Optical biometry using partial coherence interferometry prior to cataract surgery

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The Medical Services Advisory Committee (MSAC) is an independent committee which has been established to provide advice to the Australian Government Minister for Health and Ageing on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Introduction

Cataract is a disease of the eye where opacity of the crystalline lens impedes light from reaching the retina. As the degree of cloudiness increases, the visual acuity decreases. At present approximately 122,000 cataract operations are performed annually in Australia, costing $378 million per fiscal year. Through 1989-97 the number of cataract operations in the general Australian population increased nearly three-fold. The rate of cataract surgery in Australia increased from approximately 4.7 per 1,000 population (Taylor, 1997) in 1997 to 6.2 per 1,000 population in 2000 (Australian Department of Health and Ageing, 2002). In comparison the rate of cataract extractions in Sweden increased from 4.47 to 7.26 per 1,000 per population during 1992-2000 (Lundstrom et al., 2002) while in England the rate of cataract surgery in 2000 was 4.75 per 1,000 population (UK Department of Health, 2000). It is estimated that due to Australia's ageing population, the need for cataract surgery will double over the next 20 years (Taylor and Keefe, 2002, Evans et al., 2001).

A cataract forms in the lens of the eye, preventing the eye focusing properly after cataract surgery without a replacement lens. An intraocular lens is now implanted at the time of surgery for this purpose. Cataract removal and artificial intraocular lens implantation is one of the most frequent and successful ophthalmic surgical procedures today. One of the remaining problems, however, is accurate calculation of the intraocular lens power necessary for attaining the desired post-operative refraction. This accuracy, in the main, depends on the pre-operative biometric data (axial eye length, anterior chamber depth, lens thickness and refraction of the cornea).

To date ultrasound (US), using either immersion (IUS) or applanation (AUS), where the ultrasound transducer is placed on the surface of the cornea, has been used to obtain these measurements. Partial coherence interferometry (PCI) is a new technical procedure for gathering this data.

The procedure

Placement of an artificial lens after cataract surgery requires an accurate calculation of the intraocular lens power necessary for attaining the optimal post-operative refraction. The intraocular lens power is calculated using standard formulae and is dependent on accurate measurements of the axial length (AL) and corneal curvature. The corneal curvature is typically measured using keratometry, while ultrasound, using either IUS or AUS techniques, is used to assess AL. AUS is the most commonly used technique although IUS is considered to give slightly more accurate results. The various lens formulae calculate the expected post-operative position of the lens within the eye using these values to adjust a starting estimate of the expected lens position which, depending on the formulae used, is called either the 'A constant', 'lens factor', or 'anterior chamber depth'.

Of the two parameters used to calculate the intraocular lens power pre-operatively (AL and corneal curvature), errors in measurement of AL are thought to be the larger contributors to post-operative refractive errors.

A standard method of assessing the contributions of AL to the refractive error is to perform biometric measurements pre-operatively and then to measure the post-operative refraction, from which one can calculate the AL. Thus, AL measured pre-operatively can be compared with AL based on post-operative refraction. The accuracy of standard biometry techniques is estimated at 88μm to 120μm when AUS is used and 50μm to 64μm when IUS is used. Some of the errors in measurement with AUS may result if the placement of the transducer even slightly indents the surface of the eye. Based on the formulae used to calculate intraocular power, a 0.1mm error in axial length will result in a 0.25 to 0.28-diopter refractive error. Refractive errors of two diopters or more may result in a second operation to ameliorate the situation. Recently, partial coherence interferometry (PCI) has been introduced as an alternative technique to measure the axial length of the eye. PCI may also be referred to as optical, or ocular, coherence biometry/tomography or laser Doppler interferometry.

Optical coherence tomography (OCT) employs echo delay and intensity, using infrared light to reflect back from internal tissue interfaces. Since the velocity of light is high, echo delay times cannot be measured directly and interferometric techniques have to be employed. PCI uses a dual beam version of interferometric technique that eliminates any influence of longitudinal eye motions during measurement. This is achieved by using the cornea as a reference surface to perform in vivo AL measurements of cataract eyes as well as corneal thickness and thickness profile measurements.

AL measured by laser interference and US is not directly comparable. To obtain a 'good' echogram, with sharp reflection peaks, the sound beam must impinge vertically onto all the segmental interfaces with the eye. Sound reflections occur from the cornea, the front and back lens surfaces, and from the inner layer of the retina. US axial length extends from the anterior corneal vertex to the inner limiting membrane – the acoustical AL (Al_{ac}). It approximates, but may not correspond exactly, to the visual axis. PCI biometry relies on visual fixation to facilitate the measurement along the visual axis. The dominant laser reflection originates from the retinal pigment epithelium, where the photoreceptors lie in the outer layer of the retina, and an optical AL (Al_{op}) measurement is obtained (Hitzenberger, 1991). Thus, Al_{op} and Al_{ac} are slightly different distances and may be measured in slightly different directions within the eye.

Medical Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) is a key element of a measure taken by the Australian Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Australian Government Minister for Health and Ageing on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. A team from New Zealand Health Technology Assessment (NZHTA) was engaged to conduct a systematic review of literature on PCI. A supporting committee with expertise in this area then evaluated the evidence and provided advice to MSAC.

MSAC's assessment of partial coherence interferometry

Clinical need

At present approximately 122,000 cataract operations are performed per year in Australia at a cost of $378 million. Through 1989-97 the number of cataract operations in the general Australian population increased nearly three-fold. The rate of cataract surgery in Australia in 1997 was approximately 4.7 per 1,000 per population (Taylor, 1997). Due to Australia's ageing population the need for cataract surgery is estimated to double over the next 20 years (Taylor and Keefe, 2002, Evans et al., 2001).

Safety

During in vivo measurements of the human eye, laser safety standards must be considered. With the AL measurement, the light source has a centre wavelength of $\lambda \approx$ 780nm with power of about 360 μW at the cornea. Permanent illumination with this wavelength and power is safe for about one minute (American National Standards Institute, 1986, Krauss and Puliafito, 1995, Standards Association of Australia, 1994, Standards Association of Australia, 1997). The time needed for a single measurement of AL is 0.5 seconds. To obtain 10 longitudinal scans for statistical purposes, the maximum time of continuous illumination is about five seconds, well below the safety limit.

PCI machines are not fitted with a manual safety lock on the unit to prevent the misuse of power and time, nor can the operator alter the laser settings. However, the machines do have an internal automatic monitoring system and safety mechanism, and the pulsed laser system will not operate if the laser power is too strong. A further precautionary measure is that the machines will only allow a maximum of 20 axial length readings (laser pulses) to be performed on the same eye during a particular day.

With ultrasound assessment it is often claimed in studies that there is a possibility of cross-infection. However, no references to support these claims were given and no studies could be identified that addressed this issue. Expert opinion revealed that there was a remote theoretical risk of cross-infection with ultrasound, but with best practice methods this is extremely unlikely (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002).

Effectiveness

PCI biometry is a user- and patient-friendly method for AL determination and IOL planning in the preparation of cataract surgery. Its accuracy is statistically superior to that of the commonly used AUS and is comparable to that of the high-precision IUS. PCI has the potential to become a routine method for IOL calculations in cataract surgery in cases of otherwise 'normal' cataract eyes without additional pathologies and with visual acuities $\geq$ 0.1. However, it has been found that PCI is unable to optically measure cataract eyes in certain cases. Among the reasons were:

- inability to cooperate (fixate);
- keratopathy;

- corneal scarring;
- mature cataract;
- nystagmus;
- lid abnormalities;
- vitreous haemorrhage;
- membrane formation;
- maculopathy; and
- retinal detachment.

Thus, it seems that with present technology, the eyes of 9-15 per cent of the patients presenting at university eye clinics cannot be measured by PCI. In these cases, ultrasound biometry will remain indispensable.

Cost-effectiveness

The economic analysis of the three measurement techniques (PCI, AUS, and IUS) indicates that PCI may be a less costly measurement technique than AUS or IUS and that it offers comparable results to ultrasound techniques. However, there are small differences even between IUS and AUS, and these suggest that IUS is the most cost-effective of the three techniques considered. These results are based on a derived per patient cost (or Medicare rebate) of $72.65 for measurement of both eyes by PCI for an ophthalmologist facing average patient volumes. However, this amount is particularly sensitive to the assumption of saved time. Total cost analysis suggests that there could be savings of up to 10 per cent to the Australian health system if PCI were used whenever possible and at this cost.

Consideration of the capital cost of the technology as well as other costs suggests that a fee of $72.65 would cover all costs related to measurement by PCI for ophthalmologists facing average patient volumes. A higher fee would probably be required to induce ophthalmologists in low patient volume situations to adopt the technology.

Total cost analysis reveals that the choice of measurement technique makes very little difference to the total cost to the Australian Government as the differences in cost per patient are small.

Recommendation

MSAC recommended that on the strength of evidence pertaining to partial coherence interferometry (PCI), public funding should be supported for measuring axial length of one or both eyes prior to cataract surgery.

The Minister for Health and Ageing accepted this recommendation on 22 June 2004.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of partial coherence interferometry (PCI), which is a therapeutic procedure for the measurement of AL prior to cataract surgery. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are in Appendix A. MSAC is a multidisciplinary expert body comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer health and health administration.

This report summarises the assessment of current evidence for the use of PCI to measure AL prior to cataract surgery.

More explicitly, the review addresses the following questions:

- In all patients with cataracts, does the use of PCI increase the accuracy of calculation of intraocular lens power necessary for attaining the desired post-operative refraction, as measured by predicted refraction error, compared with current generation immersion and applanation ultrasound technology?

- What is the cost-effectiveness of PCI compared with current practice?

Background

Partial coherence interferometry

The procedure

A new technique called optical coherence tomography (OCT) has been developed to determine the AL of the human eye in vivo. OCT employs echo delay and intensity, using infrared light to reflect back from internal tissue interfaces, and is based on an optical measurement technique known as PCI. Since the velocity of light is high, echo delay times cannot be measured directly and interferometric techniques have to be employed. PCI uses a dual beam version of an interferometric technique that eliminates any influence of longitudinal eye motions during measurement. It does this by using the cornea as a reference surface to perform AL measurements of cataract eyes as well as corneal thickness and thickness profile measurements.

Intended purpose

Measurement of the AL of the eye is considered medically necessary as part of the pre-operative work-up of patients undergoing cataract surgery (Royal Australian and New Zealand College of Ophthalmologists, 2002, Royal College of Ophthalmologists, 2001). The corneal radius of curvature is typically measured using keratometry. Changes in cataract surgery techniques have been driven, in part, by a desire to improve post-operative refractive outcome. AL measurement of the pre-operative eye is one of the key determinants in choice of intraocular lens (IOL) power when performing cataract surgery.

Clinical need / burden of disease

A normal healthy lens, which is composed mostly of water and protein, is clear and transparent thus allowing light to pass unimpeded to strike the retina at the back of the eye (Figure 1) (Apple et al., 1989). Sometimes, some of the protein in the lens clumps together, causing an opacity or cloudy area in the lens that can block or scatter light and result in a loss of transparency. When this happens, it is called a cataract. As the degree of cloudiness increases, the visual acuity decreases. Vision may become blurred or cloudy, colours may be seen differently, and people may experience problems with glare from the sun or from lamps (eg, during night driving).

Cataract is increasingly frequent as people grow older and its occurrence doubles with each decade after the age of 40 years (Taylor, 1997). At an early stage, cataract may only reduce vision a little, but with time a mature cataract can cause marked blindness. Once a cataract has developed the opacity worsens over time and clouds more of the lens, causing progressively severe visual impairment. Studies have indicated that over a one-year period 20 per cent of cataracts get progressively worse and that 65 per cent worsen over a five-year time span (Anonymous, 1994, Magno et al., 1993, Taylor and Manoz, 1991).

Progression rates vary with the site of the opacity and the patient's age. Most people with cataracts, if left untreated, will eventually become seriously visually disabled (Dickson et al., 1996).

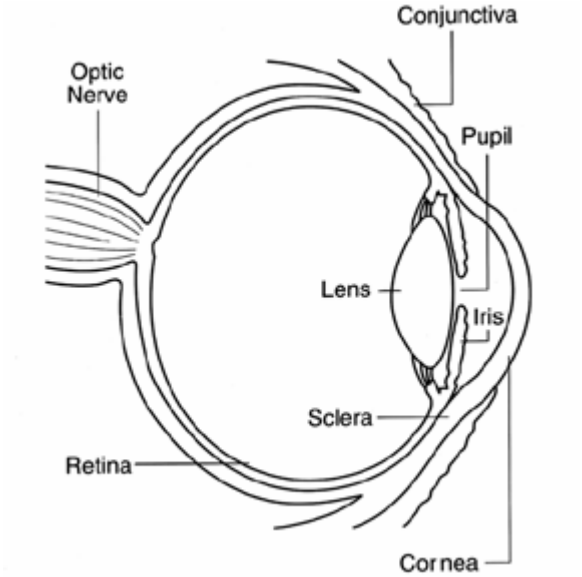

Figure 1 Side view of the eye

The diagnosis of age-related cataract is based on the presence of visible lens opacity in an older patient (eg, > 50 years). A cataract not only impairs visual function but it can also prevent inspection of, or treatment of, the retina when required. It is estimated that more than 50 per cent of blindness worldwide is due to cataract (Williams et al., 1994). There is, however, a poor correlation between visual acuity and visual function (Bernth-Petersen, 1981, Lawrence et al., 1999), especially with less severe degrees of lens opacity.

Prevalence and incidence

Estimates of the prevalence of cataract are variable but they do show that it increases with age (Appendix E). Cataracts affect more than 20 per cent of the population over the age of 65 years, more than 35 per cent over the age of 75 years and more than 60 per cent over the age of 85 years. Between a fifth and a third of people aged 65 to 74 years will develop some lens opacity over a five-year period (Anonymous, 1994, Podgor et al., 1983). By the age of 90 years, most Australians will develop cataract and half will have already had cataract surgery (Attebo et al., 1996, Weih et al., 2000).

The prevalence of 'senile cataract' in people in the Framingham Eye Study (Kahn et al., 1977) was 42 per cent in people aged 52-64 years and 91 per cent in people aged 75-85 years. However, the addition to the definition of a modest visual deficit, of Snellen 6/9[1] or worse, reduced the prevalence of cataract in the oldest age group from 91 to 46 per cent.

A British study (Gibson et al., 1985) estimated the prevalence of cataract to be 42 per cent in people aged 76-84 years, rising to 65 per cent in people over the age of 85 years. In this study the definition of cataract included visual acuity of 6/9 and worse and excluded all cataracts which could be ascribed to congenital or secondary causes. The prevalence of decreased visual acuity ($\leq$ 6/9) due to cataract in the US National Health and Nutrition Survey for people aged 45-74 years was 14.7 per cent (Hiller et al., 1986, Hiller et al., 1983).

Risk factors

The causes of cataract are multifactorial. In adults the aetiology of cataract includes physical, mechanical and chemical insults, some of which may be related to occupation. This damage may be cumulative over many years. Apart from age, recent studies have identified the following risk factors for cataract (Dolin, 1998, Agence Nationale d'Accreditation et d'Evaluation en Sante (ANAES), 2000):

- diabetes mellitus;
- use of certain medicines (eg, steroids);
- lifestyle – smoking and high alcohol consumption;
- sunlight (ultraviolet-B radiation);
- gender;
- nutrition and socio-economic status; and
- dehydration/diarrhoeal crises.

While increased age is the most important risk factor associated with cataract formation in adults, there is some debate whether it is ageing as such that causes cataract or whether the process is more complicated and related to exposure to multiple risk factors interfering with normal regeneration mechanisms. Diabetes is an important risk factor in people under the age of 60 years and carries a relative risk of three or four times that of the non-diabetic population. Several drugs have the potential to cause cataract, the most important being steroids. It is possible that paracetamol and non-steroidal anti-inflammatory drugs are associated with a decreased risk of cataract formation but the evidence for this is weak (Williams et al., 1994).

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[1] A person with 'normal' vision will be able to see the line which ought to be read at 6 metres when they are 6 metres distant, thus their visual acuity is 6/6; if when a person is at a distance of 6 metres they can only see the line which a person with 'normal' vision should see at 9 metres, their visual acuity is 6/9. In some countries Snellen values are given as decimal notation rather than in Snellen's notation of metres. A visual acuity of 6/6 would give a decimal value of 1.0 while 6/9 would be 0.7 and 6/60 would be 0.1 (more information can be found at http://www.eye.freewebsites.com/va.htm).

A key finding of two Australian studies was that cigarette smoking and ultraviolet-B exposure bring on cataract earlier, but lifetime exposure seems critical (Weih et al., 2000, Attebo et al., 1996).

The prevalence of cataract, after adjusting for age, is higher in women. The overall prevalence ratio (females:males) in one study was 1.22 (95% CI 1.07 to 1.40) (Reidy et al., 1998). Higher rates of cataract have also been recorded in poorer inner city areas (Das et al., 1994).

Treatment

Cataracts are one of the leading causes of blindness in the industrialised world. Although many advances have been made in the identification of risk factors for cataract, to date no preventive or curative medical treatment for cataract has been found to be effective when measured by clinical criteria (Agence Nationale d'Accreditation et d'Evaluation en Sante (ANAES), 2000, Desai et al., 1999). Further, there is as yet no medical treatment available to prevent the formation and progression of a cataract in the healthy adult eye (Harvard University Eye Research Institute, 1998, Agency for Health Care Policy and Research Cataract Management Guideline Panel, 1993). Therefore surgical removal of the cataractous lens remains the only effective treatment available to restore or maintain vision (Royal Australian and New Zealand College of Ophthalmologists, 2002, Royal College of Ophthalmologists, 2001). Not only has cataract surgery become the most common major eye surgery performed in the world today, it is also one of the most frequently performed surgical procedures (Royal College of Ophthalmologists, 2001, Dickson et al., 1996, Rosenthal et al., 1999).

Through 1989-97 the number of cataract operations in the general Australian population increased nearly three-fold (Taylor, 1997). The rate of cataract surgery in Australia increased from approximately 4.7 per 1,000 population (Taylor, 1997) in 1997 to 6.2 per 1,000 population in 2000 (Australian Department of Health and Ageing, 2002). In comparison the rate of cataract extractions in Sweden increased from 4.47 to 7.26 per 1,000 population during 1992-2000 (Lundstrom et al., 2002) while in England the rate of cataract surgery in 2000 was 4.75 per 1,000 population (UK Department of Health, 2000). At present, approximately 122,000 cataract operations are performed annually in Australia, costing $378 million per fiscal year. It is estimated that the need for cataract surgery in Australia will double over the next 20 years due to the ageing population (Taylor and Keefe, 2002, Evans et al., 2001).

Cataract surgery involves opening the front capsule of the eye and removing the lens (Wenzel, 1989). It is considered in an otherwise healthy eye when the medical, optical and environmental measures are no longer adequate for the individual's visual requirements (Agency for Health Care Policy and Research Cataract Management Guideline Panel, 1993). For most Australians the practical indications for cataract surgery will be when a cataract reduces their vision so that they can no longer drive a car or perform everyday activities (Royal Australian and New Zealand College of Ophthalmologists, 2002, Royal College of Ophthalmologists, 2001). For many remote services in Australia, older criteria are still used so that cataract surgery is often not performed until the person is bilaterally legally blind (Taylor, 1997). In some instances, patients having cataract surgery are required to have count finger vision (Taylor, 1997).

Cataract surgery is an effective method of restoring unimpeded light transmission to the retina. However, the benefit that patients receive will depend on:

- level of visual impairment and functioning before surgery, and the indications for surgery in that particular patient;
- surgical procedure used;
- method of aphakic correction; and
- complications of surgery.

Because a cataract forms in the lens of the eye, the eye will not focus properly after cataract surgery without a replacement or substitute lens. The choices are an intraocular lens (IOL), a contact lens, or cataract glasses. Nowadays, an intraocular lens is usually implanted at the time of surgery for this purpose. The quality of vision after modern cataract/intraocular lens surgery is usually excellent, although normal bifocal glasses are usually needed.

It has been clearly shown that the surgical procedures of phacoemulsification of the lens followed by implantation of an intraocular lens in the posterior chamber can improve not only measured visual acuity but also the patient's quality of life, including ability to drive.

However, one of the remaining problems is the accurate calculation of the intraocular lens power necessary for attaining the desired post-operative refraction.

This accuracy, in the main, depends on the pre-operative biometric data (AL, anterior chamber depth, lens thickness and refraction of the cornea). PCI is proposed as a measurement procedure for gathering this data.

Existing procedures and comparator

As part of the pre-operative work-up for patients undergoing cataract removal, the intraocular lens power has to be calculated. The two measured parameters used to calculate the intraocular power pre-operatively are AL and corneal curvature. The various lens formulae calculate the expected post-operative position of the lens within the eye, using these values to adjust a starting estimate of the expected lens position – called either the 'A constant', 'lens factor', or 'anterior chamber depth' in different formulae (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002). The lens position constants for various equations differ in their dimensions (mm vs dioptres), and express post-operative IOL position in the eye relative to different ocular structures. The corneal radius is typically measured using keratometry while the standard technique used to measure AL is the ultrasonic echo-impulse technique. Since the first measurements as early as 1956 (Mundt and Hughes, 1956), this technique has been steadily improved and is now a standard clinical technique.

Changes in cataract surgery technique have been driven, in part, by a desire to improve post-operative refractive outcome. AL measurement of the pre-operative eye is one of the key determinants in choice of intraocular lens (IOL) power when performing cataract surgery. However, of the two parameters used to calculate the intraocular lens power, pre-operative errors in measurement of AL are thought to be the larger contributor to post-operative refractive errors (Olsen, 1992). Ultrasound using either IUS or AUS is used to assess the AL pre-operatively.

Immersion ultrasound vs applanation ultrasound

AUS, which is the most commonly used technique for ocular biometry (Leaming, 1999, Olsen and Nielsen, 1989), requires direct contact between the ultrasound probe and the cornea. However, errors in measurement may result if the placement of the transducer even slightly indents the surface of the eye. It is almost impossible not to indent the cornea somewhat during AUS. Indentation leads to a shorter AL measurement, thus predicting too strong an intraocular lens power. The shorter the eye, the greater this effect would be. This may be the cause of the well-known problem of calculating extremely strong intraocular lenses in shorter eyes when the Sonometrics unit and Binkhorst's formula are used (Binkhorst, 1975).

With IUS, the ultrasound probe is suspended in a fluid-coupling medium, thus avoiding corneal touch (Ossoinig, 1979, Shammas, 1984). This means a more accurate biometry can be performed (Olsen and Nielsen, 1989). The accuracy of IUS is estimated at 0.10-0.12mm. Based on the formulae used to calculate intraocular power, a 0.10-0.12mm error in AL will result in a 0.25-0.28D refractive error. Refractive errors of 2D or more may result in a second operation to ameliorate the situation (Olsen, 1989). Statistically significant differences of 0.14-0.36mm have been reported between AUS and IUS axial length measurements (Table 1).

In the study by Olsen (1989), which was set in Denmark, it was found that when 60 cataractous patients aged 63 to 84 years (mean 72.3 ±5.4 years) had AL measured by both IUS and AUS, the mean AL was 23.49mm with IUS and 23.35mm with AUS. The same Sonometrics transducer probe was used for both techniques. This difference of 0.14mm (±0.19) was statistically significant at the 0.01 level. An AL error of 0.14mm corresponds to about 0.50D error in calculated IOL power, and 0.40D error in the spectacle plane.

Shammas (1984) conducted a prospective study in the United States to evaluate AL measurements which were obtained on 180 eyes using both AUS and IUS. Each eye was measured with the Ocuscan-DBR (AUS), the Ocuscan-400 (IUS), and the Kretz 7200 MA (IUS) units. The average AL measurements obtained were 23.28mm with the Ocuscan-DBR (AUS), 23.49mm with the Ocuscan-400 (IUS), and 23.52mm with the Kretz 7200 MA (IUS). The AL measurements obtained with AUS were shorter than measurements obtained with IUS by an average of 0.24mm, which was statistically significant ($p < 0.05$).

Schelenz (1989) compared AUS and IUS biometry in Germany by measuring 100 eyes with both techniques. Two groups were formed based on the AL measurement: a group of 46 short eyes (AL < 23.3mm) and a group of 54 long eyes (AL > 23.3mm). Results showed that in the short eyes the mean AL was 22.39mm vs 22.59mm with AUS and IUS respectively, while in the long eyes the mean AL with AUS was 24.06mm vs 24.38mm with IUS. Data were collected regarding the refraction four months post-operatively. The precision of the two techniques was taken as the post-operative deviation from the pre-operative calculated refraction.

To compare the accuracy of the different methods, a variety of formulae were applied (see Appendix F for a description of formulae). The investigators found that more eyes having IUS achieved a final refraction within ±0.50D of the attempted refraction (71 per cent in the long eyes and 77 per cent in the short eyes using IUS vs 42 per cent in the long eyes and 55 per cent in the short eyes using AUS and a theoretical formula, and 50

per cent in the long eyes and 27 per cent in the short eyes using AUS and the SRK formula (Sanders, Retzlaff, Kraff Formula). No deviation greater than ± 2D was observed with IUS in the short or long eye groups. Two cases in the long eye group and five cases in the short eye group would have been observed had AUS and the theoretical formula been chosen for the IOL power calculation. One case in the long eye group and five cases in the short eye group would have been observed had AUS and the SRK formula been chosen for the IOL power calculation.

Giers (1990) compared three biometry devices in examinations of 159 German cataract patients, each examination being repeated several times. AL averaged 23.77mm when measured by IUS; AUS and modified AUS yielded 0.14mm and 0.33mm shorter distances, respectively.

Watson and Armstrong (1999) carried out a prospective study in Australia in which 225 consecutive patients scheduled for cataract surgery in a private day surgery setting had AL measured by the same operator and machine using both AUS and IUS techniques.

Ten readings were taken manually for each method. Readings were inspected and the average of the readings accepted only if the standard deviation (SD) of the measurements was less than 0.1mm. Mean AL obtained by IUS was 23.44mm (±0.98mm) and by AUS was 23.34mm (±1.01mm).

This difference of 0.1mm was statistically significant at the 0.0001 level. The fellow eye of 12 patients was measured by both techniques at the same time and then had both techniques repeated on a separate occasion to test the reproducibility of each technique. AUS produced a mean AL of 23.59 (±1.39mm) on the first occasion and 23.58 (±1.31mm) on the second occasion. In comparison, IUS gave a mean AL of 23.70 (±1.38mm) on the first occasion and 23.70 (±1.28mm) subsequently. The measurements obtained with IUS were longer than those obtained by AUS by an average of 0.12mm, which was statistically significant ($p = 0.0021$). IUS values were used to calculate lens implant power in this series. If AUS values had been used, the average implanted IOL power would have been 0.36D greater.

Hoffmann (1998) carried out a prospective randomised trial on 288 German patients presenting for routine cataract surgery. Eyes with nanophthalmia (AL < 21mm) or a high degree of myopia (AL > 27mm or staphyloma posticum) were excluded. Using a list of random numbers the 288 patients were divided into two groups. Group one consisted of 156 patients who had AL measured with IUS and group two contained 132 patients who had AL measured with AUS. All biometry was conducted by the same researcher in both groups and used the same equipment. Ten measurements were taken and the mean was used to calculate the intraocular lens power. The operations were carried out by four different people and in all cases phacoemulsion with lens implantation in the capsular sac was carried out. Post-operative data were collected on the first day after surgery and three to six months later. Results showed that mean AL with IUS was 23.03mm (±0.82mm) and 22.88mm with AUS (±1.07mm) ($p < 0.05$).

Table 1 Studies comparing AL obtained with IUS and AUS

Study	Country	N (eyes)	Mean axial length		Difference (mm)	Probability level
			IUS (mm)	AUS (mm)		
Shammas (1984)	USA	180	23.52	23.28	+0.24	<0.05
Olsen and Nielsen (1989)	Denmark	60	23.49	23.35	+0.14	0.01
Schelenz and Kammann (1989)	Germany	46 short eyes 54 long eyes	22.59 24.38	22.39 24.06	+0.20 +0.32	<0.05 <0.05
Giers and Epple (1990)	Germany	159	23.77	23.63	+0.14	<0.05
Hoffmann et al., (1998)	Germany	156 randomised IUS 132 randomised AUS	23.03	22.88	+0.15	<0.05
Watson and Armstrong (1999)	Australia	225	23.44	23.34	+0.10	0.0001
Hennessy and Chan (2002)	Australia	36	23.25	23.28	-0.03	0.04

However, one study found that AUS gave longer AL measurements than IUS. Hennessy (2002) carried out a prospective stratified randomised study in which 36 Australian patients scheduled for cataract surgery with a pre-operative refractive error of $\pm$ 4D spherical (SE) or $\pm$ 2D refractive cylinder had AL measured with AUS and IUS.

Three technicians each measured both eyes of 12 patients by both AUS and IUS using a Biovision A/B-Scan with an 11 MHz A-scan biometry probe with a spring-loaded head for both AUS and IUS techniques. Results showed that IUS gave a mean AL of 23.25 (SD 0.87mm) while AUS gave a mean of 23.28 (SD 0.87). This difference of 0.03 was statistically significant ($p = 0.04$), but is of minimal clinical significance. This small paradoxical difference with AUS longer than IUS could be due to the small study size. The above results are summarised in Table 1.

The majority of the studies in Table 1 suggest that IUS yields statistically significantly longer measurements than AUS. It has been proposed that inadvertent indentation of the cornea while using AUS may be responsible for the shorter readings (Giers and Epple, 1990, Shammas, 1984). IUS has the theoretical advantage of the ultrasound probe having no direct corneal contact, thus obviating this possibility.

Partial coherence interferometry (PCI)

A new non-invasive optical biomedical imaging technology called optical biomedical imaging technology or optical coherence tomography (OCT) has been developed recently. It is similar to conventional ultrasonic pulse-echo imaging (ultrasound A- and B-mode), except that OCT does not require direct contact with the tissue being investigated and it measures echo delay and intensity using infrared light reflected back from internal tissue interfaces rather than using acoustic waves. OCT is based on an optical measurement technique known as PCI. Since the velocity of light is high, echo delay times cannot be measured directly and interferometric techniques have to be employed. The first medical application of this technique was ophthalmologic biometry, described by Fercher and Roth (1986). Since then, two related versions of this technique have been

developed for non-invasive high-precision and high-resolution biometry and tomography in ophthalmology (Fercher, 1996, Fercher et al., 1993, Huang et al., 1991a, Huang et al., 1991b).

A particular dual-beam version of OCT, referred to as PCI, removes any influence of longitudinal eye motions during measurement by using the cornea as a reference surface. It was used to perform AL measurements in vivo of normal (Hitzenberger, 1991) and cataract eyes (Hitzenberger et al., 1993), as well as corneal thickness and thickness profile measurements (Hitzenberger et al., 1992, Hitzenberger et al., 1994). This technique has been upgraded to a fully computer-controlled scanning instrument.

It has been reported that PCI is capable of measuring intraocular distances not only parallel to the visual axis, but at arbitrary angles, and of performing cross-sectional imaging of the human retina (Fercher et al., 1993, Drexler et al., 1998a, Drexler et al., 1995, Baumgartner et al., 1997). Depending on the measured intraocular distance, precision values from 0.3 to 10μm have been reported (Drexler et al., 1997). Several studies have been carried out to investigate the clinical feasibility of OCT in a clinical setting (Drexler et al., 1998a, Drexler et al., 1997a, Drexler et al., 1997b, Drexler et al., 1998c), including suitability for intraocular lens measurements (Findl et al., 1998b, Findl et al., 1998a) and use in determination of the group refractive indices and the group dispersion of ocular media in vivo (Drexler et al., 1998b).

PCI has been introduced as an alternative technique to measure the AL of the eye. This technique relies on a laser Doppler to measure the echo delay and intensity of infrared light reflected back from tissue interfaces. PCI may also be referred to as optical, or ocular, coherence biometry or laser Doppler interferometry.

Only one study (Hitzenberger et al., 1993) was identified that compared all three procedures. Unfortunately, this study failed to include a post-operative follow-up to determine subjective refraction. The study did, however, find that when 196 cataract eyes of 100 unselected patients from Austria were examined, the ALs measured by laser Doppler interferometry (LDI) were about 0.18mm longer than those measured by IUS (n = 50) and about 0.47mm longer than those measured by AUS (n = 177).

Limitations

A drawback of the PCI method is that light is strongly attenuated by opaque ocular media. Reliable measurements are therefore more difficult to obtain in patients with mature cataract, hence PCI measurement is not recommended in these circumstances. Also, fixation problems, as well as cornea and tear film pathologies, can hinder measurement with optical biometry (Kiss et al., 2002b).

Marketing status of the device / technology

The Therapeutic Goods Administration (TGA) listing for the IOL Master is AUST L 81765. Approximately 75 IOL Master units have been installed in Australia by ophthalmic surgeons and hospitals.

Current reimbursement arrangement

There is currently no specific Medicare Benefit Schedule (MBS) item number that would cover the use of the IOL Master machine using PCI for measurement of orbital contents of the eye. However, there are currently items in the MBS (11240 – 11243)[2] (Australian Department of Health and Ageing, 2002) applicable for the measurement of the AL using ultrasound technology. The MBS reimbursement for IUS and AUS is $64.40 (11240), $82.00 (11241) and $63.40 (11242 and 11243).

In most cases, a charge for item 11241 would be expected prior to surgery in the first eye. Both eyes would be measured so the other eye could be used for quality control as the pair would generally be close to symmetrical. It therefore would not usually be necessary to re-measure prior to surgery for the second eye, and re-measuring attracts a Medicare payment only in specified circumstances (items 11242 and 11243).

[2] Item 11240 relates to ultrasonic echography of the orbital contents of one eye. Item 11241 is the ultrasonic echography of the orbital contents of both eyes. Item 11242 is the ultrasonic echography of the orbital contents for the measurement of an eye previously measured where lens surgery has been performed and where further lens surgery is contemplated in that eye. Item 11243 is the ultrasonic echography of the orbital contents for the measurement of the second eye where surgery for the first eye has resulted in more than one dioptre of error or where more than three years have elapsed (Australian Department of Health and Ageing (2002) *Medicare Benefits Schedule,* Australian Department of Health and Ageing, Canberra.)

Approach to assessment

Review of literature

Search strategy

The medical literature was searched to identify relevant studies and reviews for the period between 1966 and 2002. Table 2 lists the electronic databases used in the search strategy.

Table 2 Electronic databases used in the search strategy

Primary databases	Period covered
Medline (now includes Healthstar)	1966-2002
Embase	1988-2002
Cochrane Controlled Trials Register	2nd Quarter 2002
Current Contents	1993-2002
Econlit	Last searched May
Secondary databases	
Cochrane Database of Systematic Reviews	2nd Quarter 2002
Evidence-based reviews (*Evidence-based Medicine/ACP Journal Club*)	Last searched July 2002
University of York databases (DARE, NHS EED, HTA)	Last searched July 2002
Science Citation Index (for subsequent references to retrieved papers)	1987-2002

Other sources

- Professional ophthalmology sites. Canadian Ophthalmology Society, American Academy of Ophthalmology, Fred Hollows Foundation, Royal Australian College of Ophthalmologists, Royal College of Ophthalmologists, North of England Ophthalmological Society, American Board of Ophthalmology, Association for Research in Vision and Ophthalmology, German Ophthalmological Society, International Society for Eye Research, International Society of Refractive Surgery.
- Websites and publications of Health Technology Assessment (HTA) organisations (see Appendix C).
- Reference lists of retrieved papers.

The search strategy used to identify relevant papers is further outlined in Appendix D.

Eligibility criteria

Inclusion and exclusion criteria

The search strategies detailed above resulted in the scanning of more than 1,800 references in the course of the search and the retrieval of more than 250 papers that were judged potentially to be relevant for optical biometry. On the basis of their abstracts, articles were excluded from this initial literature database if they were duplicates, did not address the review question, or clearly did not meet the inclusion criteria. In some cases, when the full text of the article was retrieved, closer examination revealed that it did not meet the eligibility criteria specified by the review protocol (Table 3). The reasons for these exclusions are detailed in Table 4. Consequently, these papers were not used to formulate the evidence base for the review. However, relevant information contained in these excluded papers was used to inform and expand the review discussion. The bibliographies of all publications retrieved in hard copy form were manually searched for relevant references that may have been missed in the database searches.

Table 3 Selection criteria for studies in the review

Inclusion criteria	Exclusion criteria
Relevant to a review question	Published in letter or abstract form only
PCI was performed	The paper was a comment or editorial
The sample size was more than 50 eyes	Studies which did not include a post-operative follow-up to determine subjective refraction
A suitable reference test was performed	

Reasons for inclusion/exclusion included sample size of more than 50 eyes. Small sample sizes have the potential to over-emphasise treatment effects. In order to avoid sample size bias it was agreed that studies should only be included if the study population was 50 or more eyes. Reasons for exclusion of studies that were examined in full text are stipulated in Table 4.

Table 4 Reasons for exclusion of PCI papers examined in full text

Reason for exclusion	Number
Only available in abstract form	8
Not relevant to research question	7
Comparison carried out in healthy eyes	4
Sample size < 50 eyes	3
PCI only performed post-operatively	2
Study did not include a post-operative follow-up	2
Results dealt with in another paper	2

Assessment of quality

All accepted articles underwent an assessment of study quality based on criteria that focus on important aspects of study design. The evidence presented in the selected studies was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (Australian National Health and Medical Research Council (NHMRC), 2000).

These dimensions (Table 5) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of their determination.

Table 5 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	
Level	The study design used as an indicator of the degree to which bias has been eliminated by design.*
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *p*-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

*See Table 6

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence. The designations of the levels of evidence are shown in Table 6.

Table 6 Designations of levels of evidence*

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

*Modified from (Australian National Health and Medical Research Council (NHMRC), 2000).

While randomised controlled trials (Level II) have well-established instruments to assess validity and their subjectivity to bias (Table 7), case series (Level IV) do not. Case series are inherently subject to bias and likely to overestimate the benefit of the intervention.

However, in instances when higher-level evidence is unavailable, case series require consideration, including critical appraisal to provide some objective assessment of their likely exposure to bias. Case series that have been included for critical appraisal in this report were assessed against criteria that ascertain whether the authors were aware of methodological issues.

A criteria was adopted based on the guidelines by the National Health Services (NHS) Centre for Reviews and Dissemination:

- Was the study based on an appropriate sample selected from a suitable sampling population?
- Are the criteria for inclusion in the sample stated?
- Were outcomes assessed using objective criteria?
- Were outcomes measured pre- and post-intervention — ie, could a change in an outcome measure be extracted from the paper?

Table 7 Criteria and definitions for assessing validity of intervention studies

Validity criterion	Definition
Randomisation	
Adequate	Adequate measures to conceal allocations, such as: central randomisation; serially numbered opaque, sealed envelopes; or other descriptions that contain convincing elements of concealment.
Unclear	Unclearly concealed trials in which the author failed to describe the method of concealment with enough detail to determine its validity.
Inadequate	Method of allocation is not concealed, such as alternation methods or the use of case numbers.
None	No randomisation method was employed.
Masking	Masking strategy applied (triple, double, etc).
Losses to follow-up	Losses specified.

Expert advice

A supporting committee with expertise in optical biometry was established to evaluate the evidence and provide advice to the MSAC from a clinical and consumer perspective. In selecting members for supporting committees, the MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is provided in Appendix B.

Results of assessment

Is it safe?

During in vivo measurements of the human eye, laser safety regulations must be considered. With the AL measurement, the light source has a centre wavelength of $\lambda \approx$ 780nm with power of about 360μW at the cornea. Permanent illumination with this wavelength and power is safe for about one minute (American National Standards Institute, 1986, Krauss and Puliafito, 1995, Standards Association of Australia, 1994, Standards Association of Australia, 1997). The time needed for single measurement of AL is 0.5 seconds. To obtain 10 longitudinal scans for statistical purposes, the maximum time of continuous illumination is about five seconds, well below the safety limit.

The Helium Neon (HeNe) alignment laser, as used by Hitzenberger (1991), delivers a power of about 1 μW to the fundus. With a pupil of 7mm diameter (American National Standards Institute, 1986) this is equivalent to an inter-beam viewing of a beam with a power density of less than $3\mu W/cm^2$. This is below the limit of permanent illumination of $18\mu W/cm^2$. Since the course alignment takes about 20 seconds, the safety regulations are met. The single mode laser diode delivers a power of 70μW to the fundus and yields a power density of about $180\mu W/cm^2$, if averaged over an aperture of 7mm diameter. This is permitted for several hours for λ = 780nm (American National Standards Institute, 1986, Krauss and Puliafito, 1995, Standards Association of Australia, 1994, Standards Association of Australia, 1997). The fine alignment takes about 20-30 seconds.

The measurement laser, turned on during the measuring period only, has a high intensity of about 250μW or 650 $\mu W/cm^2$ (average over 7mm aperture) that is allowed for about four minutes (American National Standards Institute, 1986, Krauss and Puliafito, 1995, Standards Association of Australia, 1994, Standards Association of Australia, 1997). During one measurement, a distance of 5mm is scanned with the interferometer plates at a speed of 1.85mm/sec, so the duration of the measurement and the duration of laser illumination is less than three seconds, (ie well below the limit) (Hitzenberger, 1991).

PCI units are not fitted with a manual safety lock to prevent the misuse of power and time, nor can the operator alter the laser settings. However, the machines do have an internal automatic monitoring system and safety mechanism, and the pulsed laser system will not operate if the laser power is too strong. A further precautionary measure is that the machines will only allow a maximum of 20 axial length readings (laser pulses) to be performed on the same eye during a particular day.

AUS requires the probe to make contact with the eye, which necessitates the use of a local anaesthetic and the potential risk of both corneal infection (Findl et al., 1998b Hitzenberger et al., 1993) and corneal abrasion (Connors et al., 2002). When carrying out IUS the ultrasound probe is supported in a scleral shell that makes contact with the eye and eyelid. With ultrasound assessment it is often claimed in studies that there is a possibility of cross-infection. However, no references to support these claims were given and no studies could be identified that addressed this issue. Expert opinion revealed that there was a remote theoretical risk of transmissible infection from any device making contact with the eye but with best practice methods this was extremely unlikely (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002).

No other safety issues relating to the use of IUS, AUS or PCI techniques were identified in the literature. Safety issues relating to cataract surgery per se are a separate and independent matter, beyond the scope of this review.

Is it effective?

Results

Six articles were identified that met the eligibility criteria for the review and these articles were critically appraised. Details of the selection process are shown in Figure 2.

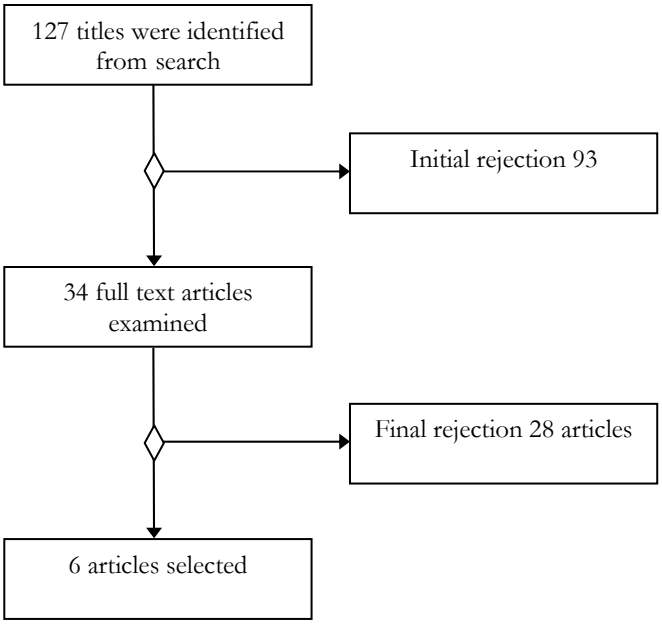

Figure 2 Study selection process for PCI papers

The selected studies consisted of:

- three that compared PCI with AUS
- three that compared PCI with IUS.

Only one study (Hitzenberger et al., 1993) compared all three interventions. However, it failed to meet the inclusion criteria as the study did not include a post-operative follow-up to determine subjective refraction.

Methodological issues

All studies selected were case series (Level IV evidence only). Only one of the six studies documented blinding between PCI and IUS measurements (ie Kiss et al, 2002b).

Performance

This section includes discussion of the measurement accuracy of PCI in determining AL prior to cataract surgery.

Two types of study were identified: those that compared PCI with AUS and those that compared PCI with IUS. The different types of studies will be dealt with in a separate section. Details of the studies assessed are summarised in Table 11 (see page 33-36). As already mentioned, only one study compared PCI vs IUS vs AUS and this study was excluded because it failed to include a post-operative follow-up to determine subjective refraction. Hitzenberger (1993) did, however, find that when 196 cataract eyes of 100 unselected patients from Austria were examined, the ALs measured by laser Doppler interferometry (LDI) were about 0.18mm longer than those measured by IUS (n = 50) and about 0.47mm longer than those measured by AUS (n = 177). Ages ranged from 43 to 97 years (mean 74, SD ± 10). Thirty-six patients were men and 64 were women. AL was determined by laser Doppler interferometry and AUS and 50 eyes were also measured by IUS.

The Opacity Lensmaster 701, a commercial instrument, measures back-scattered light from the eye lens, which is illuminated by a light beam of 1.5mm diameter to determine the cataract grade. The measurement is thus restricted to the central area of the lens. The result of the measurement is a dimensionless number between 0 and 99 that is referred to as lens meter unit (LMU). Higher LMU values indicate higher lens densities. Eyes were classified according to their LMU values into groups of width 5 LMU, ranging from 15 to 20 LMU, 20 to 25 LMU, and so on. Values above 90 LMU were combined into one group. Of the 196 (90.5%) cataract eyes examined 177 were measurable by LDI. In four cases (2%) the instrument failed because of computer problems. In seven cases (3.5%) no measurement could be taken due to fixation problems. Results showed that nine of the 125 patients who had a cataract graded in the range 15 to 55 could not be measured by the LDI. A further three of nine patients with cataracts in the range 56 to 65 LMU could not be measured by the LDI. Of the six patients who had cataracts graded in the range 66 to 90 LMU there was one failure of LDI. Nine eyes had values higher than 90 LMU and seven of them were out of the measuring range of the instrument (ie, $\geq$ 100 LMU).

Comparison of PCI and AUS

Connor (2002) examined the comparability of PCI and standard contact ultrasonic biometry (AUS) for accuracy and reproducibility of AL measurement prior to cataract surgery. In 91 consecutive American patients, 111 eyes had simultaneous biometry performed and the three to six week post-operative manifest refractions were compared with the predicted refractions produced by the two biometry techniques. Patients with known corneal curvature abnormalities such as previous penetrating keratoplasty or refractive procedures, patients who had a complication at the time of the surgery, and those with a poor visual prognosis, eg, a macular scar were excluded. The authors report that the PCI was statistically significantly better in the mean absolute error (0.53D $\pm$ 0.59D vs 0.76 $\pm$ 0.72D; p = .01) and the percentage of eyes within $\pm$ 0.5D (61.2% vs 42.3%; p = .003) and $\pm$ 1.0D (87.4% vs 77.5%; p = .05) of predicted refraction. There was insufficient detail in the paper to verify these calculations. Further, 10 per cent of patients could not be measured with the PCI due to either poor fixation, dense cataract,

or significant corneal pathology and these patients were not included in analysis. Hence, no intention-to-treat analysis was conducted.

Verhulst and Vrijghem (2001) compared the pre-operative AL measurements, obtained by both AUS and PCI, in 50 eyes of 35 Belgian cataract patients. The PCI results were included in the SRK II formula to calculate the lens implant power. Post-operative refractive assessment was performed four weeks after surgery.

In all patients, the Allergan S140 NB silicone foldable intraocular lens (A-cte 118.0) was implanted through a self-sealing 2.5mm temporal incision after phacoemulsification. The same surgeon performed all interventions. All patients were operated on using topical anaesthesia. The authors report that the mean difference in AL between AUS and PCI was 0.2mm. At the post-operative assessment the overall refractive outcome was in the range of $\pm$ 1D. Table 8 shows the reported refractive outcome achieved with AUS vs PCI biometry. For each biometric technique, the percentage of patients with refractive errors less than 0.5D, 1D, 1.5D etc is shown. Five patients were unable to undergo PCI biometry due to the density of cataract. It is unclear whether the AUS results are for all 50 eyes, as actual numbers are not given. However, the five cases that could not be measured with the PCI are not included in the results, therefore intention-to-treat analysis was not carried out. Further, it is difficult to convert the percentage figures provided in the paper to whole numbers and hence the results are unable to be verified.

Table 8 Comparison between the refractive outcome achieved with AUS and PCI biometry

	<0.5D	<1.0D	<1.5D	<2.0D	<2.5D
AUS	40.4%	72.3%	95.8%	97.9%	100%
PCI	55.3%	89.3%	100%		

Drexler (1998b) compared biometry performed by an enhanced version of dual beam PCI and AUS in a prospective study of 85 eyes of 59 patients from Austria. Mean age was 76 $\pm$10 years (range 35 to 93 years), mean pre-operative visual acuity was 20/50 (range 20/400 to 20/22) and mean refraction was -0.95 $\pm$3.6D (range -16.00 to 4.75D). Different technicians performed PCI and AUS. A significant correlation between the pre-operative visual acuity and cataract grade ($R = -0.53$, $p < .00001$) indicated that lens opacification was the main contributing factor for reduced visual acuity. Three months after cataract surgery, mean visual acuity of all 85 investigated eyes was 20/22 (range 20/200 to 20/15). Mean numerical error due to implantation of intraocular lenses determined with AUS biometry using the SRK II formula was 0.36 $\pm$0.85D (range –2.2 to 2.425D) and the mean absolute error was 0.72 $\pm$0.58D (range 0.0 to 2.425).

Any calculation of intraocular lens power may suffer from offset errors due to systematic errors in biometry, the surgical technique, or the formula. [3] When determining the mean absolute error in combination with PCI, the SRK II formula was corrected for offset errors before evaluation to obtain a numerical error of zero by calculating the A-constant

[3] When determining the mean absolute error (MAE) in combination with both biometry techniques, the SRKII formula was corrected for offset errors to obtain a mean numerical error (MNE) (ie, the difference between the refractive outcome three-months postoperatively and the predicted spherical equivalent) of zero by recalculating the surgeon factor retrospectively.

retrospectively. Pre-operative PCI data were used to determine the refractive power of the intraocular lenses retrospectively and to calculate the refractive outcome.

The researchers reported that the mean absolute error for post-operative refraction achieved with PCI was 0.49D compared with 0.67D with AUS. AL measured with the two techniques differed by a mean of 0.46mm. This study was performed with a laboratory prototype of PCI, not a commercial prototype.

Summary

Drexler (1998b) obtained a difference in AL between PCI and AUS of 0.460mm. However, apart from using a wavelength of λ=855nm in their original experimental Vienna instrument, which allowed segmental AL measurements, their US measurements were performed with the applanation technique. In contrast to the IUS method, AUS is subject to a zero point error as well as possible shortenings of the AL due to globe compression during transducer contact.

In an earlier study, Hitzenberger (1993) compared PCI measurements at 780nm to both IUS and AUS. They obtained a difference of 0.47 $\pm$ 0.25nm for 179 AUS measurements and 0.18 $\pm$ 0.12nm for 50 IUS measurements. Their Kretz 7200 MA instrument used for IUS cannot, however, match the precision of say the Grieshaber Biometric System (GBS) device (Haigis et al., 2000).

Drexler (1998b) found an improvement of 27 per cent in absolute post-operative refractive error of 85 cases if IOL calculations were based on PCI values from their experimental PCI instrument at λ=855nm instead of ultrasound data. Their acoustic measurements, however, had been performed with the Alcon OcuScan using the applanation technique. Acoustic results based on this method are of lesser quality than IUS results (Haigis et al., 2000). In addition, all the above studies used either the SRK II formula or the Holladay 1 formula (Holladay, 1997) which, although still widely applied, are well known to have poorer performance than theoretical formulas. Thus, it seems not surprising that PCI increased the percentage of correct refraction predictions in the above studies.

The various lens formulae calculate the expected post-operative position of the lens within the eye using AL and corneal curvature to adjust a starting estimate of the expected lens position. This is called either the 'A constant', 'lens factor', or 'anterior chamber depth' in different formulae. The lens position constants for various equations differ in their dimensions (mm vs diopters), and express post-operative IOL position in the eye relative to different ocular structures (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002).

Comparison of PCI and IUS

Kiss (2002b) evaluated the refractive outcome of 45 patients from Austria with age-related cataracts in both eyes three months post-operatively using PCI as well as IUS. Mean age was 73 years (range 47-93 years). A single experienced investigator performed IUS. In each patient, the first eye was randomly assigned to receive an intraocular lens using the Holladay IOL power formula based on PCI or IUS biometry. The other biometric technique was used in the contra-lateral eye. Subjective refraction was assessed

three months post-operatively. The researchers reported that the mean AL measured with the PCI was 23.7mm (range 22.3mm to 26.6mm) and with IUS was 23.5mm (range 22.1mm to 26.6mm).

The mean difference in the measured AL obtained with PCI and IUS was 0.22mm (range –0.24mm to 0.57mm), correlation R = 0.99 ($p < .05$). They further report that after AL measurements assessed with the PCI were corrected, data were not statistically significantly different ($p = 0.48$). The mean numerical error (MNE) (the difference between the refractive outcome three months post-operatively and the predictive spherical equivalent) was 0.13D and 0.03D for PCI and IUS respectively.

The mean absolute error (MAE) (the absolute value of MNE) was 0.48D (range 0.00 to 1.58D) and 0.46D (range 0.01 to 1.92D) with the PCI and IUS respectively. The researchers recalculated the surgeon factor retrospectively to correct the Holladay formula to obtain a post-operative MNE of zero; a theoretical MAE of 0.46D was obtained with both biometry techniques. The authors indicate that the refractive outcome in cataract patients using PCI biometry was as good as that achieved with IUS.

In a study by Packer (2002) and set in the United States, pre-operative AL measurement of 50 eyes was compared using PCI and IUS. Post-operative refraction in 50 eyes that had cataract extraction with posterior chamber IOL implantation was then examined to determine the accuracy of both techniques.

A single surgeon performed all phacoemulsifications and the Collamer IOL (CC4204BF, Staar Surgical) was implanted in all eyes to provide uniform results. The post-operative refraction was measured two to three weeks after surgery. Only eyes obtaining 20/30 or better corrected visual acuity were included in the study. The researchers report that the ALs obtained by IUS and PCI were highly correlated (R = 0.996). It was further reported that the mean of the AL measured by IUS was 23.40mm (range 21.03 to 25.42mm) and by PCI 23.41mm (range 21.13 to 25.26mm). No analysis was reported on the refractive outcome if PCI biometry had been used for IOL calculations.

Haigis (2000) used PCI additionally to measure the ALs of 136 eyes of 108 patients from Germany who attended between July 1997 and October 1998 for biometry for planning of cataract surgery. Whereas surgical decisions were based on IUS data, the researchers used post-operative refractive measurements to calculate retrospectively the results that would have been obtained if PCI AL data had been used for IOL calculation. For the translation of optical to geometric lengths, five different conversion formulae were used (Table 9).

Table 9 Overview of different conversion algorithms used to translate optical path length (OPL) as acquired by the ALM instrument into geometrical AL. AL0 is displayed by the ALM instrument.

ID	Biometry principal	Axial length derived from
GBS	Immersion ultrasound	Sum of ocular segments
AL0	Laser interference (PCI)	OPL/1.3549
AL1	Laser interference (PCI)	OPL/1.3549 – 0.14
AL2	Laser interference (PCI)	OPL/1.3574
AL3	Laser interference (PCI)	OPL/1.3574 – 0.14
AL4	Laser interference (PCI)	(OPL/1.3549 – 1.3033)/0.9571

Note the conversion relation for AL4 is used in the Zeiss IOLMaster.

Results showed that optical ALs were obtained for 118 eyes. In two eyes, no PCI measurements were performed. In 16 (12%) of 134 eyes, PCI could not be carried out.

Post-operative refraction and visual acuity data were available for 103 of 118 eyes. Of these, five eyes with a best corrected visual acuity ≤ 0.3 were excluded from the study for various reasons.

IOL calculation was carried out according to Haigis (2000) with and without optimisation of constants (Table 10).

The researchers found that on the basis of IUS data from their Grieshaber Biometric System (GBS), post-operative refraction after implantation of a Rayner IOL type 755 U was predicted correctly within $\pm$ 1D in 85.7 per cent and within $\pm$ 2D in 99 per cent of all cases. A similar result was obtained with PCI AL data after suitable transformation of optical path lengths into geometrical distances, although better results (by 1%) were obtained in the IUS $\pm$ 1D group.

Table 10 Mean predicted error ΔREF (true post-operative minus calculated refraction according to equation 2*) and percentages of correct predictions within $\pm$ 1D and $\pm$ 2D with and without optimisation for different AL definitions as given in Table 9 (n = 98)

	Without optimisation (std)			With optimisation (opt)		
ID	ΔREF (D)	$\pm$ 1D (%)	$\pm$ 2D (%)	ΔREF (D)	$\pm$ 1D (%)	$\pm$ 2D (%)
GBS	-0.17 $\pm$ 0.71	85.7	99.0	-0.03 $\pm$ 0.69	86.7	99.0
AL0	0.74 $\pm$ 0.76	69.4	94.9	-0.02 $\pm$ 0.72	84.7	98.0
AL1	0.37 $\pm$ 0.75	78.6	96.9	-0.02 $\pm$ 0.71	85.7	99.0
AL2	0.63 $\pm$ 0.76	72.4	95.9	-0.02 $\pm$ 0.72	85.7	99.0
AL3	0.26 $\pm$ 0.75	79.6	95.9	-0.02 $\pm$ 0.71	85.7	99.0
AL4	-0.06 $\pm$ 0.72	85.7	98.0	-0.01 $\pm$ 0.71	84.7	99.0

* see (Haigis et al., 2000)

Intraobserver and interobserver variability of PCI

Lam (2001) carried out a study to assess the repeatability of the IOLMaster. AL and anterior chamber depth were measured by two operators on the right eyes of 26 Chinese subjects (mean age 19.3 $\pm$ 0.55) using the IOLMaster followed by a conventional ultrasound biometer operated by a third practitioner. Each operator took five valid readings and the average was used for analysis. The mean spherical equivalent (spherical component + ½ cylindrical component) of the subjects was -2.28D ($\pm$2.67). There was good repeatability and accuracy of AL assessment with values of 24.44 ($\pm$1.21mm) for both IOLMaster operators and 24.54 ($\pm$1.09mm) for ultrasound biometry. The mean difference between the IOLMaster and ultrasound biometry was -0.10mm, with 95 per cent limits of agreement between 0.66 and –0.85mm ($p = 0.20$). The anterior chamber depth was repeatable but the IOLMaster was shown to give deeper results than ultrasound biometry. Anterior chamber depth was 3.60 ($\pm$0.25mm) for the first IOLMaster operator and 3.60 ($\pm$0.26mm) for the second IOLMaster operator and 3.44 ($\pm$0.24mm) for ultrasound biometry. The mean difference in anterior chamber depth was 0.15mm, with 95 per cent limits of agreement between 0.34 and -0.33mm ($p < 0.01$).

In a study by Haigis (2002) to check the inter and intra-examiner variability for the IOLMaster measurement modes, four examiners (two experienced and two beginners) measured AL of 29 volunteers at three different times. Results for repeated

measurements by the same examiner (intra-examiner variability) were 10.9μm for AL. For different examiners measuring the same patient (inter-examiner variability), the value for AL was 11.8μm. Results showed that AL was 100 per cent reliable. Similar results have been published by Vogel (2001).

Vogel (2001) reported the results of a study that evaluated the intraobserver and interobserver variability in AL, anterior chamber depth and corneal radius measurements using PCI. In this observational case series and interobserver reliability trial, the test group consisted of 30 test persons having healthy eyes without noteworthy imperfect refraction, with a visual acuity of 1.0 and proper fixation behaviour. The exclusion criteria were:

- any optical opacities or pathology at the slit lamp examination or by corneal topography;
- best corrected distance visual acuity of worse than 1.0, or improper fixation;
- history of contact lens use or medication that might affect the pupil;
- previous ocular trauma or intraocular surgery;
- corneal disease or ocular infection;
- history of ocular disease such as dry-eye syndrome, glaucoma, optic atrophy, macular degeneration, retinopathy, or ocular tumour.

To determine intraobserver variability, one observer measured the AL, the corneal radii and the anterior chamber depth 20 times each in 10 eyes. The intraobserver variability resulted from the variation of measured values obtained by this observer. The interobserver variability and reliability was determined with five different observers measuring the AL, the corneal radii and the anterior chamber depth four times each in 20 eyes. The interobserver variability resulted from the fluctuations of measured values between observers.

The researchers report that intraobserver variability was ±25.6μm for AL, ±12.9μm for corneal radii, and ±33.4μm for anterior chamber depth. The coefficients of variation were 0.1 per cent, 0.17 per cent and 0.9 per cent respectively. Erroneous measurements occurred in 11 of 600 AL measurements (1.8%). In six AL measurements (1%), the measurement curve was edited after the measurement because double peaks appeared at a distance of 200 to 250μm. The interobserver variability was ±21.5μm for AL, ±15.9μm for corneal radii, and ±29.8μm for anterior chamber depth. The coefficients of variation were 0.09 per cent, 0.21 per cent and 0.82 per cent respectively. The reliability was 99 per cent for AL, 99.8/99.5 per cent for corneal radii (r1/r2), and 97.8 per cent for anterior chamber depth. The coefficients of variation were 0.1 per cent, 0.17 per cent and 0.9 per cent respectively. The authors suggest that the reduced reliability in anterior chamber depth measurement was caused by reduced intraobserver reliability of one of the five observers (R = 0.87) (Vogel et al., 2001).

Vogel (2001) conclude that PCI accuracy is about 20μm, while a study by Kiss (2002a) reported that PCI has a precision of 9 to 26μm. The results of Vogel (2001) have, however, been challenged. Gobin (2002)reports that the reported PCI precision of approximately 20μm is an underestimate since the worst standard deviation is 33.4μm. To determine repeatability, Vogel repeated measurements 20 times.

As the coherence length of the source is 150μm, the best resolution that can be obtained is 150μm, therefore the accuracy they have obtained is 150μm/√20 = 33.5μm. The selectivity of PCI is based on the ability of the back-scattered signal to interfere with the reference signal. The resolution of such a system cannot be lower than the coherence length of the source (Gobin, 2002).

A 150μm coherence length offers lower accuracy than US, which is reported to be 88μm to 120μm when using AUS and 50 to 64μm when using IUS (Rudnicka et al., 1992b, Schachar, 1980, Drexler et al., 1998b, Kiss et al., 2002b). In AL measurements, an error of 100μm and 150μm corresponds to an error in post-operative refraction of 0.25D and 0.38D respectively (Boerrigter et al., 1985, Binkhorst, 1981).

Berges (1998) prospectively compared the reproducibility and accuracy of IUS biometry with those of AUS biometry to calculate IOL power. IUS and AUS determined the AL in 87 eyes of 72 French cataract patients. Patients were assigned to one of two groups based on the IUS biometry: non-myopic (AL < 24.5mm; n = 54) or myopic (AL > 24.5mm; n = 33). Post-operative refractive results were compared with attempted values. Results showed that the mean AL variance was statistically significantly greater when using AUS than IUS (0.157mm ± 0.260 vs 0.015 ± 0.018mm in the myopic group, $p < 0.0001$ and 0.024 ± 0.045 vs 0.009 ± 0.011mm in the non-myopic group, $p < 0.0001$). More eyes having IUS biometry achieved a final refraction within +0.50D of the attempted refraction (63 and 43% respectively, $p < 0.05$). No deviation greater than 1.60D was observed with IUS in either the myopic or non-myopic groups. Three cases with such a deviation (up to 2.24D) would have been observed had AUS biometry been chosen for IOL power calculation. In the myopic group, attempted post-operative refraction was within ± 0.50D in 78 per cent of eyes having IUS compared with 65 per cent having AUS. The difference was not statistically significant.

Hoffmann (1998) carried out a prospective randomised trial on 288 German patients presenting for routine cataract surgery. Eyes with nanophthalmia (AL < 21mm) or a high degree of myopia (AL > 27mm or staphyloma posticum) were excluded. Using a list of random numbers, the 288 patients were divided into two groups. Group One consisted of 156 patients who had AL measured with IUS and Group Two contained 132 patients who had AL measured with AUS. All biometry was conducted by the same researcher in both groups and used the same equipment. Ten measurements were taken and the mean was used to calculate the intraocular lens power. Four different people carried out the operations and phacoemulsion with lens implantation in the capsular sac was carried out in all cases. Post-operative data was collected on the first day after surgery and three to six months later. In order to determine the precision of each technique, the authors retrospectively calculated the strength of the intraocular lens, which would have resulted in emmetropia. The deviation from this ideal IOL strength, determined using SRK/T formula (calculation error) was assumed to be the measure for the precision of the measurement and calculation method taken together. Results showed that post-operative IOL error at three to six month follow-up was –0.01 ± 0.57D for IUS and 0.53 ± 0.70D for AUS. The absolute error was 0.43 ±38D for IUS and 0.64 ± 0.70D for AUS. This difference was statistically significant ($p < 0.0001$). After adjustment of the constants (A =118.79 for IUS and A = 118.42 for AUS) it was 0.00 ± 0.57D for IUS and 0.01 ± 0.71 for AUS. The absolute error was 0.43 ± 0.38D for IUS and 0.53 ± 0.48D for AUS, a difference that was also statistically significant ($p < 0.05$).

In summary, based on the above studies it can be stated that optical biometry with PCI is a highly precise and reliable examination method delivering observer-independent results comparable to IUS in lenses that do not exceed a certain opacity. Ultrasound measurements stop at the internal limiting membrane of the retina, while PCI penetrates this veil to Bruch's membrane, where the photoreceptors lie. Because the patient fixates on a light, the AL of the visual axis is measured using PCI.

However, the laser cannot penetrate advanced or mature cataracts to generate an interference pattern and therefore will not replace US biometry. The main drawback of optical biometry is therefore its limited usability in the case of fixation problems or advanced cataract (Hitzenberger, 1991, Hitzenberger et al., 1993, Haigis, 2002). Further studies must show the accuracy and observer dependence of PCI on cataract eyes with lens opacities of various degrees, as well as on highly myopic and highly hyperopic eyes.

Measurement accuracy

When calculating the optical power of the implant to be used in cataract surgery, there are three aspects of measurement accuracy for the eye that need to be considered — measurement bias, measurement precision and prediction accuracy.

Measurement bias

Measurement bias is the measurement 'offset' due to technical issues.

IUS vs AUS

AL measured by AUS is often shorter (by 0.10 to 0.32mm) than AL measured by IUS (see studies in Table 1). As stated earlier, this difference is often ascribed to corneal indentation in AUS that is eliminated in IUS. Only one study (Hennessy and Chan, 2002) found that AUS produced longer ALs than IUS. The authors query if this difference, which was statistically but not clinically significant, could be due to the characteristics of the spring-loaded US probe used with the Biovision A-scan probe.

The difference in AL found when using IUS and AUS techniques can be compensated by an individual surgeon's A constant. This adjusts measurement biases for the whole measurement set-up (ie, A-scan machine, operator and measurement technique whether IUS or AUS). Many experts (Hoffer, 1993, Holladay, 1997) regard surgeon individualised constants as being essential, whether IUS or AUS is used, and insist that once the constant is determined, it is used in future cases with the expectation that it then neutralises factors such as measurement bias. Individualised lens constants are calculated using the actual refractive results of each surgical case to determine the 'average' post-operative position of the lens that applies to the retrospective group. This gives an average prediction accuracy value of zero, as well as being an expected post-operative position of the lens for future cases.

IUS vs PCI

'Retinal thickness' is factored into the 'pre PCI' lens formulae that were originally derived using US measurements. An average retinal thickness value is added to the acoustical

length. The IOLMaster adjusts for this in the internal computations, using the PCI length and removing the retinal thickness 'correction' as in the published version of the formulae (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002).

Measurement precision

This includes the theoretical resolution of the device, arising from the physics of the wavelength of sound/light and how the machine is used, and measures the energy reflections/peaks.

In addition, there is the ability to reproduce the measurements (repeatability if it is the same operator or reproducibility if it is a different operator) (Gobin, 2002). Reproducibility is studied by looking at re-measuring the same eye (Hennessy and Chan, 2002, Watson and Armstrong, 1999). Prior to the availability of the PCI technique, reproducibility was not well reported in the literature (Vogel et al., 2001). It is therefore problematic to compare PCI with IUS or AUS. These problems include variation between studies on how reproducibility is reported/tested statistically so that it can be compared across reports. For example, it is not possible to compare the results of Vogel's (2001) study on PCI with the study by Hennessy and Chan (2002) on IUS and AUS, or with the study by Rudnicka (1992a) on AUS.

Prediction accuracy

The prediction accuracy, or numeric error, is the difference between the predicted and achieved post-operative refraction. A surgeon-individualised lens position constant from a retrospective series would be expected to give a mean series prediction error of zero when the prediction error is re-calculated with the individual constant. Future cases would also be expected to have a mean prediction error of zero if pre-operative measurement techniques stayed the same.

Given that the lens position constant should be individualised, the comparison of spread of prediction accuracy is of most interest when comparing techniques used to measure AL. When comparing the variance between two groups, the 'F statistic' would be appropriate. The Kiss et al, (2002b) data do not include standard deviation or variance for the mean numeric error, so the IUS vs PCI results cannot be compared in this way. It is common for the ophthalmic literature to use the absolute numeric error for summarising results and to present the proportion of cases within ±0.5 and ±1.0D. The absolute numeric error value is not normally distributed, so non-parametric methods are needed for statistical analysis. No studies could be found that performed this sort of statistical analysis; therefore the statistical evidence of superiority of the spread of results being smaller for PCI is lacking. PCI is, however, at least as accurate as ultrasound.

There are also no published reports that comprehensively document the claimed superiority of IUS vs AUS in the terms discussed above (ie, measurement bias, measurement precision, and prediction accuracy).

Strengths and limitations of PCI

PCI has been reported to have certain advantages over US biometry. One of these advantages is cases of staphylomatous ocular backwalls (Lege and Haigis, 2001). With US, it is often difficult to decide among different AL results from, for example, a highly myopic eye. Since optical biometry measures along the visual axis, the PCI results are reportedly more reliable if the patient is able to fixate. However, many modern ultrasound machines now have a built-in fixation light in the transducer head that applanates with the patient's cornea (Hill, [undated], Retzlaff and Linville, [undated], Schrecker et al., 1998). PCI is also reported to be superior to US in the measurement of pseudophakic and silicone oil-filled eyes. Every medium along the propagation path of light affects the optical path length by its individual propagation velocity, expressed in its group refractive index.

Compared to normal phakic eyes, a pseudophakic eye will thus have a different optical path length. In US as opposed to PCI, propagation velocities of IOL materials are considerably different from those of ocular tissues.

Therefore, considerable correction factors are needed for measuring, for example, a pseudophakic AL by US, which typically ranges from -0.6mm for silicone to 0.4mm for polymethyl methacrylate (PMMA) lenses (Haigis, 2002). Conversely, for PCI, typical pseudophakic correction factors have been reported to be approximately 0.1mm and nearly independent of IOL material (Haigis, 2002).

PCI biometry is a user- and patient-friendly method for AL determination and IOL planning in the preparation of cataract surgery. Its accuracy is superior to that of the commonly used AUS and is comparable to that of the high-precision IUS. The new optical biometry technique has the potential to become a routine method for IOL calculations in cataract surgery in cases of otherwise 'normal' cataract eyes without additional pathologies and with visual acuities $\geq$ 0.1. However, it has been found that in certain cases, eg, dense cataracts, PCI is unable to optically measure cataract eyes. Infrared light must be able to pass through the eye and return to the PCI instrument. Therefore, a certain amount of transparency along the propagation path is mandatory with no obstructions blocking out the light. Furthermore, a minimum in fixation is needed. This requires cooperation on the part of the patient. Sometimes a measurement may not be possible due to very dense cataracts as well as general inability to cooperate.

In a study carried out by Hitzenberger (1993) 196 cataract eyes of 100 unselected patients from Austria were examined. Ages ranged from 43 to 97 years (mean 74 years, SD $\pm$10 years) and 36 patients were men while 64 were women. Laser Doppler interferometry and AUS determined AL; 50 eyes were also measured by IUS. The cataract grade was determined by the Opacity Lensmaster 701, a commercial instrument that measures back-scattered light from the eye lens, which is illuminated by a light beam of 1.5mm diameter. The measurement is thus restricted to the central area of the lens. The result of the measurement is a dimensionless number between 0 and 99 that is referred to as lens meter unit (LMU) where higher LMU values indicate higher lens densities. According to the manufacturer, normal lenses give values between 0 and 20 LMU, while higher values indicate cataract lenses.

In the Hitzenberger (1993) study, the eyes were classified according to their LMU values into groups of width 5 LMU, ranging from 15 to 20 LMU, 20 to 25 LMU, and so on. Values above 90 LMU were combined into one group. Of the 196 (90.5%) cataract eyes

examined, 177 were measurable by the LDI. In four cases (2%) the instrument failed because of computer problems. In seven cases (3.5%), no measurement could be taken due to fixation problems. Results showed that nine of the 125 patients who had a cataract graded in the range 15 to 55 could not be measured. Three of the nine patients in the range 56 to 65 LMU could not be measured by the LDI. Of the six patients who had cataracts graded in the range 66 to 90 LMU, there was one failure of LDI. Nine eyes had values higher than 90 LMU and seven were out of the measuring range of the instrument (ie, $\geq$ 100 LMU). The eye lengths measured by the LDI were about 0.18mm longer than those measured by IUS (n = 50) and about 0.47mm longer than those measured by AUS (n = 177).

Connors et al (2002) conducted a study where it was found that 10 per cent of patients could not be measured with PCI due to either poor fixation, dense cataract, or significant corneal pathology.

Connors et al (2002) also found that PCI gave unpredictable keratometric readings associated with distorted corneas. These readings were not expected in the patients observed and the authors put it down to problems with drying of the cornea from applanation measurements of IOP or secondary to other anaesthetic use (Connors et al., 2002).

In an article by Haigis (2002) it was reported that up to 15 per cent of more than 2,500 eyes of patients in a university hospital surrounding could not be measured with PCI. In an earlier study, Haigis (2002) reported that 16 (12%) of 134 eyes were unsuitable. In another study, Lege and Haigis (2001) found that 58 (9%) of 678 eyes could not be measured optically, while in a study by Meyer (2001) it was found that in 11 of 79 (14%) patients measurements could not be carried out with PCI. Similar results have been reported by Verhulst and Vrijghem (2001), who found that five (10%) of 50 eyes could not be measured with PCI. Schrecker (1998) reported that 10 (11%) of 90 eyes were not suitable for PCI. Some of the reasons reported for optical biometry to fail in these studies were:

- inability to cooperate (fixate);
- corneal scarring;
- keratopathy;
- lid abnormalities;
- maculopathy;
- mature cataract;
- membrane formation;
- nystagmus;
- respiratory distress;
- retinal detachment;
- severe tear film problems;
- tremor; and
- vitreous haemorrhage.

Another possible drawback with using optical biometry is that although the instrument was not designed for ultrasound diagnosis, A-scan still carries some diagnostic information. This is because echoes of neighbouring structures and tissues along the path of the sound beam are also displayed. The IOLMaster interferogram shows no such information but rather a small window into retinal reflectivity. Thus, without careful interpretation, optical signals may hide possible pathologies.

For example, Haigis (2002) reports that reasonably good quality signals of high signal-to-noise-ratio (SNR), acceptable as good AL measurements, turned out to actually stem from a detached retina. The report states that it takes a trained person with clinical background information to avoid traps like this.

Summary

There were few studies published that specifically addressed the research question. This was due to the relative newness of PCI for the measurement of AL prior to cataract surgery. Only one study was identified which compared the PCI procedure with the two comparators; however, this study failed to meet the inclusion criteria as fewer than 50 eyes were studied. The evidence that could be extracted suggests that PCI is comparable with IUS. However, US biometry is still needed in cases of dense cataracts.

PCI and US-measured AL cannot be expected to yield the same values. First, ultrasound measures the distance from the anterior corneal vertex to the internal limiting membrane (ILM), whereas PCI measures the distance up to the retinal pigment epithelium (RPE). PCI axial lengths will thus be greater than ultrasound ones. Second, segmental measurements with individual sound velocities are possible with ultrasound, derived from the distance between the sound reflections from the cornea, the anterior and posterior lenses, and from the internal limiting membrane of the retina. However, with PCI a mean group refractive index equivalent to using a mean velocity in ultrasound has to be applied to convert optical path lengths (OPLs) into geometrical distances. Lastly, ultrasound measures along the optical axis of the eye, while PCI – as a fixation-bound method – measures along the eye's visual axis. The accuracy of PCI is equivalent to IUS and superior to the commonly used AUS. PCI may well become a routine method for IOL calculation prior to cataract surgery in cases of 'normal' cataract eyes without additional pathologies. However, for some 5-15 per cent of cataract patients, PCI fails for different reasons. In these cases, AUS or IUS will continue to be the methods of choice.

Table 11 Studies assessed in this review

Reference	Sample characteristics	Measuring tool	Results	Comments
Connors et al., (2002) Prospective case-series Country: USA	Consecutive prospective patients n = 111 eyes in 91 cataract patients Patients enrolled over 2-month period Exclusion criteria: Patients with known curvature abnormalities, refractive procedures, complications at time of surgery, poor visual prognosis.	PCI and AUS 3-6 week post-operative manifest refractions were compared with pre-operative refraction performed by both PCI and AUS.	MAE 0.533D ± 0.589 vs 0.757 ± 0.723D in PCI and AUS respectively (p = .012) The percentage of eye within ± 0.5D (61.2%) for PCI vs 42.3% for AUS (p = .003) and ± 1.0D (87.4% for PCI vs 77.5% for AUS (p = .05) of predicted refraction	• Insufficient detail given to justify these results. • 10% of patients could not be measured with PCI and these patients were not included in analysis, therefore intention-to-treat analysis was not conducted.
Verhulst and Vrijghem (2001) Prospective case-series Country: Belgium	No selection criteria given n = 50 eyes of 35 cataract patients. Exclusion criteria: No exclusion criteria given.	PCI and AUS All patients had pre-operative biometry performed by both PCI and AUS. Post-operative refraction assessed 4 weeks after surgery.	Mean difference in AL from AUS and PCI 0.2mm 40.4% AUS vs 55.3% PCI refractive outcome ± <0.5D 72.3% AUS vs 89.3% PCI refractive outcome ± <1.0D 95.8% AUS vs 100% PCI refractive outcome ± <1.5D	• Single surgeon implanted all lenses. • All implanted lenses the same make and self-sealing 2.5mm temporal incision after phacoemulsification carried out on all patients. • SRK II formula used for determination of refractive outcome. • No information on how patients were selected. • No statistical tests conducted. • Actual numbers not given so impossible to check results. Percentages do not seem to convert to whole numbers. • Unsure if AUS data contain all 50 cases or only the 45 included in PCI analysis. • Five patients could not be measured with PCI; these patients were not included in the analysis therefore intention-to-treat analysis was not conducted.

Table 11 cont/… Studies assessed in this review *(continued)*

Reference	Sample characteristics	Measuring tool	Results	Comments
Drexler et al., (1998b) Prospective case-series Country: Austria	No selection criteria given. n = 85 eyes in 59 patients. Exclusion criteria: No exclusion criteria given.	PCI and AUS. All patients had pre-operative biometry performed by both PCI and AUS. Post-operative refraction assessed 3months after surgery.	Mean age of patients 76 ± 10yrs (range 35 to 93yrs). Pre-operative MVA 20/50 (range 20/400 to 20/22). Mean refraction –0.95 ± 3.6D (range –16.00 to 4.75D) MAL 23.03 ± 1.29 (range 20.26 to 27.21) with AUS vs 23.49 ± 1.31 (range 20.46 to 27.88mm) with PCI ($p < 0.0001$). MVA 3months post-op 20/22 (range 20/200 to 20/15). MNE 0.36 ± 0.85D (range –2.2 to 2.425 D). MAE 0.67 ± 0.54D (range 0.0 to 2.65D) vs 0.49 ± 0.39D (range 0.0 to 1.44D) if PCI had been used ($p < 0.0001$) 27% improvement in RO if PCI biometry used.	• SRK II formula used for determination of refractive outcome. • All cataract operations and implantation of lenses performed by one surgeon. • One researcher performed all PCI biometry and another researcher performed all AUS biometry and determined subjective refraction 3 months after surgery. • All implanted lens the same make and self-sealing 4mm temporal incision after phacoemulsification carried out on all patients. • No information on how patients were selected. • Laboratory prototype of PCI used not a commercial prototype. • A significant correlation between the pre-operative visual acuity and cataract grade ($r = -0.53$, $p < .00001$) indicated that the lens opacification was the main contributing factor for reduced visual acuity.

Table 11 cont/... Studies assessed in this review *(continued)*

Reference	Sample characteristics	Measuring tool	Results	Comments
Kiss et al., (2002b) Prospective case-series Country: Austria	Consecutive prospective patients with age-related cataract in both eyes and scheduled for bi-lateral cataract surgery. n = 90 eye in 45 cataract patients. Exclusion criteria: No exclusion criteria given.	Prototype (ALM) of the commercial PCI instrument and IUS. All patients had pre-operative biometry performed by both PCI and IUS. Post-operative refraction assessed at 3 months.	Mean age 73yrs (range 47 to 93yrs). MAL 23.7mm (range 22.3 to 26.6mm) with PCI c.f. 23.5 mm (range 22.1 to 26.6mm) with IUS. Mean difference in AL with PCI and IUS 0.218mm (range -0.241 to 0.571mm) ($R = 0.99$, $p < 0.05$). MNE was 0.13 D for PCI c.f. 0.03 for IUS. MAE was 0.48D (range 0.0 to 1.58D) for PCI and 0.46D (range 0.01 to 1.92D) with IUS. Using a post-op MNE of zero a theoretical MAE of 0.46D was obtained for both PCI and IUS. Refractive outcome with ALM and IUS ($p = 0.28$) 3 month post-op ($p = 0.47$) in the visual acuity of eyes measured with PCI (mean 1.00, range 0.30 to 1.25) and with IUS (mean 1.00 range 0.30 to 1.25). 66.7% IUS vs 55.6% ALM refractive outcome $\pm$ < 0.5D. 91.1% IUS vs 88.9% ALM refractive outcome $\pm$ < 1.0D. 100% IUS vs 100% ALM refractive outcome $\pm$ < 2.0D.	• Prototype version of the commercial PCI used. • All ops carried out by same surgeon. • All eyes implanted with same type of lenses. • Mean value of 10 consecutive measurements by one of the two biometry techniques was used in combination with the Holladay formula. • 1st eye randomly assigned PCI or IUS; in the contra-lateral eye the other biometric technique was used.

Table 11 cont/... Studies assessed in this review *(continued)*

Reference	Sample characteristics	Measuring tool	Results	Comments
Packer et al., (2002) Prospective case-series Country: USA	No selection criteria given. n = 50 cataractous eyes.	PCI and IUS. All patients had pre-operative biometry performed by both PCI and IUS. Post-operative refraction assessed 2-3weeks post-op.	AL 23.40mm (range 21.03 to 25.42mm) with IUS c.f. 23.41mm (range 21.13 to 25.26mm). IUS and PCI highly correlated (R = 0.996). 48% IUS achieved targeted refraction precisely. 92% IUS refractive outcome ± 0.5D 100% IUS refractive outcome ± 1.0D.	• All ops carried out by same surgeon. • All eyes implanted with same type of lens. • Holladay II IOL power calculation formula used. • No p values given. • Selection criteria not revealed. • Only eyes obtaining 20/30 or better best corrected VA included in study. • No refractive outcome reported for PCI biometry.
Haigis et al., (2000) Prospective case-series. Country: Germany	Consecutive prospective patients. n = 136 eyes in 108 patients. Study period July 1997-October 1998.	PCI and IUS All patients had pre-operative biometry performed by both PCI and IUS. Post-op refraction measured between 101 – 400 days after surgery in 91/98 eyes (93%);. 4 eyes measured before 100 days post-op, 3 eyes measured more than 400 days post-op. Mean data of post-op refraction 8.2 $\pm$ 2.8 months (245 $\pm$ 85, range 2 – 515days).	98 eyes of 88 patients (72%) included in post-op refraction analysis. Mean age 71yrs (range 44 to 91yrs) 31men (35%) and 57 women (65%) MPE without optimisation for diff. AL definitions. MPE with optimisation for diff. AL definitions. 86.7% IUS vs 84.7% PCI refractive outcome ± 1.0D. 99% IUS vs 98% PCI refractive outcome ± 2D.	• All eyes implanted with same type of lens. • Three surgeons performed 3 diff types of op. • IUS biometry performed with GBS. • 16 (12%) of 134 eyes could not be measured with PCI. These patients were not included in analysis, therefore intention-to-treat analysis was not conducted.

AL = axial length D = diopter MAE = mean absolute error MNE = mean numerical error
MPE = mean prediction error MVA = mean visual acuity nssd = no statistically significant difference

What are the economic considerations?

The purpose of this section is to provide an economic appraisal of PCI relative to IUS and AUS. There are four parts to the economic analysis in this section. First, the per patient cost (and hence, the necessary Medicare rebate) of measurement by PCI is estimated; second, decision analysis is used to determine value for money on a per-patient basis for each of the three measurement techniques; third, additional economic considerations are addressed to provide context to the results of the decision analysis; and fourth, a total cost assessment is carried out to determine what the total cost implications of each technique would be for the Australian health system.

Estimated per patient cost of measurement by PCI

This analysis provides an estimate of what the Medicare rebate would have to be for PCI in order to fully cover the per patient capital and variable costs of the procedure. It is assumed, in generating this estimate, that the cost of ultrasound measurement can be decomposed into capital and capital related costs as well as labour and other variable costs. The labour and other variable costs are then carried over into the estimate of measurement cost by PCI and adjusted for the difference in time requirement. Once this cost is derived for PCI it is added to the estimate of capital costs based on the cost of the technology and any required maintenance/service costs. This is used to generate the total per patient cost of measurement by PCI or the total necessary Medicare rebate that would cover all costs.

Apart from the possible inappropriateness of assumptions, there is one major caveat: insufficient detail is known about the distribution of patients across ophthalmologists, thus the total cost or Medicare rebate derived in this analysis should be understood to be the per patient cost or required rebate, for an ophthalmologist who faces at least the *average* patient volume to purchase a PCI unit and perform as many measurements as possible by PCI. Ophthalmologists with lower patient volumes may require a higher fee[4].

In order to generate an estimated total cost per patient for measurement by PCI several cost factors are taken into account:

- the cost of the ultrasound technology (A-scan unit), which varies from $8,557 to $15,650[5];
- the cost of the PCI technology, which is $42,975;
- the cost of accessories and related equipment for ultrasound measurement, which is $1,010;

[4] In order to derive the necessary fee to induce all ophthalmologists to adopt the technology, detailed information would be required as to patient distribution across ophthalmologists and the conditions faced by the lowest volume ophthalmologist in Australia. This information is not available.

[5] These costs reflect the cost of an A-scan ultrasound unit (the necessary technology for this type of measurement) from different suppliers. A combined A- and B- scan unit would cost considerably more.

- the cost of accessories and related equipment for PCI measurement, which is $2,613;
- the expected lifetime of the ultrasound technology, which is 12 years;
- the expected lifetime of the PCI technology, which is 12 years;
- the annual maintenance and service costs of the ultrasound technology, which are approximately $1,000;
- the annual maintenance and service costs of the PCI technology, which amount to approximately $1,800;
- the number of patients measured each year, which is 122,559 but which would be only 85 per cent of this figure for measurement by PCI due to PCI's inability to measure in the presence of dense cataracts; and
- the average time needed for an ophthalmologist or their staff to perform a measurement by ultrasound (15 minutes) and by PCI (7.5 minutes)[6].

In addition to these factors, several assumptions are made:

- The existing Medicare rebate for ultrasound measurement reflects all the capital, labour and other costs involved in performing measurements on two eyes in each patient.
- On average, the hourly labour and other variable costs are the same for an ophthalmologist who uses the ultrasound technology as for an ophthalmologist who uses the PCI technology.
- There are 700 ophthalmologists in Australia who perform these measurements (a range of 600 to 800 is used for sensitivity analysis)[7] and each owns some type of measurement technology.
- No ophthalmologist would own more than one of each type of measurement technology.

The existing Medicare rebate for ultrasound measurement is $82.00. This amount covers the measurement of two eyes in a single patient, as would typically be the case. Given the average cost of ultrasound technology, this rebate can be decomposed into capital related costs and non-capital related variable costs (labour, overhead, disposables, etc.). Using the average cost for an A-scan ultrasound unit, capital related costs amount to $11.95 per patient and labour and other variable costs amount to $70.05 per patient. Given the time spent with each patient, this translates into an hourly labour and other variable cost rate of $280.20 for the average ophthalmologist.

Given the capital and related costs of the PCI technology, the per patient capital related costs amount to $37.62, more than three times that of the ultrasound technology. But the

[6] Expert opinion

[7] Expert opinion

time requirement of the ophthalmologist is only half of that for ultrasound measurement, suggesting that the per patient labour and variable costs amount to $35.03 per patient. These two cost components combine to indicate that the total per patient cost of measurement by PCI is $72.65. This would be the Medicare rebate required to cover all health system costs related to PCI measurement prior to cataract surgery. These results are shown in Table 12 below.

Table 12 Decomposition of per patient costs by measurement technique

Per patient costs	Ultrasound	PCI
Capital and capital related	$11.95	$37.62
Other (ie, labour, overhead, disposables, etc)	$70.05	$35.03
Total	$82.00	$72.65

Decision analysis

The basis for the economic analysis in this section is a decision analysis conducted on the PCI technology, using IUS and AUS technology as comparators[8]. The analysis of a decision to use either PCI or its comparator takes into account[9]:

- the effectiveness of the measurement techniques, including the probability that a particular technique cannot be used;
- the probabilities of each possible outcome of the measurement; and
- the effectiveness of any procedures which may be carried out when the results of the measurement and subsequent cataract surgery are unsatisfactory. The Medicare Benefits Schedule allows for repair[10] when the predicted refractive error is three diopters or more (Australian Department of Health and Ageing, 2002), although the need for such repairs is very rare.
- the cost of the initial measurement, which is $82.00 for measurement by ultrasound and $72.65 for measurement by PCI, as derived in the previous section;
- the cost of the repairs, which is assumed to be fully covered by the relevant Medicare rebates, with the cost of the complex repair being estimated as the average of the Medicare rebates for the two possible procedures that are defined as complex repairs; and

[8] A general guide to decision analysis and the interpretation of results is included in Appendix G.

[9] All effectiveness data included in the analysis is derived from the same sources as used in the remainder of this report. All cost data is derived from the Medicare rebates for the procedures. The probabilities were derived from the same sources as effectiveness but were further refined for the Australian context through discussion with MSAC. The final outcome value, of which there are only two possible, reflects worst possible outcome (value=0) and best possible outcome (value=100).

[10] In this analysis different types of repairs are referred to, namely 'simple' repairs and 'complex' repairs. A simple repair refers to item 42701 of the Medicare Benefits Schedule (artificial lens, insertion of, excluding surgery performed for the correction of refractive error only). A complex repair refers to either item 42704 (artificial lens, removal or repositioning of by open operation not being a service associated with a service to which item 42701 applies) or item 42707 (artificial lens, removal of and replacement with a different lens) of the Medicare Benefits Schedule.

- the final outcome, which is one of two possibilities – having visual acuity that does not require corrective lenses (assigned outcome value of 100), or needing corrective lenses (assigned outcome value of 0) – after a maximum of one repair to correct any measurement error.

These factors are combined in a decision tree[11] to show how the different probabilities and costs contribute to different expected outcomes and expected total cost per patient for each measurement technique.

As shown in the decision trees (figures 3-5, Table 13), PCI can only be used in approximately 85 per cent of cases due to its inability to generate measurements in the presence of dense cataracts. Therefore, a decision to use PCI as the standard measurement technique will still involve the use of one of the two ultrasound techniques in approximately 15 per cent of cases. The expected cost and expected outcome of a decision to use PCI will depend in part on the costs and expected outcomes of the ultrasound techniques.

Expected outcome

When the expected outcome is calculated for a decision to use each of the three measurement techniques, it is revealed that a decision to use PCI produces a better expected outcome than a decision to use AUS, but a worse expected outcome than a decision to use IUS. The expected outcome of IUS is 74.33, where 100 represents a result of visual acuity that is good enough not to require corrective lenses and 0 represents visual acuity that requires corrective lenses. A decision to use AUS provides an expected outcome of 45.97. A decision to use PCI provides an expected outcome of 56.69 or 60.94, depending on whether IUS or AUS is used as the default method of measurement in cases where measurement by PCI is not possible.

A convenient interpretation of these results is that expected outcomes below 50 mean that the measurement technique is more likely to result in patients needing corrective lenses than not needing them; whereas an expected outcome above 50 means that a technique is more likely to result in patients not needing corrective lenses. PCI therefore offers a 10.7 to 15.0 point improvement on AUS in terms of the likelihood of the best possible result, and IUS offers a further 13.4 to 17.6 point improvement on PCI. If AUS and IUS were used in equal proportions, PCI would be expected to provide an equivalent outcome to the current mix of measurement techniques.

Expected total cost per patient

The analysis of total expected cost per patient includes not only the cost of the measurement but also the cost of corrective surgery, which is required when the predicted refractive error is such that a corrective lens cannot provide satisfactory visual acuity after the cataract surgery. These costs are included in the analysis because the probability of incurring the additional costs depends on the effectiveness of the measurement technique. A less effective measurement technique would have a higher

[11] A basic guide to decision analysis can be found in Appendix G.

probability of leaving patients in need of additional surgery and would, therefore, carry a higher expected total cost.

The expected total cost per patient of a decision to use ultrasound is $82.08 (for IUS) or $82.18 (for AUS), while the expected total cost per patient of a decision to use PCI is $74.18 to $74.19. In all cases the additional corrective surgery that may be needed is used in a very small percentage of cases (ie, < 0.1 per cent) and therefore only adds a small amount to the expected total cost of a decision to use any one of the measurement techniques. The small additional costs are slightly higher for a decision to use PCI than a decision to use IUS and higher still for a decision to use AUS. It is important to note, however, that this component of total cost per patient accounts for differences within a $0.10 range and that this difference represent only about 0.1 per cent of the expected total cost of the least costly technique.

The main factors accounting for the difference in total cost per patient are the direct costs of the measurement. Although the capital cost of the PCI technology accounts for more than triple the capital costs in ultrasound measurement, non-capital related costs such as labour and overhead represent a greater fraction of total costs and are halved for PCI relative to the average ultrasound amount.

Figure 3 Decision tree for IUS vs AUS

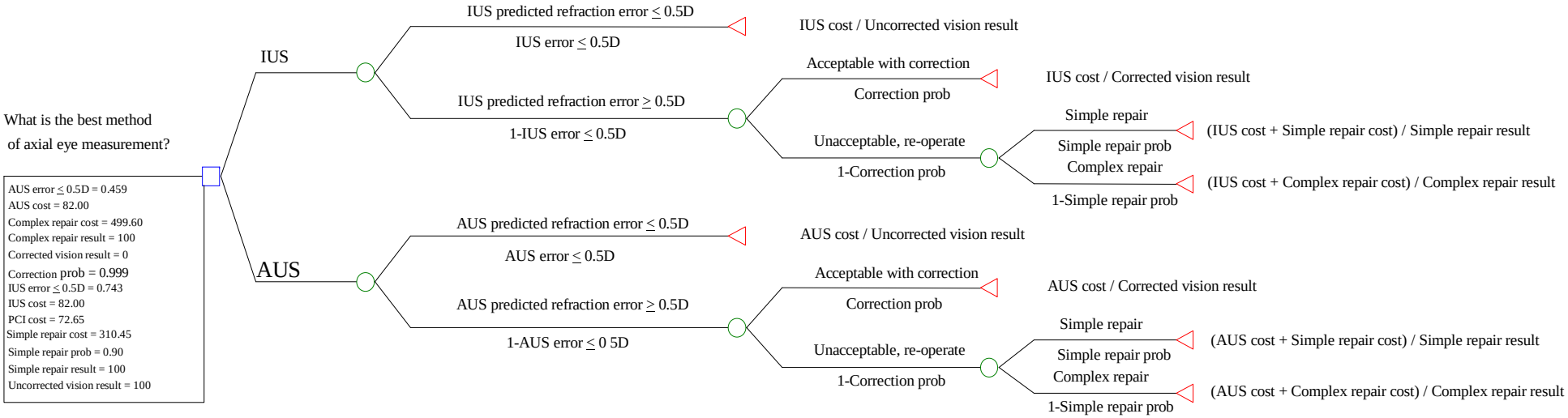

Figure 4 Decision tree for PCI vs AUS

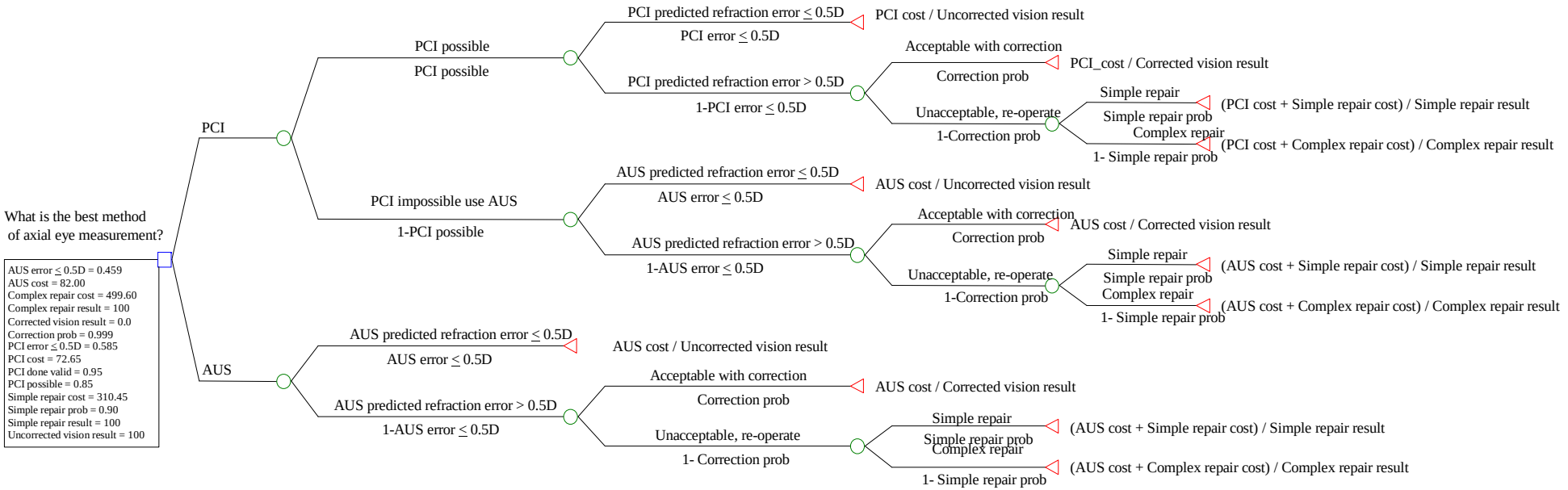

Figure 5 Decision tree for PCI vs IUS

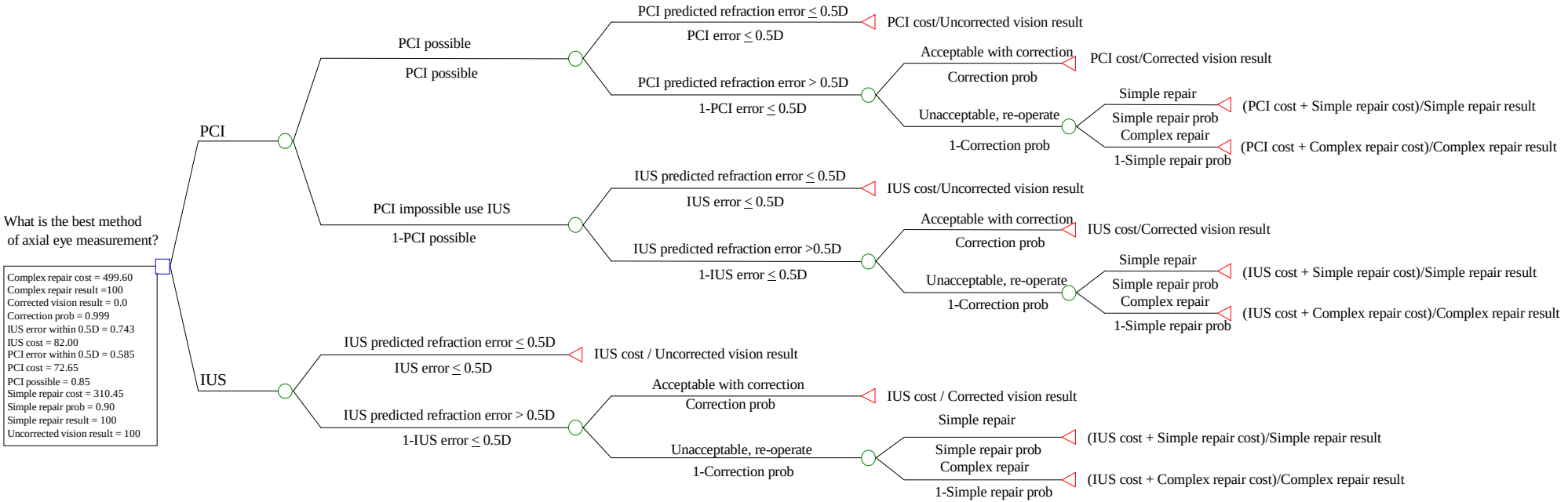

Table 13 Optical biometry decision model

Branch name	PCI possible
Meaning	Probability that PCI will be a valid measurement technique and it is not necessary to revert to IUS or AUS
Variable name	PCI possible
Probability value	0.850
Lower/upper prob. sensitivity value	0.800 – 0.900
Cost value	$72.65
Lower/upper cost sensitivity value	$68.13 – $90.19
Lower branch name	PCI impossible – use IUS/AUS
Probability value	1 – PCI possible
Cost value	$82.00
Lower/upper cost sensitivity value	n/a
References for values	Probabilities: (Kiss, 2002; Hitzenberger, 1993; Haigis, 2000; Connors, 2002; Lege, 2001; Meyer, 2001; Schrecker, 1998; Verhulst, 2001) Costs: Medicare Benefit Schedule #11241, #11240

Branch name	(AUS/PCI/IUS) predicted refraction error $\leq$ 0.5D
Meaning	AUS/PCI/IUS is used, operation yields refractive error $\leq$ 0.5D
Variable name	(measurement technique)error $\leq$ 0.5D
Probability value	AUS: 0.459 PCI: 0.585 IUS: 0.743
Lower/upper prob. sensitivity value	99% CI: AUS: 0.459+/- 6.89 PCI: 0.585 +/- 8.86 IUS: 0.743 +/- 6.71
Cost value	No associated cost
Lower/upper cost sensitivity value	N/A
Lower branch name	AUS/PCI/IUS predicted refraction error > 0.5D
Probability value	1 – (measurement technique) error $\leq$ 0.5D
Cost value	No associated cost
Lower/upper cost sensitivity value	1 – sensitivity values on upper branch
References for values	Probabilities: (Kiss, 2002; Hitzenberger, 1993; Haigis, 2000; Connors, 2002; Lege, 2001; Meyer, 2001; Schrecker, 1998; Verhulst, 2001) Costs: N/A

Branch name	Acceptable with correction
Meaning	Predicted refractive error is $\geq$ 0.5D but can be rectified by glasses/lenses
Variable name	Correction probability
Probability value	0.999
Lower/upper prob. sensitivity value	0.900 – 1.000
Cost value	No associated cost
Lower/upper cost sensitivity value	N/A
Lower branch name	Unacceptable, re-operate
Probability value	1 – Correction probability
Cost value	No associated cost
Lower/upper cost sensitivity value	1 – sensitivity values on upper branch
References for values	Probabilities: (Royal Australian & New Zealand College of Ophthalmologists, 2002; Royal College of Ophthalmologists, 2001) and expert opinion Costs: N/A

Table 13 Optical Biometry Decision Model *(continued)*

Branch name	Simple repair
Meaning	Predicted refractive error is > 3D and cannot be rectified with glasses/lenses - requires simple operation to reset or reshape lens
Variable name	Simple repair probability
Probability value	0.900
Lower/upper prob. sensitivity value	0.850 – 0.950
Cost value	$310.45
Lower/upper cost sensitivity value	No sensitivity
Lower branch name	Complex repair
Probability value	1 – Simple repair probability
Cost value	$499.60
Lower/upper cost sensitivity value	$368.70 – $630.50
References for values	Probabilities: expert opinion Costs: Medicare Benefit Schedule #42701(simple) #42704, #42707(complex)

Outcomes	Meaning and value
Uncorrected vision result	The result of visual acuity that does not need corrective lenses or further surgery is obtained after cataract surgery. Value: 100
Corrected vision result	The result of visual acuity that requires corrective lenses but is not bad enough to require further surgery is obtained after cataract surgery. Value: 0
Simple repair result	The result of visual acuity that does not need corrective lenses is obtained after a simple repair. Value: 100
Complex repair result	The result of visual acuity that does not need corrective lenses is obtained after a complex repair. Value: 100

Cost-effectiveness

When the analysis of expected cost per patient is combined with the expected outcome analysis, the results indicate that using PCI results in an expected outcome that is comparable to the ultrasound techniques – better than AUS but not as good as IUS – at a lower cost per patient for average or above average patient volume ophthalmologists. The results are summarised in Table 14.

Table 14 Expected total cost per patient and expected outcome

Procedure	Expected cost per patient	Expected outcome
AUS	$82.18	45.974
PCI	$74.18 - $74.19	56.690 - 60.943
IUS	$82.08	74.326

However, calculation of standard cost-effectiveness ratios favours IUS over either PCI or AUS, though the differences are not large. These results are shown in Table 15.

Table 15 Cost-effectiveness analysis

Strategy/ Decision	Cost per patient	Incremental cost per patient	Effectiveness	Incremental effectiveness	Cost effectiveness*
Use IUS	$82.08		74.326		$1.10
Use AUS	$82.18	$0.10	45.976	-28.350	$1.79
Use PCI	$74.19		56.690		$1.31
Use AUS	$82.18	$7.99	45.974	-10.716	$1.79
Use IUS	$82.08		74.326		$1.10
Use PCI	$74.18	-$7.90	60.943	-13.383	$1.22

* cost per percentage point of effectiveness

In particular, it should be noted that the difference in expected outcome between PCI and IUS, or between PCI and AUS, is smaller than the difference between IUS and AUS.

Sensitivity analysis

The most likely area for sensitivity in these results is the decomposition of ultrasound measurement costs and the use of this decomposition to derive a cost for PCI measurement. For this reason, several factors and assumptions used in that section of the analysis have been included in the sensitivity analysis. This involved testing for the effects of the following variations:

- The number of ophthalmologists, and hence the number of ultrasound or PCI units being used, was varied from the original 700 figure to a lower bound of 600 and a higher bound of 800[12].

- The cost of the ultrasound unit and accessories was varied from the average of $13,113.50 to a lower bound of $9,567.00 and a higher bound of $16,660.

- The time savings involved in performing a measurement by PCI rather than by ultrasound were reduced from 50 per cent (7.5 minutes savings out of 15 minutes) to 25 per cent (3.75 minutes savings out of 15 minutes).

By introducing the above variations, the analysis indirectly takes into account different hourly costs for non-capital factors such as labour and overhead, a different capital cost per patient, and different non-capital costs per patient. By following the same method of decomposing the ultrasound fee and then using the results to help construct a fee for PCI, these variations will lead to different total per patient costs for PCI measurement. The results are presented in Table 16 below.

[12] Expert opinion

Table 16 Sensitivity analysis results

Per patient costs	Ultrasound	PCI
Original estimates		
Capital cost	$11.95	$37.62
Other costs	$70.05	$35.03
Total	$82.00	$72.65
Assuming a low/high number of ophthalmologists (600/700)		
Capital cost	$10.25 / $13.66	$32.25 / $43.00
Other costs	$71.75 / $68.34	$35.88 / $34.17
Total	$82.00	$68.13 / $77.17
Assuming a low/high cost for the ultrasound technology ($9,567.00/$16,660.00)		
Capital cost	$10.26 / $13.64	$37.62
Other costs	$71.74 / $68.36	$35.87 / $34.18
Total	$82.00	$73.49 / $71.80
Assuming reduced time savings from PCI		
Capital cost	$11.95	$37.62
Other costs	$70.05	$52.54
Total	$82.00	$90.16

As shown in Table 16, the only single factor that can be reasonably varied enough to make the total per patient cost of measurement by PCI higher than that of measurement by ultrasound is the reduced time savings in measurement by PCI. It would also be possible to see a higher total per patient cost for PCI if more than one of these variations were true. Therefore, there is clearly some scope for the cost of measurement by PCI to exceed the cost of measurement by ultrasound.

A final note as to the sensitivity of these base calculations is related to the question of distribution of patients. In order to derive the fee that would be required to make PCI a worthwhile technique, and therefore to make the technology a worthwhile investment for all ophthalmologists, detailed knowledge of the conditions facing the lowest volume ophthalmologist would be needed as volume of patients significantly affects per patient costs for any technological adoption. In order to induce all ophthalmologists to use PCI, the fee would have to be high enough to be an incentive to the lowest volume practitioners. The extent to which patients are unevenly distributed across ophthalmologists will affect the extent to which the results of this analysis are biased, as an estimate of what would apply to *all* ophthalmologists. If it is assumed that the lowest volume ophthalmologist performs measurements on a certain *fraction* of the number of patients that are seen by an average volume ophthalmologist, some idea can be gained as to how results may be affected by patient distribution. These results are presented in Table 17 below:

Table 17 Per patient costs for hypothetical low volume ophthalmologists

Per patient costs	Ultrasound	PCI
Original estimates (average volume ophthalmologist)		
Capital cost	$11.95	$37.62
Other costs	$70.05	$35.03
Total	$82.00	$72.65
Hypothetical low volume ophthalmologist (75% of the volume of the average ophthalmologist)		
Capital cost	$17.93	$56.44
Other costs	$64.07	$32.04
Total	$82.00	$88.48
Hypothetical very low volume ophthalmologist (50% of the volume of the average volume ophthalmologist)		
Capital cost	$23.90	$75.25
Other costs	$58.10	$29.05
Total	$82.00	$104.30

As shown in Table 17 above, ophthalmologists with lower volumes of patients than the average would generate higher costs. Therefore, they may require a higher fee in order to adopt the PCI technology. It is possible, however, that some low volume ophthalmologists may incur short-term losses if there is a belief that using PCI may increase the volume of patients and, in turn, reduce per patient costs.

Sensitivity analysis on the results of the decision analysis shows that the results are robust to statistically reasonable changes in all probability and effectiveness parameters. Distributions were estimated for the effectiveness of the measurement techniques and the ranking of techniques in terms of expected cost and expected outcome were found to be robust, with a 99 per cent confidence interval.

The results of the decision analysis are sensitive to the cost of PCI measurement, which is sensitive to the underlying calculation as described above.

Varying the cost of the complex repair to any value from the lowest of the two procedure costs, which assumes all complex repairs involve the lower cost procedure, to the highest of the two procedure costs, which assumes all complex repairs involve the higher cost procedure, results in no significant change in results. This is explained by the very low probability of incurring a cost for a complex repair (0.003% to 0.005% probability).

The bottom line of the decision analysis

PCI is associated with results that are comparable to the two ultrasound techniques and potentially with a slightly lower cost, owing to the time savings involved in measurement by PCI. The cost of PCI, however, is sensitive to the assumption of 50 per cent time saving and is representative of costs to an ophthalmologist facing average patient volumes. For the same fee as for ultrasound measurement ($82.00), PCI should be a worthwhile technique for average and above average volume ophthalmologists, as well as some with below average patient volumes.

Other economic considerations

In considering the results of this analysis, certain contextual factors should be considered:

- Most ophthalmologists do not currently offer patients a choice of measurement techniques.
- Patients are generally referred to a particular ophthalmologist by their general practitioner and, as a result, would normally have their eyes measured using the technique favoured by that ophthalmologist rather than making a choice themselves.
- If a patient had an unsatisfactory refractive result after a first cataract operation, the second eye would usually be re-measured, and this may be done by a different operator or with a different technique.

Leaving the choice of measurement technique to the ophthalmologist or even the general practitioner, who may refer a patient to a particular ophthalmologist, is not likely to lead to significantly different outcomes than those achieved if measurement techniques are chosen by fully informed patients, as the range of possible outcomes is fairly narrow.

Finally, it should be noted that an investment in a particular technology by an ophthalmologist is a business decision that may depend on factors that are not reflected in a health system-wide cost-effectiveness analysis. These may include such considerations as space constraints, preferences over changing techniques, preferences over technological aspects of the technique, beliefs about patient preferences, and personal valuations of time.

Possibly the most important factor in an ophthalmologist's decision to purchase the PCI technology will be the choice of whether to own it instead of an ultrasound A-scan unit or as well as the ultrasound A-scan unit. Choosing to own both types of technology and to use PCI in all cases where PCI can be used may increase the per patient cost of ultrasound measurement as the cost of this technology will be spread over fewer patients. Ophthalmologists may factor this consequence into their decisions.

Total cost estimates

In this section, the total annual cost to the Australian health system is estimated. Total costs are estimated assuming a total of 122,559 patients having both eyes measured. This is based on 122,559 cataract surgeries performed in 1999 – 2000, public and private combined (Australian Institute of Health and Welfare, 2001) and a Medicare cost per patient of $82.00 for both eyes (Australian Department of Health and Ageing, 2002) for ultrasound measurement and $72.65 for PCI measurement (as derived earlier).

The probability, and hence the number, of further repairs following cataract surgery is estimated using the available data on effectiveness for each measurement technique. This means the estimates reflect what the numbers would be if a decision were made to

perform all measurements with only one of the three techniques[13]. In this respect, estimated total costs may be different from those observed in reality as current total cost figures would reflect the fact that all three measurement techniques are used in unknown proportions. The estimates in this section remove the uncertainty generated by the unknown proportions of the three measurement techniques by considering what costs would be if the same technique were used by all ophthalmologists. This approach makes it possible to observe the magnitude of the per patient differences when applied to the entire relevant population. What cannot be estimated is the effect on total costs of a move toward increased use of PCI, because the current level of usage of PCI is unknown. However, the estimates provided in this section suggest a maximum possible change in total costs in response to a change in the proportions of the different measurement techniques.

The indirect costs, the cost of a simple repair and the cost of a complex repair are obtained directly from the Medicare Benefit Schedule (Australian Department of Health and Ageing, 2002). The cost of a complex repair, which includes two possible procedures (Medicare codes 42704 and 42707) with different Medicare rebates, is estimated using the average of the two costs.

As shown in Table 18, estimated total costs for measurements done exclusively with each one of the three techniques are all within a $1 million range. This difference implies that even if all measurements were performed using the least costly technique (PCI) the savings would be less than 10 per cent of the total cost of the next least costly technique (IUS).

[13] Although a decision can be made to apply a single technique to perform all measurements, PCI alone could never be used to generate 100 per cent of the measurements due to its inability to generate measurements in the presence of dense cataracts. Therefore, the decision to use PCI in all cases will, in practise, result in the use of one of the two ultrasound techniques in approximately 15 per cent of cases. In this analysis, IUS is used as the default technique when PCI fails as it provides for best case scenario implications of a decision to use PCI.

Table 18 Total cost estimates

	Measurement Technique		
	AUS	PCI	IUS
Number of measurements	122,559	122,559	122,559
Cost per measurement	$82.00	$72.65 (for 85%) $82.00 for 15%)	$82.00
Total measurement cost	$10,049,838.00	$9,075,800.35	$10,049,838.00
Probability of need for simple repair	0.049%	0.035%	0.023%
Estimated number of simple repairs	60.054	42.896	28.189
Cost per simple repair	$310.45	$310.45	$310.45
Total cost of simple repairs	$18,643.76	$13,317.06	$8751.27
Probability of need for complex repair	0.005%	0.004%	0.003%
Estimated number of complex repairs	6.128	4.902	3.677
Cost per complex repair	$499.60	$499.60	$499.60
Total cost of complex repairs	$3,061.55	$2,449.04	$1,837.03
Total direct costs	$10,049,838.00	$9,075,800.35	$10,049,838.00
Total indirect costs	$21,705.31	$15,766.10	$10,588.30
Total cost	$10,071,543.31	$19,091,566.45	$10,060,426.30

Conclusions

Safety

During in vivo measurements of the human eye, laser safety regulations must be considered. With the AL measurement, the light source has a centre wavelength of $\lambda \approx$ 780nm with power of about 360 μW at the cornea. Permanent illumination with this wavelength and power is safe for about one minute (American National Standards Institute, 1986, Krauss and Puliafito, 1995, Standards Association of Australia, 1994, Standards Association of Australia, 1997). The time needed for single measurement of AL is 0.5 seconds. To obtain 10 longitudinal scans for statistical purposes, the maximum time of continuous illumination is about five seconds, well below the safety limit. Additional protection from any harmful effects of the laser are afforded by the opacity in the lens of the eye caused by the cataract (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002).

A possible safety issue with machines that use PCI is that they are not fitted with a manual safety lock on the unit to prevent the misuse of power and time, nor can the operator alter the laser settings. However, the machines do have an internal automatic monitoring system and safety mechanism, and the pulsed laser system will not operate if the laser power is too strong. A further precautionary measure is that the machines will only allow a maximum of 20 axial length readings (laser pulses) to be performed on the same eye during a particular day.

With ultrasound assessment it is often claimed in studies that there is a possibility of cross-infection. IUS involves the use of a scleral shell that makes contact with the eye and eyelids and with AUS the probe touches the eye. However, no references to support these claims were given and no studies could be identified that addressed this issue. Expert opinion revealed that there was a remote theoretical risk of transmissible infection from any device making contact with the eye but with best practice methods this is extremely unlikely (Dr M Hennessy, MSAC Supporting Committee, personal communication, 2002). The probe and the scleral shell cannot be sterilised and therefore should be cleaned according to accepted standards for disinfection.

Effectiveness

Manufacturers of ultrasonic and laser interferometry equipment often state the accuracy of their biometric unit to be within 0.1mm or better. However, this only refers to the reproducibility between repeated measurements. It does not apply to the true accuracy of estimating the distance from the corneal surface to the sensory retina, which is valid for the prediction of the refractive state after the operation. In the clinical situation, a number of errors may arise, such as:

- errors in calibration of the instrument;
- signal detection and treatment;
- alignment of transducer probe;

- possible corneal indentation;
- the cataractous lens;
- assumed velocity of ultrasound;
- the thickness of the neuroretina; and
- pulsation etc.

Each of which adds a variation to the ultimate accuracy of ultrasound.

While AL is regarded as the most important parameter that influences the prediction accuracy, it does not follow that improving AL measurement accuracy beyond a particular level will translate into more accurate predictability of results. This is because prediction accuracy may be influenced by other factors that have either not been measured or cannot be measured. As AL error is significantly reduced by optical biometry, other variables such as IOL power accuracy and prediction of the axial position of the IOL within the eye are becoming the limiting factors in refractive outcome after cataract surgery (Vogel et al., 2001).

At least some of the literature indicates that while the PCI measurement precision may be better than US, it does not translate into more accurate prediction of the refractive result: that is, improving measurement accuracy does not contribute to refractive accuracy beyond a certain level. It must also be kept in mind that measuring AL by ultrasound or PCI does not necessarily measure the true AL, but is more accurate than histological measurements.

PCI biometry is a user- and patient-friendly method for AL determination and IOL planning in preparation for cataract surgery. Its accuracy is superior to that of the commonly used AUS and is comparable to that of the high-precision IUS. The new optical biometry technique has the potential to become a routine method for IOL calculations in cataract surgery in cases of otherwise 'normal' cataract eyes without additional pathologies and with visual acuities ≥ 0.1. However, it has been found that in certain cases PCI is unable to optically measure cataract eyes. Among the reasons were:

- inability to cooperate (fixate);
- keratopathy;
- corneal scarring;
- mature cataract;
- nystagmus;
- lid abnormalities;
- vitreous haemorrhage;
- membrane formation;
- maculopathy; and
- retinal detachment.

Thus, it seems that with present technology, the eyes of 5-15 per cent of the patients of a university eye clinic cannot be measured by laser interferometry. In these cases, ultrasound biometry will continue to be indispensable.

Cost-effectiveness

The economic analysis of the three measurement techniques — PCI, AUS, and IUS — indicates that PCI may be a less costly measurement technique than AUS or IUS while offering comparable results to ultrasound techniques. However, there are small differences, even between IUS and AUS, and these suggest that IUS is the most cost-effective of the three techniques considered. These results are based on a derived per patient cost (or Medicare rebate) of $72.65 for measurement of both eyes by PCI for an ophthalmologist facing average patient volumes. This amount, however, is particularly sensitive to the assumption of saved time. Total cost analysis suggests that there could be up to 10 per cent savings to the Australian health system if PCI were used whenever possible and at this cost.

Consideration of the capital cost of the technology, as well as other costs, suggests that a fee of $72.65 would cover all costs related to measurement by PCI for ophthalmologists facing average patient volumes. A higher fee would probably be required to induce ophthalmologists in low patient volume situations to adopt the technology. Total cost analysis reveals that the choice of measurement technique makes very little difference to the total health system cost, as the differences in cost per patient are small.

Recommendation

MSAC recommended that on the strength of evidence pertaining to partial coherence interferometry (PCI), public funding should be supported for its use in measuring axial length of one or both eyes to cataract surgery.

The Minister for Health and Ageing accepted this recommendation on 22 June 2004.

Appendix A MSAC terms of reference and membership

The MSAC's terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to AHMAC.

The membership of the MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	**Expertise or Affiliation**
Dr Stephen Blamey (Chair)	general surgery
Professor Bruce Barraclough	general surgery
Professor Syd Bell	pathology
Dr Paul Craft	clinical epidemiology and oncology
Professor Jane Hall	health economics
Dr Terri Jackson	health economics
Ms Rebecca James	consumer health issues
Professor Brendon Kearney	health administration and planning
Associate Professor Richard King	internal medicine
Dr Ray Kirk	health research
Dr Michael Kitchener	nuclear medicine
Mr Lou McCallum	consumer health issues
Dr Ewa Piejko	general practice
Professor John Simes	clinical epidemiology and clinical trials

Professor Richard Smallwood	Chief Medical Officer, Commonwealth Department of Health and Ageing
Dr Robert Stable	Australian Health Ministers' Advisory Council representative
Professor Bryant Stokes	neurological surgery,
Professor Ken Thomson	radiology
Dr Douglas Travis	urology

Appendix B Supporting committee

Supporting committee for MSAC application 1050 - Optical biometry

Professor Peter Phelan (Chair) BSc., MBBS, MD, FRACP Emeritus Professor of Paediatrics University of Melbourne	member of MSAC
Mr Matthew Blackmore Consumer Representative	nominated by the Consumers' Health Forum of Australia
Professor Minas Coroneo BSc. (Med), MBBS, MSc, MD, MS, FRACS, FRACO Ophthalmologist	nominated by Royal Australian and New Zealand College of Ophthalmologists
Dr Michael Hennessy FRANZCO Ophthalmologist	co-opted ophthalmologist
Dr Michael Steiner MB, BS, DO (Sydney), FRACO, FRCOphth Ophthalmologist	nominated by Royal Australian and New Zealand College of Ophthalmologists

Appendix C Website sources of information

HTA Organisations	Website URL
Agence d'Evaluation des Technologies et des Modes d'Intervention (AETMIS)	http://www.aetmis.gouv.qc.ca/
Agencia de Evaluacion de Tecnologias Sanitarias (AETS)	http://www.isciii.es/unidad/aet/caet.html
Agencia de Evaluacion de Tecnologias Sanitarias de Andalucia (AETSA)	http://www.csalud.junta-andalucia.es/orgdep/AETSA/
Alberta Heritage Foundation for Medical Research (AHFMR)	http://www.ahfmr.ab.ca/
Agency for Health Research Quality (AHRQ)	http://www.ahrq.gov
L'Agence nationale d'Accréditation et d'Evaluation en Santé	http://www.anaes.fr
L'Agence Nationale pour le Developpement de l'Evaluation Medicale (ANDEM)	http://www.upml.fr/andem/andem.htm
British Columbia Office of Health Technology Assessment (BCOHTA)	http://www.chspr.ubc.edu.ca/bcohta
Catalan Agency for Health Technology Assessment (CAHTA)	http://www.aatm.es/
Canadian Coordinating Office for Health Technology Assessment (CCOHTA)	http://www.ccohta.ca
Centre for Clinical Effectiveness, Monash University	http://www.med.monash.edu.au/healthservices/cce
Center for Medical Technology Assessment (CMT)	http://ghan.imt.liu.se/cmt/
College voor Zorgverzekeringen (CVZ)	
German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DIMDI)	http://www.dahta.dimdi.de/
Danish Centre for Evaluation and Health Technology Assessment (DACEHTA)	http://www.dihta.dk/
Danish Institute for Health Services Research (DSI)	http://www.dsi.dk/
ECRI (USA)	http://www.ecri.org
Unidad de Tecnologias de Salud (ETESA)	http://www.minisal.cl
EUROSCAN	http://www.ad.bham.ac.uk/euroscan/index.asp
Finnish Office for Health Care Technology Assessment (FinOHTA)	http://www.stakes.fi/finohta/
Health Council of the Netherlands (GR)	http://www.gr.nl/
Health Technology Board for Scotland	http://www.htbs.org.uk/
Minnesota Health Technology Advisory Committee (HTAC)	http://www.health.state.mn.us/htac/
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org
Institute of Technology Assessment of the Austrian Academy of Science (ITA)	http://www.oeaw.ac.at/ita/hta/
International Network of Agencies for Health Technology Assessment (INAHTA)	http://www.inahta.org

International Society of Technology Assessment in Health Care	http://www.istahc.org
Medical Technology Assessment Group (M-TAG)	http://www.m-tag.net/
Medical Technology and Practice Patterns Institute	http://www.mtppi.org/
National Coordinating Centre for Health Technology Assessment (NCCHTA)	http://www.soton.ac.uk/~hta
National Horizon Scanning Centre (NHSC)	http://www.bham.ac.uk/PublicHealth/horizon
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk/
New Zealand Health Technology Assessment (NZHTA)	http://nzhta.chmeds.ac.nz
Medical and Health Research Council (MW-NWO)	http://www.nwo.nl
Basque Office for Health Technology Assessment (OSTEBA)	http://www.euskadi.net/sanidad/
Swedish Council on Technology Assessment in Health Care (SBU)	http://www.sbu.se
Norwegian Centre for Health Technology Assessment (SMM)	http://www.oslo.sintef.no/smm/
Swiss Science Council/Technology Assessment (SWISS/TA)	http://www.ta-swiss.ch/
TNO Prevention and Health (TNO)	http://www.tno.nl/homepage.html
University Health Consortium Technology Assessment Monitor	http://www.uhc.edu
Veterans' Affairs Technology Assessment Program (VATAP)	http://www.va.gov/vatap/
WHO Health Technology Assessment Programme (Collaborating Centres)	http://www.who.int/pht/technology_assessment/index.html
Other organisations	
Australian Institute of Health & Welfare (AIHW)	http://www.aihw.gov.au
Australian National Health & Medical Research Council	http://www.health.gov.au/nhmrc/index.htm
Commonwealth Department of Health and Aged Care	http://www.health.gov.au
Centres for Medicare and Medicaid Services (US Health Care Financing Administration)	http://www.hcfa.gov
Health Economics Research Group (Brunel University)	http:// www.brunel.ac.uk/depts/herg
US Federal Drug Administration	http://www.fda.gov
Health Canada	http://www.hc-sc.gc.ca/
UK Department of Health publications	http://www.doh.gov.uk/publications/index.html
US Centers for Disease Control	http://www.cdc.gov
Professional Associations/Societies	
American Academy of Ophthalmology	http://www.aao.org
American Board of Ophthalmology	http://www.abop.org
Association for Research in Vision and Ophthalmology	http://www.arvo.org
Canadian Ophthalmology Society	http://www.eyesite.ca
Fred Hollows Foundation	http://www.hollows.com.au/
German Ophthalmological Society	http://www.dog.org/engl
International Society for Eye Research	http://www.iser.org
International Society of Refractive Surgery	http://www.isrs.org

North of England Ophthalmological Society	http://www.neos.demon.co.uk
Royal Australian and New Zealand College of Ophthalmologists	http://www.raco.org.au
Royal College of Ophthalmologists	http://www.rcophth.ac.uk/
and other relevant associations	
Controlled Clinical Trials	http://www.controlled-trials.com/
Clinical trials.gov	http://www.clinicaltrials.gov

Appendix D Search strategy

The strategies below were designed for Medline and Embase databases using subject headings and free text searching. Keywords from these strategies were used in searches of the Cochrane and York databases, Current Contents, the Science Citation Index, and EconLit. Full copies of the Medline, Embase, and Current Contents searches are available on request from NZHTA.

Because of the relatively small amount of literature on the topic it has been possible to use a broad general search strategy and scan all references. This has been preferred to a more detailed search including other terms such as outcome measures, and cost-related concepts, which might potentially have restricted the number of references, retrieved.

Medline search strategy

#	Search History
1	optical biomet$.mp.
2	partial coherence interferometry.mp.
3	pci biometry.mp
4	eye length measurement.mp.
5	precision biometry.mp.
6	intraocular lens calculation.mp.
7	carl zeiss jena.tw.
8	laser-doppler interferometry.mp.
9	or/1-8
10	From 9 keep [SELECTED REFERENCES]
11	Interferometry/
12	Biometry/
13	exp cataract extraction/ or lens implantation, intraocular/ or cataract/
14	(11 or 12) and 13
15	From 14 keep [SELECTED REFERENCES]
16	Ultrasonics/ae [Adverse effects]
17	Ultrasonography/ae [Adverse effects]
18	exp eye/us [Ultrasonography]
19	Or/16-18
20	13 and 19
21	From 20 keep [SELECTED REFERENCES]
22	Interferometry/
23	Biometry/
24	Eye/us [Ultrasonography]
25	Diagnostic techniques, ophthalmological/
26	Refractive errors/di,us [Diagnosis, Ultrasonography]
27	Or/22-26
28	Lenses, Intraocular/
29	Pseudophakia/
30	Refraction, Ocular/
31	Refractometry/
32	Exp cataract extraction/
33	Lens implantation, intraocular/
34	Or/28-33
35	27 and 34
36	From 35 keep [SELECTED REFERENCES]

Embase search strategy

#	Search History
1	optical biomet$.mp.
2	partial coherence interferometry.mp.
3	pci biometry.mp.
4	eye length measurement.mp.
5	precision biometry.mp.
6	intraocular lens calculation.mp.
7	carl zeiss jena.tw.
8	laser-doppler interferometry.mp.
9	"partial coherence interferometry"/
10	or/1-9
11	biometry/
12	interferometry/
13	11 or 12
14	eye refraction/
15	eye axis length/
16	lens implant/
17	cataract extraction/
18	or/14-17
19	13 and 18
20	10 or 19
21	From 20 keep [SELECTED REFERENCES]
22	exp cataract/
23	cataract$.tw
24	22 or 23
25	ultrasound/
26	exp echography/
27	ultraso$.tw
28	or/25-27
29	exp treatment outcome/
30	complication/
31	adverse effect$.mp
32	or/8-10
33	24 and 28 and 32
34	From 33 keep [SELECTED REFERENCES]
35	a scan/ or b scan/
36	interferometry/
37	biometry/
38	refractometry/
39	or/35-38
40	Eye refraction/
41	Cataract extraction/
42	eye axis length/
43	lens implant/

44	pseudophakia/
45	aphakia/
46	refraction index/
47	*cataract/
48	Exp *cataract extraction/
49	or/40-48
50	39 and 49
51	limit 50 to human
52	From 51 keep [SELECTED REFERENCES]

Appendix E Studies included in the review

Table 19 Prevalence of cataract in population-based studies by age and gender

Study	Age band	Male (%)	Female (%)
McCarty et al., (2000)	40 – 49	3.00	2.36
Victoria study,	50 – 59	7.47	6.92
Australia	60 – 69	22.0	30.3
	70 – 79	48.1	61.0
	80 – 89	79.3	92.6
	90+	98.8	98.6
Kahn et al., (1977)	50 – 64	43.	4.7
Framingham study,	65 – 74	16.0	19.3
USA	75 – 84	40.9	48.9
	85+	-	-
Klein et al., (1992)	50 – 64	3.9	10.0
Beaver Dam study,	65 – 74	14.3	23.5
USA	75 – 84	38.8	45.9
	85+	-	-
Gibson et al., (1985)	75 – 84	37.1	43.8
Melton Mowbray study,	85+	60.0	66.2
England			
Guiffer et al., (1995)	40 – 49	3.5	4.3
Casteldaccia Eye Study,	50 – 59	9.2	8.4
Italy	60 – 69	20.2	22.6
	70+	45.7	64.4
Sasaki et al., (2000)	50 – 59	2.4	2.1
Reykjavik eye study*	60 – 69	10.4	10.6
Iceland and Japan	70 – 79	30.6	40.8
	80+	66.7	58.6
Lundstrom et al., (1999)	50 – 54	1.6	1.9
National Swedish Cataract study$^{\delta}$,	55 – 59	2.8	3.3
Sweden,	60 – 64	5.5	5.8
	65 – 69	7.7	11.8
	70 – 74	14.0	22.6
	75 – 79	25.5	39.9
	80 – 84	34.8	50.8
	85 – 89	40.2	49.7
	90 – 94	33.3	34.9
Mitchell et al., (1997)	43 – 54	1.5	3.7
Blue Mountain Eye Study,**	55 – 64	5.4	4.7
Australia	65 – 74	19.1	23.6
	75 – 84	48.4	57.6
	85+	56.5	83.8

* = grade I opacities not included ** = data excluding past cataract surgery

$^{\delta}$ = not prevalence but cataract operations performed

Appendix F IOL power calculation formulae

Table 20 Theoretical formulae

Theoretical formulae	
Modified Binkhorst formula	$P_e = \frac{1{,}366\,(4r - L)}{(L - C)(4r - C)}$
Colenbrander formula	$P_e = \frac{1{,}366}{L - C - 0.00005} - \frac{1{,}336}{\frac{1{,}366}{K} - C - 0.00005}$
Gullstrand formula	$P_e = \frac{1{,}348}{L} K + 4$
FGL	$P_e = \frac{1{,}336 - LK}{(L - C)(1 - \frac{C}{1{,}336} - K)}$
Regression formulae	
SRK formula	$P_e = A - 2.5L - 0.9K$
Axt formula	$P_e = 120.6 - 2.49L - 0.97K$
DKG formula	$P_e = A - 0.9K - 58.75 + 58.75\,[(23.5 - L)/L]$

P_e = Emmetropic IOL power (diopters); L = axial length of eye (mm); K = corneal dioptric power (diopters); C = pseudophakic depth of the anterior chamber lens; r = average corneal radius (mm) = 337.5/K; A = constant derived for each type of lens and manufacturer; SE = spherical equivalent

As can be seen, there are a number of options to choose from when using formulae. In a review of 900 eyes comparing SRK I, SRK II, SRK/T, Holladay, Hoffer and Binkhorst II formulae, Sanders et al., (1990) found that the SRK/T and Holladay formulae worked best overall. In a further study of 450 eyes Hoffer (1993) compared regression and theoretical formulae and found that SRK I and II were least accurate. In the same study Hoffer found that there was no statistical difference between SRK/T, Hoffer Q and the Holladay formulae.

Dr Michael Hennessy (MSAC Supporting Committee, 2002) designed a table containing the different lens calculation formulae to teach trainees (see table 21).

Table 21 Commonly used lens calculation formulae (as devised and used by Dr M Hennessy)

Formula Generation		Regression	Theoretic
1st	Fixed LPC	SRK	
2nd	LPC adjusted by length	SRK II	
3rd	LPC adjusted by length and K	SRK/T	SRK/T Hoffer Q Holladay I
4th	LPC adjusted by length, K, other anterior segment measurements		Holladay II

LPC = lens position constant

Appendix G A guide to decision analysis

Decision analysis is a tool that allows the analyst to compare a number (typically two) of possible decisions in terms of what the outcomes are most likely to be. It is most useful when a particular decision can result in different outcomes with different probabilities attached to them, so that at the outset it is not always clear which decision would be most likely to deliver the best outcome.

The basic tool in decision analysis is the decision tree. The decision tree typically depicts the consequences of the decision that needs to be made, according to the known or estimated probabilities of obtaining each outcome or of facing each consequence. Usually, a decision tree can also be read from left to right as a series of chronological events that follow the decision that is made in the first set of branches on the tree and that leads to various possible outcomes that are represented by the end nodes of the tree.

In medical decision-making, the decision tree is typically used to compute and compare total expected costs and expected outcomes of at least two comparable procedures. When these two measures are combined, we obtain an estimate of cost-effectiveness. It is important to note that the definition of effectiveness in this context differs slightly from the definition that is normally used. In decision analysis, effectiveness refers to the expected outcome of the decision to use the procedure, which can be very different from the effectiveness of the procedure. For example, if a procedure is generally 90 per cent effective at providing a perfect outcome but the remaining 10 per cent can be dealt with using another procedure, which is 100 per cent effective at providing a perfect outcome, then the decision to use the 90 per cent effective procedure will have an expected outcome of perfect 100 per cent of the time because all patients who undergo the procedure will eventually obtain a perfect outcome. This 100 per cent figure would be reported as effectiveness in a decision analysis. The calculation of cost would generally account for the fact that two procedures are used in 10 per cent of cases, so that the calculation of cost-effectiveness accounts for all the cost and outcome implications of a decision to use a procedure and not just the effectiveness of the procedure in question.

The implications of a medical decision can have far-ranging implications, in that they may be broadly based or last a long period of time, it is usually necessary to cut off the decision analysis at some appropriate point. This is typically achieved by appropriately defining the outcome measures or by applying a time limit such that the decision tree ends at a point that corresponds to a certain point in time after the initial decision is made. Common non-cost outcomes include the total number of days of hospitalisation, quality of life, the number of life years saved, the number of lives saved, etc. The time duration of a decision tree can be measured in weeks, months, etc or in cycles of care, eg, allowing a maximum of three procedures.

When a decision tree is rolled back for cost-effectiveness, the results show the expected total cost and the expected outcome for each decision in terms of the chosen outcomes within the chosen time frame. So, if the basic assumptions of the tree are accepted by the decision-maker, the results show clearly which decision is preferred and what, if any, are the trade-offs in terms of cost and expected outcome.

Abbreviations

ACD	anterior chamber depth
AL	axial length
AUS	applanation ultrasound
cf	compared with
CI	confidence interval
D	diopter
f/u	follow-up
GBS	Grieshaber Biometric System
HTA	Health Technology Assessment
IOL	intraocular lens
IOP	intraocular pressure
ITT	intention to treat
IUS	immersion ultrasound
K	optical corneal power
LDI	laser Doppler interferometry
LMU	lens meter unit
MAE	mean absolute error
MAL	mean absolute length
MNE	mean numerical error
MPE	mean predictive error
MVA	mean visual acuity
nssd	no statistically significant difference
OCT	optical coherence tomography
PCI	partial coherence interferometry
PE	phacoemulsification
RO	refractive outcome
SNR	sound-to-noise ratio
SRK	Sanders, Retzlaff, Kraff Formula
ssd	statistically significant difference
VA	visual acuity
vs	versus

Terminology

Aphakic	refers to a patient who has had a lens removed.
A-scan	one-dimensional presentation of echo spikes displayed from the baseline (time). The height of the echoes represents the amplitude.
Biometry	the application of statistics to biologic science. Measurement of distance between various structures. In ophthalmology, this study is commonly called axial length.
D-Diopter	unit of measure of degree that light converges or diverges.
Emmetropia	a refractive condition in which no refractive error is present when accommodation is at rest. Distant images are focused sharply on the retina without the need for accommodation or corrective lenses (aka 20/20).
ECCE	extracapsular cataract extraction: surgical procedure to remove the cataract, including the surrounding capsule bag.
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.
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, which helps to focus light on the retina.
Phacoemulsification (PE)	a surgical technique that is a modification of the extracapsular cataract extraction procedure. A probe oscillating at ultrasonic frequency fragments the nucleus of the cataract. Nuclear fragments are simultaneously aspirated from the eye. An intraocular lens is then implanted.
Phakic	a term used to describe a patient with their native lens.
Pseudophakic	indicates a patient whose native lens has been replaced with an IOL.
Pupil	the adjustable opening at the centre of the iris that allows varying amounts of light to enter the eye.

Refractive error	light beams are not brought to a sharp focus precisely on the retina; this can be corrected with eyeglasses, contact lens, surgery, or an IOL.
Retina	the light-sensitive layer of tissue that lines the back of the eyeball and sends visual messages through the optic nerve to the brain.
Snellen visual acuity test	a standard method of measuring visual acuity used during visual 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.

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