounted for losses to FU)	Same as [81]	FU 3 yrs logMAR VA with Early Treatment Diabetic Retinopathy Study Chart and contrast sensitivity with Pelli Robson Chart	Nd"YAG capsulotomy if VA decreased by two Snellen lines since last assessment and clinically opaque capsule Nd:YAG capsulotomy Rate at 3 yrs Grp 1 26% (6/23) Grp 2 14% (3/22) Grp 3 0% SS less YAG capsulotomies in grp 3 compared to grps 1 and 2 Grp 1 56.1 (4.8, 94.2) Grp 2 39.9 (5.5, 74.3) Grp 3 10.2 (3.4, 53.7) UR and CS were worse for PMMA grp before YAG but NSS		IOL material can have an effect on PCO, with significant reduction in PCO and YAG rates with foldable acrylic lens compared to PMMA and silicone lenses	*wide overlapping ranges from % PCO

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Jacobi et al. 1995 [31] Retrospective "Best" post op case series	N= 42 pts from consecutive series of 152 pts Inclusion criteria: uneventful intra & post op; absence of ocular pathology; post op VA at least 0.8 logMAR, no capsular fibrosis or IOL tilt or decentration. Grp 1 PMMA mean age 73.9 yrs +/-7.5 N=15 Grp 2 Si plate mean age 67.2 yrs +/- 8.7 N=15 Grp3 Si disc mean age 68.6yrs +/- 9.7 N=12	Grp 1 one piece PMMA 809P modified C shape loop Pharmacia 5mm optic Grp 2 Silicone plate haptic C10 Chiron 6mm optic Grp 3 silicone disc haptic 90D Adatomed All surgery performed by one surgeon. PE via self-sealing temporal clear corneal incisions, in the bag implantation Random allocation to one of IOLs. Grp 1 5mm incision & grps 2,3 3.5 to 4 mm injection cartridge	FU 6 mo CS under photopic light using Vistech wall chart with 3 orientations CS & glare disability under mesopic light using Mesotest	CS & glare disability no SS difference among grps Pooled sample and divided into 2 age grps - <70 yrs & >70 yrs CS SS lower for >70 yr grp for all lens types but glare disability scores at Mesotest were unaffected		Examination of VA by CS & glare disability testing showed no SS difference among the three lenses. Pt age was more important factor in CS than IOL type.	*Did not attempt to blind observer *The number of evaluators not mentioned
Kohnen et al. 1995 [38] Randomized comparative	Inclusion criteria: 45 to 55 yrs; no pre-existing corneal topographic abnormalities; no previous surgery in study eye. Block-wise randomization into one of three incision sizes. Grp 1: Silicone, 3.5mm, incision N=20. Grp. 2: Silicone, 4.0mm, incision N=20. Grp. 3: PMMA 5.0mm, incision N=20.	Grp. 1: plate-haptic Chiron CID Grp. 2: disc lens Adatomed 90D Grp. 3: round optic, Pharmacia 809; one radial 10-0 nylon suture. All surgeries performed by one surgeon through temporal, clear corneal tunnel incision; CCC, PE, bimanial irrigation/aspiration. Both silicone lenses implanted using syringe injector.	Preop-computerized video keratography (Eye Sys Laboratory). Pre-op .70D to .75D in all grps. Post-op - 1 week and 6 mos. Overall change between pre-op and post-op assessed using difference map. SIA-Vector analysis method of Jaffe.		Mean total astigmatism: Grp. 1: .86D at 1 wk; .72D 6 ms. Grp. 2: .93D 1 wk; 0.74D 6 ms. Grp. 3: 1.06D 1 wk; 0.82D 6 mos. Mean SIA changes: Grp. 1: .63 (± .41) 1 wk.; .37 (±.14) 6 mos. Grp. 2: .64 (± .35) 1 wk.; .56 (± .34) 6 mos. Grp. 3: .91 (± .77) 1 wk.; .7 (± .50) 6 mos. SS difference in SIA after 6 mos between Grp. 1 and Grps. 2 and 3.	SIA was significantly lower in the plate-heptic silicone lens grp. compared to the disc silicone and PMMA lenses grps. Vector analysis demonstrated that temporal corneal tunnel incisions induced clinically minimal astigmatism over a 6 month period, depending on incision size.	* No comparison among grps for SS differences in age and pre-ocular morbidities. * No mention if evaluator was "blinded" or number of evaluators. * Fairly large ranges of overlapping standard deviations.

Table 5: Comparative studies of different types of IOLs (cont'd)

Author/ study design	Patient characteristics	Surgical procedure & lens specifications	Pre/post evaluation & length of follow up	Lens performance	Surgical Complications	Study Conclusion	Comments
Martin and Sanders 1992 [46] Randomized comparative	Inclusion criteria: 50 to 90 yrs of age Exclusion criteria: Preoperative pathology other than cataract Grp 1: Silicon, 3.2 mm incision N=58 patients Grp 2: PMMA, 6.0 mm incision N=54 patients NNS differences between grps in terms of gender, age (mean age 73 to 75 y) and BCVA	Grp 1: Staar AA-4203 one piece; 10-0 polypropylene sutires, 2 tissue bites, 10 tangential or horizontal sutures Grp 2: IOLAB 6606B one piece biconvex; running 10-0 polypropylene sutures; 5 tissue bites. PE and wet-field cautery. Randomized into groups using Professional Database Analysis System software.	Preop – uncorrected and best corrected VA FU 1 day, 3 mo and 1 y Refractive and keratometric cylinder, Kowa (FC-1000) laser flare/cell-meter, specular microscopy	BCVA – no SS difference over FU Best uncorrected VA SS better in grp 1 than grp 2 at day 1 and 3m. Flare and cell measurements significantly lower at day 1 for grp 1 Mean ECL no SS difference.	Mean keratometric cylinder SS at day 1 but not at 3 m. Mean refractive cylinders SS at 3 m and 1 y.	Benefits of small incision cataract surgery are faster visual rehabilitation, less SIA and decreased inflammation.	*No results reported for 1 y FU for most outcome measures. *No mention of who conducted FU evaluation. *No mention of who did surgery. *Very little detail of surgical procedure.

APPENDIX D: STUDIES ON SAFETY AND EFFICACY OF IOLS WITH THE SAME OPTIC MATERIAL

BCVA: best corrected visual acuity

CCC: continuous curvilinear capsulorhexis

D: diopters

ECCE: extracapsular cataract extraction

HSM: Heparin surface modification

IOL: intraocular lenses

IOP: intraocular pressure

Mo: Month

Nd:YAG: neodymium:yttrium aluminum garnet

NSD: No significant difference

PCO: posterior capsule opacification

PMMA: polymethyl-methacrylate

PE: phacoemulsification

Wk: Week

Y: Year

Table 6: Studies on safety and efficacy of IOLs

Author/study design	Patient characteristics (n=# of patients)	Pre-/post- operative evaluation, length of follow-up	Surgical technique, IOL type	Surgical complications	Postoperative complications and outcomes	Study Conclusions
Steinert et al. 1995 [75] Non-controlled clinical series Comparison of silicone lenses to FDA grid values of PMMA lenses	Patients divided into subgroups based on length of follow up Grp 1: n=423* Grp 2: n=4458* Grp 3: n=401* (*best case patients- those with no preoperative pathologies or postoperative macular degeneration) Patients had visually disabling cataract(s), age ≥ 60 y.	Preop: not mentioned Follow-up: Grp 1: up to 12-14 mo. Grp 2: up to 1 y Grp 3: up to 3 y included BCVA, incidence of postoperative complications, adverse reactions, PCO, Nd:YAG and assessment of laser damage to IOLs.	Grp 1: 5% ECCE, 95% PE Grps 2 and 3: not mentioned **IOL type:** AMO PhacoFlex S1-18B foldable intraocular lens, 6.0 mm biconvex optic, haptics are a polypropylene monofilament, shaped in a modified-J configuration with a 10-degree angulation.	Persistent complications: Grp 1: 1.4% Grp 2: 2.3% Grp 3: 3.2% (included corneal edema, iritis, macular edema, secondary glaucoma, retinal detachment and IOL dislocation).	PCO incidence through 1 y- Grp 1: 33% Grp 2: n/a Grp 3: 32% Nd:YAG: Grp 1: 18.3% within 1 y Grp 2: 21.9% within 1 y Grp 3: 30.2% within 3 y. Outcomes: 20/40 or better BCVA. Grp 1: 96.5% Grp 2: 90.8% Grp 3: 91.4%.	- Good corrected VA maintained in a large series at long term follow-up. - PCO rates typical for procedure/lenstype.
Oshika et al. 1996 [62] Non-controlled clinical series	n = 64 0 age: 71.0 y ± 7.7 (SD) y no apparent ocular pathologies other than age-related cataract	Pre-op: visual acuity measurements, keratometry and specular microscopy. Follow-up visits at 2 y Post-op: visual acuity, keratometry, flare intensity. Specular microscopy at 6 mo and 2 y.	PE, 3.8 mm incision, widened to desired length. There were 56 eyes that had sutureless surgery and 8 that had 10-0 nylon horizontal sutures. **IOL type**: Alcon AcrySof® (foldable) (MA60BM), 6.0 mm optic, modified-C monofilament PMMA haptics	One posterior capsule rupture at the time of IOL implantation. In four cases the folded lens rotated laterally and opened upside down.	There were 7 eyes (11.1%) that developed clinically significant PCO. Nd:YAG was safely performed in each case. Outcomes: At day one 96.9% of patients had a visual acuity of 20/40 or better, 50% had 20/20 or better. At 2 y all patients had a visual acuity of 20/40 and 86.3% had 20/20.	A feature of the IOL was the tacky nature of the surface. In several cases a second instrument was needed to release the lens from the forceps. In most cases, the incision needed to be widened to 3.8 – 4.0 mm to avoid grasping the optic too forcefully and to prevent its sticking. Low PCO rates: Good outcomes for visual acuity at long term follow up.

Table 6: Studies on safety and efficacy of IOLs (cont'd)

Author/study design	Patient characteristics (n=# of patients)	Pre-/post- operative evaluation, length of follow-up	Surgical technique, IOL type	Surgical complications	Postoperative complications and outcomes	Study Conclusions
Linnola & Holst 1998 [44] Non-controlled clinical studies	N = 50 Age 76.7 = 6.9 ys. Exclusion: uncontrolled glaucoma, amblyopia, history of uveitis, diabetic retinopathy, corneal pathologies, iris atrophy or aniridia, shallow anterior chamber, mucrophthalmos or macrophthalmia	FU 1 day, 1 week, and 1, 6 and 12 months. UA and IOP measured. Slitkump microscopy for presence of cells and/or flare of anterior chamber Mean pre-op IOP Pre-post-operative evaluation 17.7 ± 3.7 mm Hg SS difference Pre-op BCVA	PE, 3.0 mm from incision, 16/50 eyes schleral wound sutured with 10.D nylon. All surgeries done by same surgeon. IOL type: CeeOn, 3 piece foldable, Si Optic, PMMA haptic, C-loop angulated 5 degrees, model 920, 6.0 mm optic	Excluded 1 patients, one had capsule tear and the other did not have secure in-the-bag IOL placement	No post-op complications. FU 45/50 patients at 12 mo. Nd:YAG laser capsulotomy.	
Milazzo S, et al. 1996 [49] This series is part of a prospective study of consecutive surgeries comparing PE with silicone IOLs and ECCE with PMMA IOLs.	0 age:73.8 y Range: 59-89 y n=111 consecutive patients, 4 had intraoperative complications and were excluded. n=107 (best cases)	0 preop visual acuity 21/142 (light perception to 20/70) All patients had follow-up visits at 1, 15 and 90 d, reexamined at 0 of 20 mo. Eighty-six patients (80%) had a 0 follow-up of 57 months, 105 (98%) patients - 20 months. Only 38 patients (36%) were seen at every visit and had a maximum follow-up of 6 y.	PE, 3.2-mm scleral incision, widened to 4.0 mm, 2.0 mm from the limbus. In 54 eyes the IOL was placed in the sulcus after can-opener capsulotomy and in 53 eyes the IOL was placed in the capsular bag after CCC. Incision sutured with nylon. **IOL type:** AMO silicone optics, 14 mm polypropylene haptics, foldable. Lens styles were SI-18, SI-19, and SI-20.	Two complications were linked to lens insertion. A large Descemet's tear (25% of corneal area) led to persistent corneal edema and, a lens was inserted wrong side up, upside down inside the anterior chamber with no effect on visual acuity.	Iridocapsular synechias (10-11%) occurred early and remained stable. IOL pigment deposits were significant at the 57th mo (11.6%) but had no effect on visual acuity. PCO: 13.7% of eyes at 20 months; 40.6% at 57 months required Nd:YAG, laser treatment caused pitting of the silicone in most cases; this had no effect on visual acuity. There was no visual acuity below 20/35 in the series.	Significant PCO rates, acceptable visual acuity at long term follow up.

Table 6: Studies on safety and efficacy of IOLs (cont'd)

Author/study design	Patient characteristics (n=# of patients)	Pre-/post- operative evaluation, length of follow-up	Surgical technique, IOL type	Surgical complications	Postoperative complications and outcomes	Study Conclusions
Brown et al. 1998 [6] Postoperative examinations for patients enrolled in the FDA Phase I clinical study of the Staar Collamer IOL.	n=125 enrolled by 6 investigators. n=74, best case patients*. Approximately 97% of patients 60 y. The top three ocular pathologies were corneal guttata (15.2%), macular degeneration (12.0%) and glaucoma (8.8%) * Those patients without pre-existing pathology.	Preop: BCVA Follow-up: up to 4 to 6 mo. Postop: BCVA	PE, sutureless, clear corneal tunnel incisions, except 2, who had scleral tunnel entries. Wound size at lens insertion 3.0mm in 84.8%. **IOL type:** Staar surgical Co. CC-4203VF foldable lens, 5.5 mm optic, plate haptic, biconvex optic. The lenses were injected into the PC and positioned in the capsular bag.	There was a minor corneal burn secondary to PE in 2 (1.6%) patients.	Of 107 patients, 2 (1.9%) had non-pigmented precipitates and 19 (17.8%) presented with PCO at 4 to 6 mo, 5 of whom required Nd:YAG. At 4 to 6 mo follow-up 100% of best case and 97.1% of all patients had 20/40 or better BCVA.	Acceptable short term results for PCO rates and visual acuity.
Sanchez and Artaria 1996 [68] Case series.	0 age: 72.9 y ± 11.9 y Range: 33 - 91 y n= 50 consecutive patients (1 patient had a traumatic cataract, 4 patients had age-related macular degeneration and were excluded).	Preop: visual acuity, intraocular pressure, keratometry Follow-up: (0 follow-up 12.1 ± 3 mo, range 6 - 16 mo) Post-op: BCVA, intraocular pressure, subjective/ objective refractions and lens centration.	PE with local retrobulbar anesthesia, 3.2 mm wide scleral tunnel incision followed by a 5.0 mm continuous curvilinear capsulorhexis. Sclerocorneal tunnel widened to 3.5 mm to allow insertion of a foldable acrylic. **IOL type:** ACR360 lens with 6.0 mm biconvex body, 5.0 mm optical zone, polypropylene monofilament haptics, modified C-shape, angulated 5 degrees anteriorly.	One radial tear of the capsulorhexis and one posterior capsule rupture. The IOL optic had a tendency to stick to the folding instrument.	1-fibrinoid reaction; 1-elevated IOP, 1-atonic pupil, 1-clinical cystoid macular edema, 2-optic decentration less than 1.0 mm 5-damaged IOL surfaces. After a 0 follow-up of 12 mo there were no cases of clinically significant PCO. However, the follow-up was too short to allow any conclusions about the incidence of PCO. At 6 mo follow-up BCVA of 20/40 or better was achieved by 100% of best-case patients.	The three-piece ACR360 acrylic lens combines the advantages of both foldable and rigid IOLs. The clinical results of this prospective study compare favourably to those describing implantation of rigid PMMA lenses or of soft lenses of different materials.

Table 6: Studies on safety and efficacy of IOLs (cont'd)

Author/study design	Patient characteristics (n=# of patients)	Pre-/post- operative evaluation, length of follow-up	Surgical technique, IOL type	Surgical complications	Postoperative complications and outcomes	Study Conclusions
Hayashi K et al. 1998 [24] Randomized prospective study. Measurements were made independently by 3 ophthalmic technicians who were not informed of the purpose of the study.	n=100 0 age: 69.3 y Range: 38 - 89 y Patients had age-related cataract surgery in both eyes with IOL implantation	Preop: not mentioned Follow-up: up to 6 mo Nine patients lost to follow-up, outcomes were measured on 91. Postop: Decentration and tilt were examined using the anterior eye segment analysis system (EAS-1000)	PE with 6.5 mm incision, 3.0 mm posterior to the anterior margin of the limbal vascular arcade for implanting the IOL. The CCC measured 5.5 mm in diameter. **IOL type:** PMMA MZ60BD, Alcon one piece, 6.0 mm optic, biconvex PMMA UV22 or UV25T, Menicon, 3 piece, 6.0 mm optic Planoconvex, polyvinylidene fluoride haptics A 3-piece PMMA IOL was implanted in one eye and a 1-pc PMMA IOL was implanted in the other.	None reported.	No postop complications mentioned. At 1-wk after surgery, all IOLs were confirmed to be implanted in the capsular bag. There was a statistically significant difference in decentration with the larger for the 3-pc PMMA than the 1-pc PMMA lens. The tilt was the same for the two IOLs.	

Table 6: Studies on safety and efficacy of IOLs (cont'd)

Author/study design	Patient characteristics (n=# of patients)	Pre-/post- operative evaluation, length of follow-up	Surgical technique, IOL type	Surgical complications	Postoperative complications and outcomes	Study Conclusions
Lai & Fan 1996 [40]. Randomized double blind trial at 2 centres.	A = 51 modified PMMA lens A = 48 unmodified PMMA lens All patients were Asian and were scheduled for ECCE. Age: modified PMMA 0 = 67.5 y (44 - 87) Unmodified PMMA 0 = 64.8 y (38 - 87) Exclusion: diabetic retinopathy, chronic or recurrent uveitis, corneal transplant, endothelial dystrophy, inability to participate in 12 mo FU Both grps were comparable	Preop: BCVA, pachynetry, IOP, anterior chEMbe depth, ocular pathology Follow up: up to 12-14 mos. Post-op: BCVA, IOP anterior chamber depth and general other measures. Main outcome measure was presence of call, pigment, and fibrinlike deposits on the IOL surface	Standard ECCE, IOL placed in capsular bag when possible. **IOL type:** PMMA Pharmacia Ophthalmics 725, 7 mm optic, one piece a) PMMA IOL (non-HSM) b) PMMA IOL with heparin grated to its surface (HSM)	Two introspecutive complications in HSM and four in non-HSM group.	Cell deposits: HSM 27% non-HSM 64% (SS difference) [highest levels were at 3-6 months). Pigment deposits: None in non-HSM group, but NSD after 12-14 months. BCVA: 86% in HSM and 87% in non-HSM attained ~A of ≥ 0.5 at 12-14 months.	Heparin surface modification to PMMA reversed post-op inflammatory reaction to PMMA over 12-14 months.

APPENDIX E: SURVEYS OF PRACTICE PATTERNS FOR CATARACT SURGERY/IOL IMPLANTATION IN DEVELOPED COUNTRIES

Abbreviations:

ACIOL:	Anterior capsule IOL
ECCE:	Extracapsular cataract extraction
ICCE:	Intracapsular cataract extraction
Mo:	Month
PCIOL:	Posterior capsule IOL
Phaco:	Phacoemulsification
PMMA:	Polymethyl-methacrylate
Post op:	Post operative
Pre op:	Pre-operative
RR:	Response rate
Wk:	Week
Y:	Year

Table 7: Surveys of practice patterns

Authors, Response rate, Country, Year	Methodology And Referral practices	Pre-/post- operative evaluation	Surgical technique, Anesthesia, IOL type	Surgery complications, rates of Nd:YAG capsulotomy	Comments/Conclusions
Survey conducted in three parts: Courtney P [10] Desai P [11] Global Response Rate: 66.2% United Kingdom 1990	Prospective cross-sectional survey of ophthalmologists who performed age-related cataract surgery representing n=1498 patients aged 50 years or older, admitted during the week of the survey. Referrals: GP: 82.7% Ophthalmic practitioners/ optometrists: 7.7% Other hospital depts: 7.8%	Snellen visual acuity exam both before and after surgery. At 3 mo post-op complications included: posterior capsule thickening (6.3%), raised intraocular pressure (2.3%), presence of clinically detectable cystoid macular oedema (1.2%).	Of all patients admitted for surgery: 8% had day-case surgery, of these 95% had local anesthetic. In-patient surgeries: 42% local anesthetic, 58% general anesthetic Surgery: 92% ECCE, 4% ICCE, 4% Phaco IOLs: 95% PCIOL 3% ACIOL 2% none	Of the 6.3% (n=63) of patients presenting at 3 months with posterior capsule thickening, over half (n=36) required YAG capsulotomy. This should be considered to be a minimum estimate, as the number of patients who will require a capsulotomy will increase with longer follow-up.	The 3 papers provided information about the methods, the clinical outcomes and the processes involved in the cataract surgery survey. The authors addressed the access, delivery and outcome of age-related cataract surgery with IOL implantation. This survey has also established the first step in the development of a national database for cataract surgery at the College of Ophthalmologists. Risk factors and quantification of the level of risk involved were identified which may better advise patients on the outcome of cataract surgery. An interesting point made by the authors is that the thresholds for surgery have been observed to be decreasing since the introduction of microsurgical techniques and intraocular lenses.
Oshika et al. [61] RR: 46.7% Japan 1996	Surveys mailed to ophthalmologist members of the Japanese Society of Cataract and Refractive Surgery. ±26.6 cataract surgeries per month in 1995, an increase from '93 and '94. Most patients were hospitalized for their surgery, 44% of surgeons were performing some outpatient cataract procedures, an increase from '93 and '94. Follow-up frequency for these patients averaged 3.31 days during the first week.	Pre- and post-operative evaluations not mentioned.	All used local anesthesia for cataract surgery. Use of a facial block was more popular with surgeons who preferred ECCE to phaco. Phaco grew in popularity with 53% of surgeons using it over other surgical techniques. Preference for phaco was dependent on surgical volume; the more surgeries per mo, the more phaco was used. 97% of those doing over 51 procedures per mo used phaco. Self-sealing wound construction was the main wound closure technique in phaco for 42% of the ophthalmologists, up from 25% in '92, 30% in '93 and 38% in '94. Running radial suture was preferred by 20%. IOL type used: 41% soft acrylic, 39% foldable silicone 27% PMMA 4% oval PMMA	Rate of posterior capsular rupture was 2.5%. Occurrence rate for displacement of the nucleus into the vitreous was 1.12 cases per 1,000 cataract operations. 23% of respondents had experienced explantation of an IOL during the past year. The most frequently cited reason was IOL power miscalculation, followed by endophthalmitis, IOL decentration, corneal endothelial damage and retinal detachment. Incidence of PCO not mentioned.	Results of survey may not reflect the opinions of all members of the Japanese Society of Cataract and Refractive Surgery. The limitations of a survey by questionnaire are discussed.

Table 7: Surveys of practice patterns

Authors, Response rate, Country, Year	Methodology And Referral practices	Pre-/post- operative evaluation	Surgical technique, Anesthesia, IOL type	Surgery complications, rates of Nd:YAG capsulotomy	Comments/Conclusions
Hansen [18] RR: not given Denmark 1997	Members of the Danish Ophthalmological Society were surveyed by questionnaire. Only those ophthalmologists performing cataract surgery were asked to respond; there were 90 respondents.	57% of surgeons always saw their own cataract patients before surgery, 21% saw them most often, and 22% seldom saw them. 50% of surgeons saw their own patients on the first post-operative day, 29% saw them most often, 21% seldom saw them. Further follow-up is not mentioned.	82% preferred phaco, an increase from 78% the prior y. The use of ECCE dropped to 18% from 22% in '96 and 43% in '95. No suture after phaco increased from 47% in '96 to 59% in '97. Retrobulbar anesthesia was used 41% of the time, a decrease from 48% in '96. Peribulbar was preferred by 41%, a slight drop from the 43% in '96 and subtenon was preferred by 10%, up from 6% in the prior y. Topical anesthetic was preferred by 9% which was up from 2% the previous y. PMMA optic was the most preferred optic but decreased from 83% in '96 to 64% in '97. Silicone optic stabilized at 16%, acrylic IOL at 11%.	Total occurrence rate of dropped nucleus was 1.05 cases per 1,000 surgeries.	The weaknesses of a multiple-choice questionnaire were discussed. This form of survey is necessary to describe trends and standardize answers.
Bellan, et al. [5] RR: 67% Canada 1997	Random sample of ophthalmologists from the mailing list of the Canadian Ophthalmological Society. From this list a 60% sample of ophthalmologists was selected by means of a systematic random sampling technique. Several stages of follow-up reminders by mail and telephone were sent out. Because no comparable survey of Canadian ophthalmologists could be found, findings were compared with recommendations from the CPG for cataract surgery published by the AHCPR.	Preop: > 95% of the time dilated fundus exam, refraction and A-scan ultrasonography were done. Postop: The mean number of postop visits was 4.25 (range 2 - 10). Follow-up visits were greater for ECCE surgeons (4.7) than for phaco surgeons (3.75). Performance of slit-lamp exam and tonometry within 4 mo of surgery was almost equivalent to the reported rate of follow-up visits.	Most frequent surgical technique reported was ECCE at 52%, followed by phaco at 46% and ICCE at 2%. It was noted that those reporting a more frequent use of phaco were more likely to report higher surgical volumes. Suture style not mentioned. A total of 57% reported a high use of retrobulbar anesthesia, (ie. in 90% or more of routine cases), 18% reported high use of peribulbar anesthesia and 0.7% reported use of general anesthesia. IOL type not mentioned	17.9% of patients were estimated as undergoing Nd:YAG laser capsulotomy within 1 y after cataract extraction. Most surgeons estimated their rate of Nd:YAG as less than 40% but there were some significant outliers with rates over 60%.	Data obtained in this 1993 survey may not reflect current practice patterns. Although ECCE is the most common type of surgery performed at this time, the number of surgeons "trying out" phaco will most likely adopt it as their predominant form of surgery in the next few years. Since phaco surgeons tend to have fewer follow-up visits, the change may imply changes in funding and allocation of surgeons' time. Overall, the self-reported practices of Canadian surgeons with relation to preoperative testing and postoperative follow-up appear to be consistent with the CPG for cataract surgery. There remain, however, significant variations in number of postoperative visits and Nd:YAG capsulotomy rates, which warrant further study. [Authors conclusions]

Table 7: Surveys of practice patterns

Authors, Response rate, Country, Year	Methodology And Referral practices	Pre-/post- operative evaluation	Surgical technique, Anesthesia, IOL type	Surgery complications, rates of Nd:YAG capsulotomy	Comments/Conclusions
Leaming [43] RR:29% United States 1998	A survey of the practice styles and preferences of members of the American Society of Cataract and Refractive Surgery. The survey forms are multiple-choice. Neither questionnaire nor return envelope was marked or labeled to maintain the confidentiality of the respondent.	Not mentioned	63% of respondents no longer used planned ECCE; phaco was the preferred cataract extraction technique for the majority along with 73% of respondents using the no-suture closure technique. 30% of surgeons used periocular block, 18% used retrobulbar without a facial block, 21% used retrobulbar with a facial block. Use of topical anesthetic increased from 8% in 1995 to 30% in 1997. As in all years since 1986, PMMA was the preferred optic material. As surgical volume increased, preference for silicone increased. The most dramatic change was in the preference for an acrylic optic, it increased from 2% in 1994 to 38% in 1997 surpassing the preference for silicone. Although use of foldable IOLs is currently low, it is expected to rise since 79% of respondents said they were 'very interested'.	Surgery complications and capsulotomy rates are not mentioned.	The primary purpose of this survey was to increase the availability of this information to ophthalmologists so they will be better able to pick up trends within the profession. [Authors comments]

REFERENCES

1. Agency for Health Care Policy & Research. Patient Outcomes Research Team. Principle Investigator: Earl P. Steinberg. Variations in cataract management: patient and economic outcomes. www.ahcpr.gov/clinic/ *medtep/catport.htm.* Spring 1995.
2. Agency for Health Care Policy & Research Cataract Management Guideline Panel. *Cataract in adults: management of functional impairment.* Clinical Practice Guideline No. 4. Rockville; U.S. Department of Health and Human Services, January 1993.
3. American Academy of Ophthalmology Quality of Care Committee Anterior Segment Panel. *Cataract in the Otherwise Healthy Adult Eye*. San Francisco, The American Academy of Ophthalmology, 1989.
4. Apple DJ, Kincaid MC, Mamlis N, et al. *Intraocular lenses: evolution, designs, complications and pathology.* Baltimore, Williams & Wilkins, 1989.
5. Bellan L, Dunn E, Black C. Practices associated with cataract surgery in Canada: results of a national survey. *Canadian Journal of Ophthalmology* 1997;32:315-23.
6. Brown DC, Grabow HB, Martin RG, et al. Staar Collamer intraocular lens: Clinical results from the Phase I FDA core study. *Journal Of Cataract And Refractive Surgery* 1998;24(8):1032-38.
7. Cassard SD, Patrick DL, Damiano AM, et al. Reproducibility and responsiveness of the VF-14. *Archives of Ophthalmology* 1995;113:1508-13.
8. Clark DS, Emery JM, Munsell MF. Inhibition of posterior capsule opacification with an immunotoxin specific for lens epithelial cells: 24 month clinical results. *Journal of Cataract & Refractive Surgery* 1998;24:1614-20.
9. Clark DS, Munsell MF, Emery JM. Mathematical model to predict the need for neodymium: YAG capsulotomy based on posterior capsule opacification rate. *Journal of Cataract & Refractive Surgery* 1998;24:1621-25.
10. Courtney P. The National Cataract Surgery Survey: I. Method and Descriptive Features. *Eye* 1992;6:487-92.
11. Desai P. The National Cataract Surgery Survey: III. Process Features. *Eye* 1993;7:667-71.
12. Dick HB, Kohnen T, Jacobi FK, et al. Long-term endothelial cell loss following phacoemulsification through a temporal clear corneal incision. *Journal of Cataract & Refractive Surgery* 1996;22(1):63-71.

13. Erie JC, Hardwig P, Hodge DO. Effect of intraocular lens design on neodymium: YAG laser capsulotomy rates. *Journal of Cataract & Refractive Surgery* 1998;24(9):1239-42.

14. Fruscella S, Ducoli P, Manni GL. Decentration of posterior chamber IOL: Effects of loop material and fixation technique. *European Journal of Ophthalmology* 1994;4(2):111-14.

15. Gimbel HV, Anderson-Penno E. Cataracts: Pathogenesis and treatment. *Canadian Journal of Clinical Medicine* 1998;5(11):232-41.

16. Gimbel HV, Neuhann T. Development, advantages, and methods of the continuous circular capsulorhexis technique. *Journal of Cataract & Refractive Surgery* 1990;16:31-37.

17. Gonvers M, Sickenberg M, Van MG. Change in capsulorhexis size after implantation of three types of intraocular lenses. *Journal of Cataract & Refractive Surgery* 1997;23(2):231-38.

18. Hansen TE. Practice styles and preferences of Danish cataract surgeons - 1997 survey. *Acta Ophthalmologica Scandinavica* 1997;75:577-80.

19. Harvard Medical School. Intraocular lenses and cataract surgery. *www.eri.harvard.edu/documentation/cataracts* September 15, 1998.

20. Hayashi H, Nakao F, Hayaski F. Quantitative comparison of posterior capsule opacification after polymethylmethacrylate, silicone, and soft acrylic intraocular lens implantation. *Archives of Ophthalmology* 1998;116:1579-82.

21. Hayashi K, Hayashi H, Nakao F, et al. Reproducibility of posterior capsule opacification measurement using Scheimpflug videophotography. *Journal of Cataract & Refractive Surgery* 1998;24:1632-35.

22. Hayashi K, Harada M, Hayashi H, et al. Decentration and tilt of polymethyl methacrylate, silicone, and acrylic soft intraocular lenses. *Ophthalmology* 1997;104(5):793-98.

23. Hayashi K, Hayashi H, Nakao F, et al. Reduction in the area of the anterior capsule opening after polymethylmethacrylate, silicone, and soft acrylic intraocular lens implantation. *American Journal of Ophthalmology* 1997;123(4):441-47.

24. Hayashi K, Hayashi H, Nakao F, et al. Comparison of decentration and tilt between one piece and three piece polymethyl methacrylate intraocular lenses. *British Journal of Ophthalmology* 1998;82(4):419-22.

25. Health Services Utilization and Research Commission. Cataract surgery rates. http://www.sdh.sk.ca/hsurc/cataracthomepage.htm May 28, 1998.

26. Hirsch NA, Cowley DE, Lea AR, et al. *Health care technology and the older person*. Canberra, Australia: Australian Institute of Health & Welfare, December 1, 1993.

27. Holladay JT. International Intraocular Lens Registry. *Journal of Cataract & Refractive Surgery* 1999;25:128-36.

28. Hollick EJ, Spalton DJ, Ursell PG, et al. The effect of polymethylmethacrylate, silicone, and polyacrylic intraocular lenses on posterior capsular opacification 3 years after cataract surgery. *Ophthalmology* 1999;106(1):49-55.

29. Hollick EJ, Spalton DJ, Ursell PG, et al. Biocompatibility of poly(methylmethacrylate), silicone, and AcrySof intraocular lenses: Randomized comparison of the cellular reaction on the anterior lens surface. *Journal of Cataract & Refractive Surgery* 1998;24(3):361-66.

30. Holweger RR, Marefat B. Corneal changes after cataract surgery with 5.0 mm sutured and 3.5 mm sutureless clear corneal incisions. *Journal of Cataract & Refractive Surgery* 1997;23(3):342-46.

31. Jacobi FK, Kohnen T, Dick B. Contrast sensitivity and glare disability in different IOL types after clear-corneal cataract surgery. *European Journal of Implant & Refractive Surgery* 1995;7(4):214-18.

32. Jaffe GJ. Management of condensation on a foldable acrylic intraocular lens after vitrectomy and fluid-air exchange. *American Journal of Ophthalmology* 1997;124(5):692-93.

33. Keeffe JE, Taylor HR. Cataract surgery in Australia 1985-94. *Australian & New Zealand Journal of Ophthalmology* 1996;24(4):313-17.

34. Klein BE, Klein R, Linton KL. Change in visual acuity associated with cataract surgery. The Beaver Dam Eye Study. *Ophthalmology* 1992;99(4):546-52.

35. Kohlhaas M, Kless M, Kammann J, et al. Endothelial cell loss secondary to two different phacoemulsification techniques. *Ophthalmic Surgery and Lasers* 1998;29(11):890-95.

36. Kohnen T. The variety of foldable intraocular lens materials [editorial]. *Journal of Cataract & Refractive Surgery* 1996;(22(Suppl. 2):1255-58.

37. Kohnen T, Dick B, Hessemer V, et al. Effect of heparin in irrigating solution on inflammation following small incision cataract surgery. *Journal of Cataract & Refractive Surgery* 1998;24(2):237-43.

38. Kohnen T, Dick B, Jacobi KW. Comparison of the induced astigmatism after temporal clear corneal tunnel incisions of different sizes. *Journal of Cataract & Refractive Surgery* 1995;21(4):417-24.

39. Kohnen T, Magdowski G, Koch DD. Scanning electron microscopic analysis of foldable acrylic and hydrogel intraocular lenses. *Journal of Cataract & Refractive Surgery* 1996;22(Suppl. 2):1342-50.

40. Lai YK, Fan RF. Effect of heparin-surface-modified poly(methyl methacrylate) intraocular lenses on the postoperative inflammation in an Asian population. *Journal of Cataract & Refractive Surgery* 1996;22)Suppl. 1):830-34.

41. Laidlaw DAH, Harrad RA, Hopper CD et al. Randomised trial of effectiveness of second eye cataract surgery. *Lancet* 1998;352:925-29.

42. Leaming DV. Practice styles and preferences of ASCRS members--1995 survey. *Journal of Cataract & Refractive Surgery* 1996;22(7):931-39.

43. Leaming DV. Practice styles and preferences of ASCRS members - 1997 survey. *Journal of Cataract & Refractive Surgery* 1998;24:552-61.

44. Linnola RJ, Holst A. Evaluation of a 3-piece silicone intraocular lens with poly(methyl methacrylate) haptics. *Journal of Cataract & Refractive Surgery* 1998;24:1509-14.

45. Mamalis N, Phillips B, Kopp CH, et al. Neodymium:YAG capsulotomy rates after phacoemulsification with silicone posterior chamber intraocular lenses. *Journal of Cataract & Refractive Surgery* 1996;22(Suppl. 2):1296-1302.

46. Martin RG, Sanders DR. Visual, astigmatic, and inflammatory results with the Starr AA-4203 single-piece foldable IOL: a randomized, prospective study. *Journal of Cataract & Refractive Surgery* 1996;23(11):770-75.

47. Masket S, Tennen DG. Astigmatic stabilization of 3.0 mm temporal clear corneal cataract incisions. *Journal of Cataract & Refractive Surgery* 1996;22(10):1451-55.

48. Mendivil A. Intraocular lens implantation through 3.2 versus 4.0 mm incisions. *Journal of Cataract & Refractive Surgery* 1996;22(10):1461-64.

49. Milazzo S, Turut P, Artin B, et al. Long-term follow-up of three-piece, looped, silicone intraocular lenses. *Journal of Cataract & Refractive Surgery* 1996;22(Suppl. 1):1259-62.

50. Moran D, Gillies M, Brian G, et al. Low-cost intraocular lenses for cataract patients [letter]. *Lancet* 1997;349(9055):885-86.

51. Newland TJ, McDermott ML, Eliott D, et al. Experimental neodymium: YAG laser damage to acrylic, poly(methyl methacrylate), and silicone intraocular lens materials. *Journal of Cataract & Refractive Surgery* 1999;25:72-76.

52. Ng DT, Rowe NA, Francis IC, et al. Intraoperative complications of 1000 phacoemulsification procedures: A prospective study. *Journal of Cataract & Refractive Surgery* 1998;24:1390-95.

53. NHS Centre for Reviews and Dissemination, Nuffield Institute for Health. *Management of Cataract.* York: NHS Centre for Reviews and Dissemination, 1996.

54. Norregaard JC, BernthPetersen P, Bellan L, et al. Intraoperative clinical practice and risk of early complications after cataract extraction in the United States, Canada, Denmark, and Spain. *Ophthalmology* 1999;106(1):42-48.

55. Norregaard JC, Hindsberger C, Alonso J, et al. Visual outcomes of cataract surgery in the United States, Canada, Denmark, and Spain: Report from the International Cataract Surgery Outcomes Study. *Archives of Ophthalmology* 1998;116(8):1095-1100.

56. Oh KT. Optimal folding axis for acrylic intraocular lenses. *Journal of Cataract & Refractive Surgery* 1996;22(6):667-70.

57. Olson RJ, Crandall AS. Prospective randomized comparison of phacoemulsification cataract surgery with a 3.2-mm vs a 5.5-mm Sutureless incision. *American Journal of Ophthalmology* 1998;125(5):612-20.

58. Olson RJ, Crandall AS. Silicone versus polymethylmethacrylate intraocular lenses with regard to capsular opacification. *Ophthalmic Surgery & Lasers* 1998;29(1):55-58.

59. Omar O, Mamalis N, Veiga J, et al. Scanning electron microscopic characteristics of small-incision intraocular lenses. *Ophthalmology* 1996;103(7):1124-29.

60. Oshika T, Nagahara K, Yaguchi S, et al. Three year prospective, randomized evaluation of intraocular lens implantation through 3.2 and 5.5 mm incisions. *Journal of Cataract & Refractive Surgery* 1998;24(4):509-14.

61. Oshika T, Masuda K, Majima Y, et al. Current trends in cataract and refractive surgery in Japan--1995 survey. *Japanese Journal of Ophthalmology* 1996;40(3):419-33.

62. Oshika T, Suzuki Y, Kizaki H, et al. Two year clinical study of a soft acrylic intraocular lens. *Journal of Cataract & Refractive Surgery* 1996;22(1):104-9.

63. Oshika T, Tsuboi S, Yaguchi S, et al. Comparative study of intraocular lens implantation through 3.2- and 5.5- mm incisions. *Ophthalmology* 1994;101(7):1183-90.

64. Powe NR, Schein OD, Gieser SC, et al. Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation. Cataract Patient Outcome Research Team. *Archives of Ophthalmology* 1994;112(2):239-52.

65. Powe NR, Tielsch JM, Schein OD, et al. Rigor of research methods in studies of the effectiveness and safety of cataract extraction with intraocular lens implantation. Cataract Patient Outcome Research Team. *Archives of Ophthalmology* 1994;112(2):228-38.

66. Ravalico G, Baccara F, Lovisato A, et al. Postoperative cellular reaction on various intraocular lens materials. *Ophthalmology* 1997;104(7):1084-91.

67. Roman ST, Auclin FX, Chong-Sit DA, et al. Surgically induced astigmatism with superior and temporal incisions in cases of with-the-rule preoperative astigmatism. *Journal of Cataract & Refractive Surgery* 1998;24:1636-41.

68. Sanchez E, Artaria L. Evaluation of the first 50 ACR360 acrylic intraocular lens implantations. *Journal of Cataract & Refractive Surgery* 1996;22(Suppl. 2):1373-78.

69. Schaumberg DA, Dana MR, Christen WG, et al. A systematic overview of the incidence of posterior capsule opacification. *Ophthalmology* 1998;105(7):1213-21.

70. Schein OD, Steinberg EP, Javitt J, et al. Variation in cataract surgery practice and clinical outcomes. *Ophthalmology* 1994;101(6):1142-52.

71. Seward HC. Folding intraocular lenses: materials and methods [Commentary]. *British Journal of Ophthalmology* 1997;81(5):340-41.

72. Singh AR, Fang T, Rath R. Cartridge cracks during foldable intraocular lens insertion. *Journal of Cataract & Refractive Surgery* 1998;24:1220-22.

73. Stark BI, Worthen DM, Holladay JT, et al. The FDA Report on Intraocular Lenses. *Ophthalmology* 1983;90(4):311-17.

74. Steinberg EP, Tielsch JM, Schein OD, et al. National study of cataract surgery outcomes. *Opthalmology* 1994;100(6):1131-41.

75. Steinert RF, Bayliss B, Brint SF, et al. Long-term clinical results of AMO PhacoFlex model SI-18 intraocular lens implantation. *Journal of Cataract & Refractive Surgery* 1995;21(3):331-38.

76. Steinert RF, Brint SF, White SM, et al. Astigmatism after small incision cataract surgery. *Ophthalmology* 1991;98(4):417-24.

77. Steinert RF, Deacon J. Enlargement of incision width during phacoemulsification and folded intraocular lens implant surgery. *Ophthalmology* 1996;103(2):220-25.

78. Tobacman JK, Lee P, Zimmerman B, et al. Assessment of appropriateness of cataract surgery at ten academic medical centers in 1990. *Ophthalmology* 1996;103(2):207-15.

79. Tognetto D, Baccara F, Parentin F, et al. Posterior capsule opacification in PMMA and Poly-Hema IOL implantation [Italian]. *Annali di Ottalmologia e Clinica Oculistica* 1994;120(5):349-55.

80. Ursell PG, Spalton DJ, Pande MV. Anterior capsule stability in eyes with intraocular lenses made of poly(methyl methacrylate), silicone, and AcrySof. *Journal of Cataract & Refractive Surgery* 1997;23(10):1532-38.

81. Ursell PG, Spalton DJ, Pande MV, et al. Relationship between intraocular lens biomaterials and posterior capsule opacification. *Journal of Cataract & Refractive Surgery* 1998;24(3):352-60.

82. Uusitalo RJ, Tarkkanen A. Outcomes of small incision cataract surgery. *Journal of Cataract & Refractive Surgery* 1998;24(2):212-21.

83. Wang M-C, Woung L-C, Hu C-Y, et al. Position of polymethyl methacrylate and silicone intraocular lenses after phacoemulsification. *Journal of Cataract & Refractive Surgery* 1998;24:1652-57.

84. Zambarakji HJ, Rauz S, Reynolds A, et al. Capsulorhexis phymosis following uncomplicated phacoemulsification surgery. *Eye* 1997;11(5):635-38.