

WHO/PBL/91.1
Original: English
Distr: Limited



Report of a WHO consultation

Geneva, 3 - 7 December 1990



World Health Organization
Programme for the Prevention of Blindness

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Report of the consultation on the use of intraocular lenses in cataract surgery in developing countries

1. THE GLOBAL MAGNITUDE OF VISUAL LOSS DUE TO CATARACT

According to a global estimate of blindness in 1987, there are between 27 and 35 million blind in the world, with more than 90% of these living in developing countries. This estimate was based on the internationally accepted definition of blindness as vision less than 0.05 or 3/60 (inability to see to count the fingers of a hand at a distance of 3 metres or 10 feet). This vision level represents less than the minimal "walk about" vision.

Cataract is by far the most common cause of loss of vision all over the world and approximately 50% of all blindness is caused by this disorder. There are several types of cataract, but the one of public health significance is usually referred to as "aging-related", or sometimes, misleadingly, as "senile" cataract. A number of risk factors have been put forward as the causation of this type of cataract, such as UV-light exposure, poor nutrition or severe dehydration, but it is probable that the cataractogenesis is of multifactorial origin. Thus, as there is at present no prevention possible of this type of cataract, the only available strategy against this condition is surgery, which, however, allows for a very good restoration of sight lost.

Delivery of cataract surgery is often difficult in developing countries, mainly due to lack of manpower and other resources, but sometimes also due to less efficient utilization of existing services and facilities. These circumstances have led to an accumulation of unoperated cases of cataract in many developing nations. Thus, it is presently estimated that there are more than 13 million blind representing the "backlog" of cases which could benefit from cataract surgery, if it were made available. Still, these figures do not take into account all those suffering from partial loss of sight, which may more than double the number of people concerned, suffering from severe visual disability, and who could benefit a great deal from surgery.

The cataract backlog is mostly found in underserved rural areas in Africa, Asia and Latin America, as seen in the following table:

Continent	Population ^a		Estimated number of cataract blind	% of world backlog
	1990	%		
Africa	645 276	12.3	2 949 000	21.6
America				
Latin	451 072	8.6	677 000	5.0
North	275 325	5.3	55 000	0.4
Asia	3 057 648	58.1	9 737 000	71.3
Europe	498 592	9.5	100 000	0.7
Oceania	26 467	0.5	9 000	0.06
USSR	291 822	5.6	120 000	0.9
Total	5 246 202	100	13 647 000	100

^a Population in thousands.

Note: It should be explained that the above figures for the number of cataract blind represent the minimum estimated.

Overall, the problem of cataract is increasing in the world, due to the growing number of elderly in all populations and the close relationship between aging and the common "senile" cataract. Furthermore, the impact of cataract, in terms of social and economic consequences, is very significant all around the world. In developed countries, cataract surgery is becoming the most common surgical procedure and is increasingly attended by the problem of escalating cost. In the developing world, the repercussions of blinding cataract are seen in loss of productivity of the individual, devalued quality of life and deteriorating well-being of the family. To this should be added the grim fact that the blind suffer a significantly increased mortality in the setting of developing countries. This is further compounded by the fact that cataract appears to have an earlier onset and progresses more rapidly to blinding propensity in many of those countries concerned. Thus, data from India, Kenya and Saudi Arabia indicate that already 10% of persons in the age group of 40-50 years suffer from significant visual loss from cataract, with 1%-3% being blind. The corresponding rates in European or North American populations would not be found before the age of 60 or 70 years.

Unfortunately, there are almost no data available on the incidence (new cases) of cataract blindness in different populations. The estimated minimum incidence of cataract blindness of 1 case per 1000 population/year is a useful planning figure in the projected need for cataract surgery. If this incidence figure is applied to the present global population, it elucidates the staggering fact that there are more than 14 000 new cases of cataract blindness per day in the world. However, recent data extrapolated from mortality and prevalence figures suggest that the incidence could be as high as 2 per 1000 population/year.

Considering the present situation in most developing countries with severe constraints for the delivery of cataract surgery, it is clear that priority must be given to sight restoration in the individual already blind from cataract. Similarly, the visual needs in different settings must be considered, as well as the cost of intervention, which is likely to be one of the major determining factors for how much surgery can be provided. Present experience from eye camps in India shows that the total cost for cataract surgery is in the order of US\$ 25, when the routine procedure of cataract extraction plus provision of spectacle correction is carried out. A more sophisticated procedure, such as an intraocular lens implantation, will increase this cost threefold or more.

Other major factors limiting the delivery of cataract surgery include the shortage of trained manpower in many countries; this refers particularly to Africa, south of the Sahara, where there is, in general, only one ophthalmologist per million population, as compared to one per 20 000 population in Europe. This situation calls for drastic new approaches in manpower development, and the same applies to the cost-effectiveness of service delivery, including the social acceptability and optimal utilization of available resources. The case of Africa is, again, an alarming example in that even out of a low estimate of 500 000 new cases of blindness due to cataract each year, only about 50 000, or one out of 10 cases, are being operated on. This situation explains further the urgent need and rationale for operations research and possible new approaches to the delivery of cataract surgery in developing countries.

2. SURGICAL TECHNIQUES AND ALTERNATIVES FOR POST-OPERATIVE OPTICAL CORRECTION

2.1 Surgical techniques

The objective of treatment of blindness from cataract is the restitution of the pathway to light along the visual axis, obstructed by the opaque lens, and the correction of the visual deficit.

Displacement or relocation of the cataractous lens (couching) within the eye but away from the visual axis is an ancient technique that is still practised largely by itinerant "couchers" in remote communities where eye care services, especially for cataract surgery, are presently unavailable. As presently practised, it is generally fraught with much danger of various forms of damage to the eye and irreversibly blinding sequelae. The method is legally disallowed in most countries of the world.

Lens extraction refers to the removal of the offending lens in part, or as a whole, from the eye.

Intracapsular cataract extraction (ICCE) entails the total removal of the cataractous lens intact in its capsule.

Extracapsular cataract extraction (ECCE) describes the technique in which the lens material is removed, but leaving in place some amount of the anterior capsule and the whole of the posterior capsule and zonule, which remain intact within the eye.

Historically, ECCE was the method of choice in the nineteenth and in the early half of this century, when it was generally superseded by ICCE.

However, in the last two decades, there has been a renewed interest in, and adoption of, ECCE as the preferred method of lens extraction, particularly in developed countries. This has come about mainly from refinements in instrumentation which permit the removal by irrigation/aspiration of nearly all lens material from the eye under magnification (microsurgical techniques). The upsurge in its popularity is also due to the feasibility of safely replacing the extracted lens with a biocompatible lens implant, resulting in a superior degree of visual rehabilitation of the operated patient.

ICCE vs ECCE

In the developed countries, the great majority of operations for cataract are performed using the ECCE technique. This is generally combined with the implantation of an intraocular lens in the posterior chamber of the eye.

However, in most developing countries, the more widespread method is still ICCE, which is combined with spectacle correction of the resultant visual deficit.

The relative merits and demerits of the two techniques are set out in the table below, and need to be considered in the context of the local situation prevailing in a given region or country in terms of trained manpower, equipment, supplies, financial resources, surgical work-load and facility of patient follow-up.

<u>ICCE</u>
<ol style="list-style-type: none">1. Does not require sophisticated equipment, therefore costs are lower.2. Most Third World cataract surgeons are adept at this procedure.3. Average time required is less than for ECCE.4. Higher vitreous-related complications but no possibility of posterior capsular opacification.5. Permits anterior chamber but not posterior chamber intraocular lens implantation.
<u>ECCE</u>
<ol style="list-style-type: none">1. Requires more sophisticated equipment and supplies.2. Increased training/retraining requirements.3. Entails more manipulation within the eye - greater risk of infection and post-operative inflammation.4. Posterior capsular opacification causes visual deterioration in 20%-50% of cases, requiring secondary intervention - surgical/laser.5. Permits both anterior or posterior chamber intraocular lens implantation.

An overwhelming consideration should necessarily be the safety of the adopted procedure in a given circumstance.

Despite the merits of ECCE, a major disadvantage in a Third World setting stems from the fact that post-operative posterior capsular opacification takes place in an estimated 20%-50% of patients within two years of primary surgery. This would require either a second invasive procedure (capsulotomy) or the use of a Neodymium YAG laser, which at the present time is not a generally affordable technology in Third World settings, where much of the cataract surgery needs to be performed.

2.2 Alternatives for optical correction of aphakia

Aphakia refers to the status of the eye deprived of its crystalline lens, the visual consequences of which are generally a marked long-sightedness (hypermetropia) and a loss of the focusing capability of the eye.

The surgical removal of the cataractous lens is incomplete in itself, as a treatment of cataract, unless it is combined with the provision of an optical correction of the ensuing aphakia.

The methods available for correcting the aphakic refractive error are the following (see also Fig. 1):

1. Spectacle correction
2. Contact lens
3. Intraocular lens implant (IOL)
4. Refractive corneal surgery

A spectacle correction is, until now, the safest and commonest method of correcting aphakia, especially in Third World settings.

Although functionally it is not as good, in terms of quality of visual rehabilitation, when compared to contact lenses and, more particularly, the IOL, its greater availability resulting from simplicity and low-cost technology often renders it the preferred method of optical correction.

The reported non-compliance of operated patients to using cataract glasses may stem from a number of factors such as, among others, unavailability and unsuitability of spectacles and cultural preferences. Non-compliance, therefore, cannot be considered as an argument against their usefulness in Third World settings, particularly where pre-operative visual levels are often dismally poor and post-operative visual demands generally are not necessarily those of persons in the industrialized nations. Methods to ensure greater availability and affordability of cataract glasses and improved measures to match more closely the power of the spectacles provided to the actual refractive error of the given patient are likely to enhance compliance.

Contact lenses provide a method of optical correction of aphakia which normalizes the size of the image. Despite improvements in contact lens technology in recent years, permitting extended wear and thereby obviating the need for daily or frequent removal and reapplication of the lens, increasing reports of corneal infections resulting from extended wear have detracted from this potential advantage. The limitations of contact lens use in elderly individuals with functional problems in handling contact lenses have, to a large extent, limited the number of aphakes who have resorted to their use. This has diminished further with the advent of IOL surgery. Because of the high cost of contact lenses, their potential complications and the environmental considerations presenting serious problems with sterilization, their use is contraindicated in the rural population of developing countries.

Intraocular lenses permit the restoration of visual function *par excellence* following extraction of the lens. Its placement in a plane that approximates the plane of the normal lens prevents the optical and physical shortcomings of spectacle correction and obviates the cultural attitudes to thick cataract glasses.

Refractive corneal surgery, e.g. epikeratophakia, where a plus lenticule is sutured to the cornea, is still largely experimental, but may have an application in congenital cataract surgery.

3. INTRAOCULAR LENSES: MODELS AND EXPERIENCE GAINED

For numerous socioeconomic and logistic reasons, the introduction of IOLs on a large scale into most of the developing world will be a long process, probably extending well into the next century. It is therefore clear that, as work is being done to achieve this goal, the major type of cataract surgery that will be used in most of the developing world for at least the next decade will be intracapsular cataract extraction (ICCE) - the procedure that is now most practised and within the range of expertise of the majority of surgeons.

The use of IOLs in the developing world has so far been extremely limited. The simple ICCE operation with aphakic spectacles would, therefore, need to be continued *en masse*, while at the same time efforts should be made to introduce, carefully and in the simplest and safest way, the use of IOLs to as many patients as possible. With a choice of using IOLs in either the posterior or the anterior chamber, three options exist:

- (1) ICCE with spectacles (aphakic correction)
- (2) ICCE with anterior chamber lenses (AC-IOLs)
- (3) ECCE with posterior chamber lenses (PC-IOLs)

The ECCE-PC-IOL is in the present state of the art the sought-after ideal, but it may not be generally applicable for widespread use in developing countries for the following reasons:

- (1) Lack of proper equipment and supplies, including the availability of a well-manufactured IOL at an affordable price.
- (2) The need for retraining in the surgical technique for ECCE which will require a transition period.
- (3) Lack of opportunity for post-operative care.

The AC-IOL is not widely used in the industrialized countries at present, because the ECCE-PC-IOL has proved to be so satisfactory. Still, since ECCE is not widely practised in the developing world, the AC-IOL implantation following ICCE deserves further study to determine if it may safely provide the much better visual rehabilitation than that achieved with aphakic spectacle correction.

IOL technology and understanding of how IOLs of various types and designs behave in the eye have advanced to a considerable degree, so that it is now possible to predict reasonably what type of lenses should be used and what the outcome will be. High standards for lens production and design are now available, and being put into practice.

Until the 1940s, the only rehabilitation of aphakia (regardless of the type of lens removal that was performed) was with spectacles. In 1949, Harold Ridley, in the United Kingdom, performed the first cataract operation implanting a disc lens of polymethylmethacrylate (PMMA) that roughly approximated the true crystalline lens in size and shape. He implanted the lens into the capsular bag of a crystalline lens, the contents of which had been removed. This was called a posterior chamber lens (PC-IOL). This original operation was not widely accepted, primarily because of difficulties in the surgical technique at the time, particularly centration of the implant, and post-operative inflammation.

In the early 1950s, primarily to address the problems of decentration, other types of artificial IOLs (named by their site of placement in the eye) were introduced. The early AC-IOLs failed because of surgical problems at that time, and also due to defects in the design. These early AC-IOLs were situated very close to the anterior chamber angle outflow structures and the cornea, so that even with an appropriate design (including appropriate vault of the lens) they caused a very high incidence of glaucoma and corneal decompensation and opacity. Furthermore, in those early days the lenses were poorly polished and had sharp edges which damaged the ocular tissues. Also, some inappropriate biomaterials (for example nylon, which biodegraded in the eye) were unfortunately chosen. After a promising start, the early AC-IOLs thus led to numerous complications and therefore fell into disrepute.

By the late 1950s and into the 1960s, surgeons attempted to attach an IOL to the iris, in order to centre the lens securely and to avoid problems of decentration. These lenses also failed because of excessive contact of the delicate, vascular uveal tissues (iris and ciliary body) to the lens, causing high incidence of complications such as inflammation and recurrent bleeding. Today, almost all iris-fixated or iris-plane lenses have been withdrawn from the market and are not used. These are therefore not considered in this report. However, one lens, which is characterized by iris contact, is a "lobster-claw" or iris-claw lens. This is a lens used in parts of northern India and in some parts of Europe. There are no published reports in the refereed scientific literature showing convincing evidence as to the efficacy of this lens; it therefore requires further study before being considered for any large-scale use.

Between the early 1960s and through the mid-1980s, new forms of anterior chamber IOLs were introduced. The overwhelming majority of these IOLs, particularly the group of the so-called closed-loop type, were persistent failures for various reasons. In general, they eroded into the delicate tissues, and caused destruction of the cornea: problems that obviously were unacceptable. These lenses gave the whole generic group of anterior chamber IOLs a very bad reputation. By 1987, these were all excluded from the American market and, as far as is known, no more are being manufactured. However, it is clear that some are still being shipped to the developing world in an inappropriate fashion, primarily as "donations". This may unfortunately occur until the available stock is exhausted.

By the late 1970s and early 1980s, two viable options of IOLs had been introduced and were on their way to acceptance, namely, the PC-IOL that is used with ECCE, that is now the state of the art in developed countries, and some open-loop, or rigid, AC-IOL models. The PC-IOLs have taken over the overwhelming part of the IOL market in those countries, well over 90% in the United States. The AC-IOLs that have stood the test of time are the various well-polished all-PMMA flexible, open-loop designs, such as the Kelman or Kelman-Choyce modifications, as well as the licensed Choyce rigid IOL designs. These are the lenses that can be combined with ICCE and may offer a possible potential for easy implantation in the setting of developing countries where ICCE is the method of choice.

4. OPERATIONAL PREREQUISITES FOR CATARACT SURGERY USING INTRAOCULAR LENSES

The cost of IOLs is presently coming down and this may make their use in developing countries more realistic. However, there are more costs involved in IOL implantation than the cost of the IOL alone. The surgical and diagnostic equipment needed for safe IOL implantation is more expensive than that required for simple ICCE. Furthermore, lens implantation makes additional demands on the surgeon's time and availability.

In most developing countries, the problem of cataract blindness is presently being addressed by ICCE with provision of aphakic spectacles. In considering the requirements for IOL implantation, it is assumed that the necessary technology and facilities for simple ICCE already exist and are widely available.

The following are the minimum requirements for plain ICCE and their estimated cost:

Intraocular surgery instruments (US\$ 1500)

Light source (US\$ 750)

Autoclave/instrument sterilizer (US\$ 2500)

Drapes (US\$ 5)

Sutures (US\$ 1)

Gloves (US\$ 1)

Drugs (US\$ 5)

It will cost approximately US\$ 4750 to equip a cataract surgeon for plain ICCE, and every operation will cost an additional US\$ 7.

The equipment required for ICCE and AC-IOL is different from that needed for ECCE + PC-IOL, although there is some overlap. The requirements for both procedures which are additional to those necessary for plain ICCE are listed in the following chart. It should be noted that all the prices quoted do not include costs of buildings, personnel or depreciation, and are merely a guide to the relative costs of the equipment and supplies necessary for each operation.

ICCE	+ AC-IOL	ECCE	+ PC-IOL
Essential	Desirable	Essential	Desirable
Loupes (x 3 minimum) US\$ 200	A-scan ultrasound US\$ 5000	Operating microscope with co-axial light source US\$ 5000	YAG Laser US\$ 40 000
Lens introducing forceps US\$ 80	Keratometer US\$ 2000	Lens introducing forceps and lens hook US\$ 120	A-scan ultrasound US\$ 5000
Miotic for rapid pupillary constriction US\$ 10		I/A System (Irrigation/Aspiration) US\$ 10	Keratometer US\$ 2000
Viscoelastic material for protection of endothelium and maintenance of AC during IOL insertion US\$ 20		Irrigating solution (Hartmann's or balanced- salt solution) US\$ 10	Miotic US\$ 10
IOL of suitable quality US\$ 40		Viscoelastic material for protection of the endothelium and maintenance of the AC during IOL insertion US\$ 20	
Slit lamp US\$ 2000		IOL of suitable quality US\$ 40	
Topical steroid eye drops US\$ 5		Slit lamp US\$ 2000	
Caliper for measuring anterior chamber diameter US\$ 20		Topical steroid eye drops US\$ 5	

All cost estimates represent medium costs and only approximate real prices (1990).

This means that to equip a cataract surgeon to perform ICCE and AC-IOL will cost approximately US\$ 2300 and every IOL implanted will cost an additional US\$ 75, whereas for ECCE and PC-IOL it will cost approximately US\$ 7200 for equipment and every IOL implanted will also incur US\$ 75 expenditure. It should be emphasized that these costs are over and above the costs of plain ICCE.

Insertion of an IOL will make further demands on resources as follows:

1. Facilities

Because of the greater complexity of these procedures, it is recommended that IOL implantation should not be performed outside of established eye surgical centres, unlike plain ICCE which can safely be done in an "eye camp" setting.

2. Time

Insertion of an AC-IOL increases the length of time to perform an ICCE by 15%-20%. In an experienced surgeon's hands, this will be an additional 5-10 minutes. ECCE and PC-IOL will take approximately twice as long as plain ICCE. In an experienced surgeon's hands, this will be 30-45 minutes. The increased time taken will increase the cost per operation of theatre time and nursing as well as reducing the number of operations that can be performed in a given period by the ophthalmologist.

3. Follow-up

It is generally agreed that follow-up for a minimum of two months post-operatively is essential following implantation of any IOL. At each follow-up visit, the eye must be examined with a slit lamp microscope. This will be a call on the surgeon's time and will further reduce his availability. It will also increase the costs to the patients as they have to return for their follow-up visits. It is, however, essential that the patient be able to comprehend the necessity of returning immediately in the event of pain, reduced vision or other symptoms in the operated eye.

5. MANPOWER DEVELOPMENT

5.1 Approaches

Considering the fact that scarcity of properly trained manpower is one of the main constraints in tackling the huge, and still growing, backlog of unoperated cataracts in developing countries, it is clear that effective and imaginative approaches to training of needed personnel are urgently needed. The two main options are:

- efficient utilization of existing manpower; this implies optimal settings for effective delivery of surgery, and full utilization of available trained personnel, possibly including also the private sector;
- a training programme for the development of additional manpower, including both specialist training and the training of other categories of "cataract surgeons", as well as supporting auxiliary staff.

5.2 Cataract surgery and lens implantation

The introduction of any kind of IOL implantation requires some additional skills in terms of surgical ability. However, the transition to IOL implantation is not the main limiting factor. Over 90% of the difficulty in any cataract operation is the removal of the opaque lens material (either the entire lens in ICCE, or the lens contents inside the capsule in ECCE). If an excellent ICCE can be performed, the additional introduction of an AC-IOL is not too difficult. Similarly, a cataract surgeon who is capable of doing a good ECCE (and surgeons in the developing world who can do this are relatively few at present) can easily learn to insert the PC-IOL.

5.3 Type of training

Currently, cataract surgeons are trained in national and regional programmes. The period of training varies from one to five years. Surgical training is carried out at hospitals and universities and in outreach programmes, resulting in diploma or certificate awards upon completion of the prescribed course of study. Because the quality of training is variable, depending on supervision by ophthalmologists, surgical volume, interest of attending faculty, etc., determination of capability for IOL surgery should be made on a case-by-case basis. However, the need for surgical experience with the procedure within the training period should be kept in mind before the cataract surgeon is left to work without supervision.

5.4 Who is to be trained in IOL surgery?

The selection of those to be trained in intraocular lens implantation surgery depends on their previous training and experience in intraocular surgery. In some countries, both doctors and ophthalmic assistants are trained in cataract surgery. Those with appropriate intraocular surgical skills may be selected for IOL surgical training which will require retraining under appropriate supervision.

The extracapsular cataract extraction with intraocular lens implantation is presently taught only in some developing nations.

5.5 Scope of training

It is imperative that overall cataract surgical skills be mastered before the techniques of IOL implantation are taught. Training and skill development in ICCE should therefore be the primary objective for training of cataract surgeons in developing countries.

Having mastered ICCE, the scope of training may then be ICCE/AC-IOL with loupe magnification. In certain circumstances, training in skill development in ECCE will be the preferred option; this requires co-axial light surgical microscopy. Having mastered ECCE, the training may be extended to ECCE and PC-IOL implantation.

Apart from imparting skills related to surgical techniques to cataract surgeons to perform implant surgery, training should include the following facets:

1. Pre-operative assessment including slit lamp examination
2. Case selection, including indications/contraindications to surgery
3. Prevention, recognition and management of complications
4. Post-operative follow-up

The need to provide information to patients on post-operative care of the eye, follow-up examination, etc., should be kept in mind in drawing up the training modules for the appropriate eye care personnel.

5.6 Visiting eye care personnel

Visiting ophthalmologists may have a role to play in teaching appropriate skills related to intraocular surgery. They should not be permitted to perform ocular surgery except with prior communication, knowledge and permission of appropriate national health authorities. Where such surgery is carried out, acceptable post-operative follow-up must be ensured.

6. PRESENT STANDARDS, AVAILABILITY AND COST OF INTRAOCULAR LENSES

In the developed world, a large number of manufacturers have expertise in producing numerous models of intraocular lenses for both the anterior chamber and the posterior chamber, in one-, two- and three-piece designs. In the developing world, lens manufacture has been a recent development and standards for lens quality and design have yet to be established. Adequate quality control measures are also limited.

Frequently, lenses of the older, inadequate styles from some suppliers have made their way to the developing world. Many of these lenses, particularly those that were injection-moulded, were mass-produced and not sufficiently polished. Regarding the use of previously manufactured IOLs, it is therefore generally recommended that no surgeon use any injection-moulded IOL models. Furthermore, the surgeon should insist upon the availability of some scanning electron micrographs of the batch of IOLs to be used, of high enough magnification (from x10 to x100) to ascertain finish and edge quality. In general, it is best to avoid lenses manufactured prior to 1988. Since that time, most of the IOLs manufactured in industrialized nations appear to be of good quality.

Three-piece IOL designs (most commonly polypropylene loops and PMMA optics) have been most frequently used throughout the 1980s. These lenses, while purportedly less expensive to make, may actually turn out in the future to be somewhat more expensive than the one-piece all-PMMA designs which are now being used more frequently. The one-piece all-PMMA designs are good in that they can be lathe-cut and mass-produced from a blank, at relatively low cost. They are amenable to good surface polishing. Those manufactured after 1988 will, in general, resist breakage.

Currently, IOLs available in developing countries are either produced in those countries or are imported from manufacturers in developed countries. The lenses generally range in price from US\$ 20 to US\$ 40. All of these lenses meet the criteria for appropriate biocompatibility. It is therefore possible to produce a useful intraocular lens for either the anterior or the posterior chamber within this price range. These prices may drop as economies of large-scale production or procurement come into play.

The following generic IOL designs are recommended for use on a trial basis in developing nations (see also Fig. 2).

Anterior chamber IOL

The preferred choice of IOL is a one-piece all-PMMA, flexible open-loop design, with three or four point foot plate fixation. These lenses are manufactured from lathe-cut Perspex CQ and tumble-polished until the edges are smooth. The lenses available now include three or four point fixation designs, which are Kelman-Choyce modifications.

With these flexible open-loop designs only two overall sizes are necessary, in that these lenses approach the concept of "one size fits all".

The other type of IOL recommended for study is the classic rigid Choyce Mark IX design. Sizing is more difficult with this type, since no flexibility is inherent in the lens, and a possible mis-sizing exists to a greater extent than with the flexible designs. For this reason, three overall sizes are needed.

While an AC-IOL can be implanted after the completion of the surgeon's standard ICCE technique, it should only be inserted in favourable cases, such as:

- (1) those with no history of pre-existing diseases such as glaucoma;
- (2) patients who have an open anterior chamber angle as determined pre-operatively at least by torchlight examination;
- (3) patients who have no intraoperative complications, particularly vitreous loss;
- (4) patients who are most likely to be available for more extended follow-up examinations.

Posterior chamber IOL

A. One-piece all-PMMA design

This type will probably be preferred in the future from both clinical and cost considerations. The preferred lenses are one-piece all-PMMA designs manufactured from lathe-cut, high molecular weight Perspex CQ. A total diameter of between 12.0 mm and 13.75 mm, with modified C loops (preferred) or modified J loops (acceptable), is recommended. It is preferred but not necessary that the optic be biconvex, and some posterior angulation of the lens (5° to 10°) is desirable but not essential. Evidence is now accumulating that a down-sizing of total lens diameter from 13.75 mm to 12.0 mm will indeed be beneficial. The smaller size lenses are easier for the surgeon to insert (a very important factor) and scientific studies have shown that these lenses may fit better in the eye.

B. Three-piece designs

The three-piece designs consisting of lenses with loops made of polypropylene or PMMA (extruded or monofilament) are equally satisfactory. The choice of designs depends on local costs. As opposed to the one-piece designs, no down-sizing of the current 13.5 mm - 14 mm diameter is necessary with three-piece designs. The modified C-loop configuration is preferred, although the modified J-loop configuration is acceptable.

RECOMMENDATIONS

The following steps should be considered to maintain the use of high-quality IOLs:

1. The establishment of one or more WHO-recognized independent laboratories, which would be able to attest to the quality of lens design and surface polishing. Lenses would be submitted on a random basis for inspection. This function might be assumed by selected WHO Collaborating Centres for the Prevention of Blindness.
2. The American National Standards Institute (ANSI) standards for IOL quality should be made available to each nation to serve as a guide in establishing individual minimum national standards.
3. The preparation of a WHO monograph on intraocular lens standards, listing all relevant information. This document would also include standards for training/retraining of cataract surgeons as well as a description of the various implantation procedures.
4. Standards for other materials used in IOL implantation must be established. Intraocular solutions used in IOL surgery can have potentially damaging side-effects if not carefully standardized and quality control maintained. Sterility, pH control, tonicity and purity are essential to achieve good results. It is strongly recommended that appropriate guidelines for production, quality control and sterility be published and strictly followed.

7. RESEARCH NEEDS AND OPPORTUNITIES

The objective of research in IOL implant cataract surgery would primarily address the feasibility, applicability and safety of the use of the newer technologies in settings in the developing world, in which ideal conditions for the institution of such treatment may not be presently attainable.

7.1 The first research priority would be the comparison in a developing world setting of ICCE and spectacle correction with ECCE and PC-IOL. Taking cognizance of the fact that visual rehabilitation of IOL correction of aphakia is superior to that of ICCE with spectacle correction, studies must be conducted taking into account safety, cost and quality-of-life outcomes.

7.2 Given the widespread practice of ICCE in the developing world, as the surgical technique which obviates the need for more expensive equipment and major retraining of surgeons, a second area for research would be the comparison between ICCE and spectacle correction and ICCE with AC-IOL implantation. Despite the fact that AC-IOL implantation has had a poor track record and is less accepted due to a high complication rate in the past, there is now evidence that specific AC-IOLs appear to be both safe and effective. A randomized clinical trial is needed to confirm these observations.

These two types of studies should be conducted in different populations of the world, taking into account differences in settings that may determine safety and outcome.

7.3 Other areas of study that have direct relevance to the trials proposed above are:

(a) research on appropriate technology for (i) adequate magnification with co-axial light source (microscopes and/or loupes), (ii) portable Nd:YAG laser for posterior capsulotomy, (iii) less expensive sutures;

(b) evaluation of alternative viscoelastic preparations such as hyaluronic acid, methylcellulose, cellugel and autologous blood serum;

(c) evaluation of the efficacy and safety of topical pilocarpine versus intracameral pilocarpine and other solutions in achieving pupillary constriction during ICCE with AC-IOL surgery;

(d) determining how meaningful is the use of spectacles as compared to IOL correction of aphakia in the concerned patient population. This study could include assessment of compliance of patients to wearing spectacles, and reasons, if any, for non-compliance. The benefits of visual rehabilitation with IOLs could also be assessed in relation to the visual needs of the patient.

7.4 Studies are needed on behavioural patterns in different communities in respect to acceptance of cataract surgery, including the identification of barriers, such as costs to the patient.

7.5 Epidemiological studies should be considered in the following areas:

- (a) Assessment of age-specific rates of cataract blindness, with and without associated eye diseases.
- (b) Determination of the incidence of cataract blindness in different populations.

These studies will assist in both the planning as well as the evaluation of future cataract intervention programmes.

EXECUTIVE SUMMARY

Visual loss and disability from cataract represents a massive public health and socioeconomic problem in most developing countries. The present backlog of some 13.5 million cases in the world will increase, as most countries in the Third World are so far unable to cope with the annual number of new cases of blinding cataract (representing approximately the need to operate 1000 cases per million population per year).

Cataract extraction with intraocular lens (IOL) implantation is now the established and preferred technology for dealing with cataract in industrialized countries. However, the introduction of intraocular lenses in developing countries becomes a more complex matter because of far-reaching implications for the training of manpower and the required availability of facilities, equipment and supplies, including IOLs, needed for surgery. This, in turn, inevitably leads to a cost increase per operated case which may detract from already scarce resources for cataract surgery in many developing countries. However, this may be compensated by the improved restoration of vision experienced by the patient.

The experience gained over the last decade has led to the preference of, in principle, a few recommended generic designs for IOLs:

- One-piece or three-piece C-loop polymethylmethacrylate (PMMA) posterior chamber lens
- Flexible or rigid one-piece all-PMMA anterior chamber lens (Kelman-Choyce modifications)

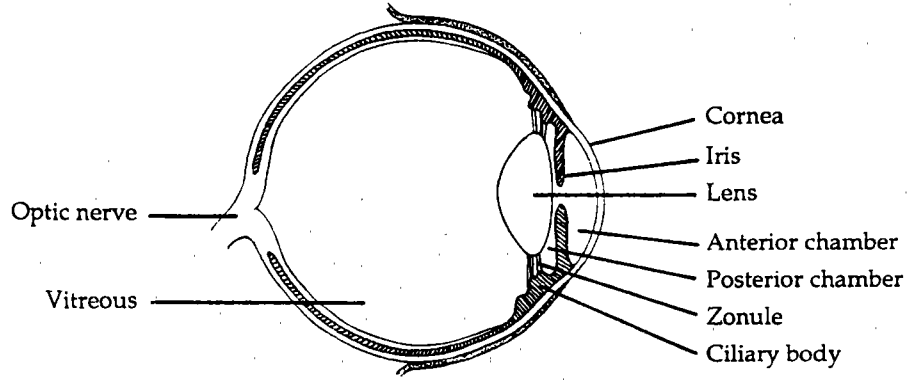
Although the use of posterior chamber IOLs greatly dominates the market today, there are recent indications that the two above-mentioned anterior chamber lens models may represent a valid alternative in many circumstances. There is still a need for further scientific evaluation of these lenses in relation to their use in the wide variety of settings typical of developing countries before they are recommended for general introduction.

Similarly, a great deal of operations research is needed in order better to define and standardize the various steps and procedures in the surgical and post-operative management of IOL implantation in Third World settings. Meanwhile, it is imperative that a number of conditions be fulfilled to ensure safe and good quality cataract surgery using IOLs in developing countries. These conditions include: properly trained surgeons, availability of needed facilities, equipment and regular supplies, availability of a good quality lens of appropriate design, and the necessary means for careful follow-up of operated patients.

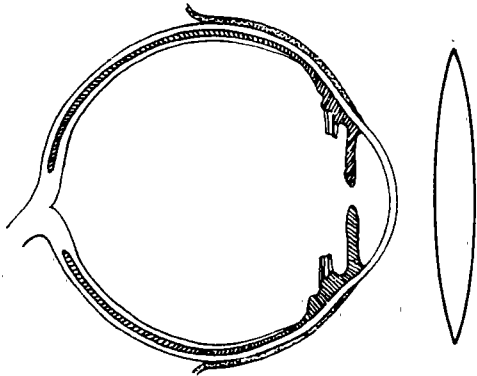
All these factors will inevitably increase the cost of cataract surgery, and the increased complexity of the surgical procedure will decrease the output in terms of operated cases per surgeon. These two factors are likely to be, in the next decade, the most important consideration in the large-scale introduction of IOL surgery in developing countries, battling with the ever-increasing load of cataract blind. However, they should be considered in the context of the superior visual rehabilitation and improved quality of life that intraocular lens implantation may bestow on operated patients.

FIG. 1

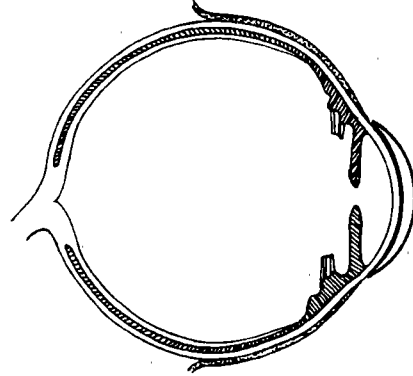
Cross-section of the normal eye



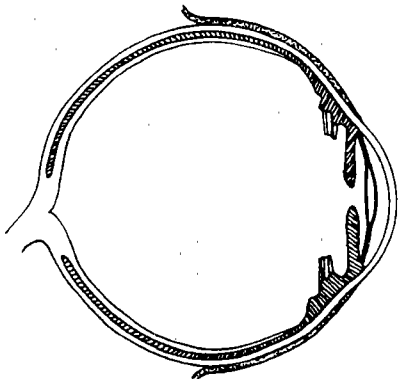
Aphakia with spectacle correction



Aphakia with contact lens correction



Aphakia with anterior chamber lens implantation



Aphakia with posterior chamber lens implantation

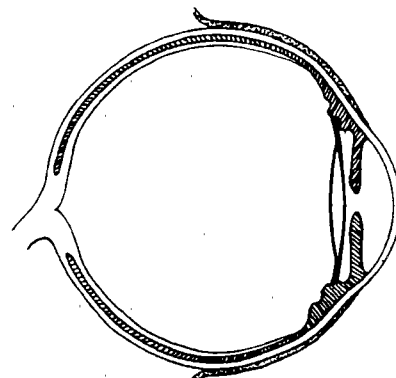
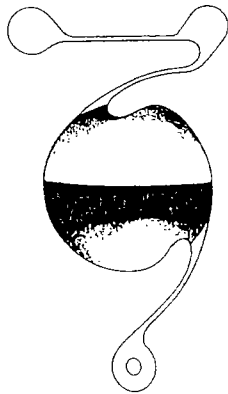


FIG. 2

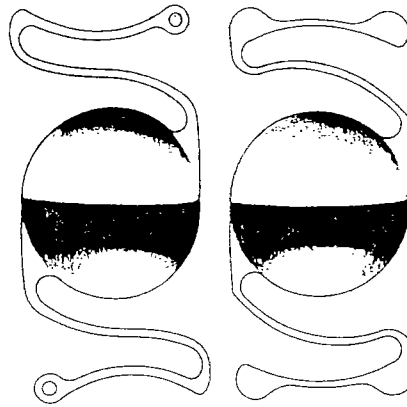
I. ANTERIOR CHAMBER IOLS

A. THREE POINT FIXATION

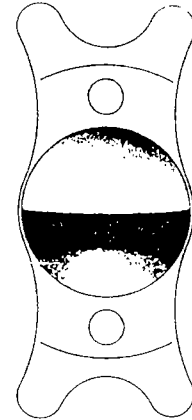


Kelman flexible one-piece
PMMA tripod IOL

B. FOUR POINT FIXATION

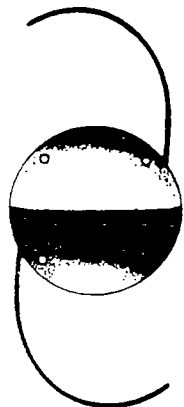


One-piece PMMA flexible
open-loop quadrupod IOLs
(based on Kelman and Choyce designs)

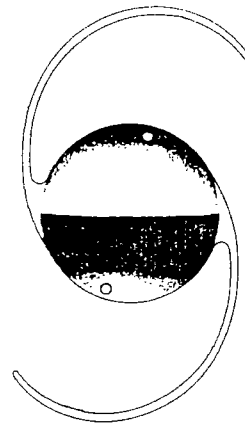


One-piece PMMA rigid IOL
(Choyce Mark IX)

II. POSTERIOR CHAMBER IOLS



MODIFIED SHORT C-LOOP IOL



ONE - PIECE PMMA LENS

ANNEX 1

LIST OF PARTICIPANTS

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ANNEX 2

AGENDA

Opening of the Meeting

Election of Officers

Adoption of the Agenda

1. The global magnitude of visual loss due to cataract
2. Surgical techniques and alternatives for post-operative optical correction:
 - intracapsular extraction
 - extracapsular extraction
 - aphakic correction:
 - (i) spectacles
 - (ii) contact lenses
 - (iii) intraocular lenses
3. Intraocular lenses; models and experience gained:
 - anterior chamber lenses
 - iris-fixated lenses
 - posterior chamber lenses
4. Operational prerequisites for cataract surgery using intraocular lenses:
 - magnification and illumination
 - instrumentation
 - viscoelastic material
 - follow-up of patients
5. Manpower development for cataract surgery:
 - needs and constraints
6. Present standards and regulations, availability and cost of intraocular lenses:
 - developed countries
 - developing countries
7. Research needs and opportunities

Conclusions and recommendations

Closure

NOTES

Further information can be obtained from:

Programme for the Prevention of Blindness
World Health Organization
1211 Geneva 27, Switzerland