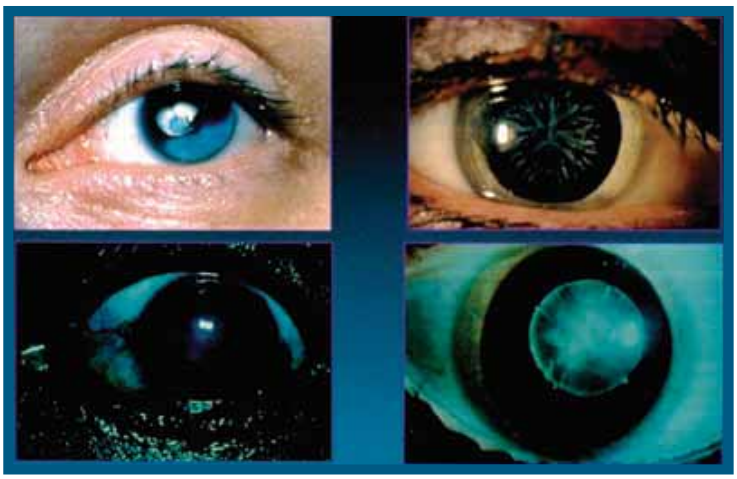
THE VISION RISK FOR CANADIANS



MEDEC OPHTHALMIC SECTOR REPORT

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Advances in ophthalmic technologies improve sight for more cataract patients and increase economic savings – but Canadian healthcare policies threaten improvements

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CANADA'S MEDICAL DEVICE TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIE DES DISPOSITIFS MÉDICAUX

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THE VISION RISK FOR CANADIANS

Productivity gains from innovations in vision care abound—clearer vision, fewer complications, quicker recovery, and greater convenience. But Canadian healthcare policies threaten patient access to care and continued innovation in ophthalmic technologies – even at a time when incidence of age-related eye diseases is rising rapidly.

Unacceptably long waiting times for ophthalmic procedures and a shortage of research funding are barriers to the delivery of optimal levels of vision care in Canada. These issues must be addressed if Canadians are to reap the quality-of-life and productivity benefits that modern ophthalmic technology has the potential to deliver.

MEDEC OPHTHALMIC SECTOR REPORT – 2005

VISION DISORDERS INCREASE AS POPULATION AGES

“The aging of the Canadian population will have dire consequences on the health care system. More medical problems and disabilities of every kind appear with an aging population. This is no different for vision impairment. The 1994 HALS Post Censal Survey indicated that by age 65, 1 in 9 individuals will experience severe vision loss and by 85, this increases to 1 in 4.

“In 2000, the Canadian National Institute for the Blind (CNIB) had 101,000 registered clients, which does not necessarily represent the true prevalence of blindness and visual impairment since registration with the CNIB is strictly voluntary. We expect to have 187,000 clients by the year 2015.

“The four leading causes of visual impairment are all age related:

- Age Related Macular Degeneration
- Glaucoma
- Diabetic Retinopathy
- Cataracts

“The cost of severe vision-impairment or blindness, be it personal or societal is significant. Fortunately, this is an area where prevention and health maintenance policies could keep to a minimum the level of disability related to aging.

“Important advances in research allow many types of vision impairment to be treated successfully. For example, cataract surgeries now outnumber births in this country. Successful research and treatment result in lower costs to health care and social assistance systems. However, Canada still lags behind the majority of industrialized countries in spending on research into vision loss.”

THE CANADIAN NATIONAL INSTITUTE FOR THE BLIND
EXCERPTS FROM SUBMISSION TO THE COMMISSION ON THE FUTURE OF HEALTH CARE IN CANADA
DECEMBER 21 2001

A STORY OF SIGHT, SAVINGS, AND AN AGING SOCIETY

The story of ophthalmic surgery and technology is a story about miracles—about regaining vision despite a disease that could otherwise snatch it away. Ophthalmic surgery and technologies give back the gift of sight and allow patients to get back to their normal lives. Ophthalmic technologies are also a story about economic miracles—about the savings and productivity gains that come from good health and from efficient, high quality delivery of health care to patients.

> When Canadians are asked one of three kinds of physical abilities they most fear losing, a large majority choose loss of sight (69%) over loss of the use of their legs (20%) or loss of hearing (5%).
>
> *Canadian Council of the Blind, 2003 Survey*

But current Canadian health care policies threaten to limit access to physicians and reverse the productivity improvements brought about by ophthalmic technologies—at a time when the incidence of age-related eye diseases is rising rapidly. This paper will explain the problem, the solution, and what is at stake.

How We See

Vision is possible because of the brain's ability to interpret information our eyes receive when light is reflected off objects. The front surface of the eye, or cornea, is a dome-shaped clear structure that allows light to enter the eye. It covers the iris - the coloured part of the eye, which has the pupil in its centre. The pupil is actually an opening through which light enters and is passed to the back of the eye.

In bright conditions, the muscles of the iris contract to reduce the size of the pupil, which decreases the amount of light entering the eye. In poor lighting, the iris muscles dilate, making the pupil bigger, to allow more light to enter the eye. Behind the iris is the lens of the eye, which allows us to focus on objects at different distances. The lens focuses light rays that reflect from objects and places them as images on the retina, which can be compared to a camera film for the eye.

Images received by the retina are transformed into electrical signals. The retina then sends these signals along the optic nerve to the brain. Once received by the brain, the signals recreate pictures.

CLOUDED VISION: CATARACTS STRIKE AGING CANADIANS

In most cases, a cataract is a natural part of aging. In fact, if a person lives long enough, every individual will develop a cataract. Some people develop dense cataracts at age sixty, while others remain cataract-free until the age of ninety. According to Statistics Canada, seniors will make up 21 per cent of the population by 2026 (one in five), compared to 13 per cent in 2000.

Cataracts are a disease in which the lens of the eye gradually becomes cloudy. The images on this page give a sense of the blurring that many cataract sufferers experience. The photo on the left is what a person with cataract sees; the photo on the right is the view through normal vision. Untreated, cataracts can seriously impair vision and eventually lead to blindness.

[1]Photo

Cataracts can strike people in their 40s and 50s, but they occur most commonly in those over age 60— with a rapid increase in prevalence after age 65. More than 36 percent of over-65 Canadian males have cataracts and nearly half of Canadian women over age 65.[2] As Baby Boomers age, more and more of them will be affected by cataracts.

Not long ago, treating cataracts required patients to undergo more invasive surgery and stay in the hospital for as long as one week. Today, thanks to a series of advances, patients are treated safely with minimally invasive techniques in outpatient settings and return home the same day.

Dr. David K. Foot, professor of economics at the University of Toronto and co-author of the best selling book, *Boom, Bust and Echo: How to Profit from the Coming Demographic Shift*, says that Canada has about 20 years until an enormous crisis of blindness and low vision hits the baby boom generation as the members of that group reach their 70's.

Consequently, cataract surgery is one of the most frequently performed and successful surgeries in Canada —totaling approximately 250,000 annually.[3] In fact, cataract surgery is one of the most successful surgical procedures performed today – about 95% or all cataract surgeries result in an improvement in vision.

To treat cataracts, today's surgeons remove the clouded lens with sophisticated equipment and devices. They then replace it with an implant called an intraocular lens (IOL). Over the past three decades, the advances in the equipment and devices used to remove the cataract have been continuous—and dramatic. The materials, design, and size of IOLs have also undergone continuous change, resulting in ever-improving patient outcomes. In concert with the refinements in surgeons' techniques, these technological developments have reduced complications, pain, and recovery time.

In addition to offering elderly patients improved treatment and quality-of-life benefits —including reduced rates of falls and accidents and improved mental acuity — these advances have yielded millions of dollars in savings and efficiency gains to the health care system in general.

Reasons for cost savings include:

- Lessening the recovery period
- Eliminating the need for lengthy hospital stays
- Reducing subsequent complications that require follow-up treatment or surgical intervention.

This journey— of new medical advances, improved outcomes and greater efficiencies — continues. Ongoing research and emerging breakthroughs in ophthalmic technology promise to bring even more improvements to cataract surgery in the coming years.

> "The wait is…is an unreasonable amount of time for a procedure that takes less than a half hour, for an operation hundreds of hundreds seniors need"
>
> *Interview with waiting cataract patient Arlene Silver, CTV TV, April 2005*

At the present time, however, Canadians are not enjoying the full benefits of available ophthalmic technology. A recent report by the Fraser Institute found patients waited an average of 28.7 weeks between referral by their GPS and actual treatment.[4] Waits of more than half a year are clearly unacceptable to patients whose quality of life may be seriously compromised by vision problems. In an interim report released by the Wait Time Alliance in 2005, the recommended reasonable medically acceptable wait time for visually significant cataract surgery is 4 months with higher priority cases having expedited surgery with the shortening of waiting time to be proportional to the relative degree of priority.[5]

Long waits for treatment are also unacceptable to health professionals. A recent survey of doctors and nurses found 82 percent were concerned about the impact of waiting times on patients.[6] Finally, excessive waits for treatment are also a drain on the Canadian economy, as they are associated with potentially high levels of lost productivity due to impaired vision.

SEEING IS BELIEVING: RESTORING THE MIRACLE OF SIGHT

Advances in ophthalmic technology have preserved the sight of millions of patients whose vision would have otherwise failed them. In years past, such patients would have had to plan for a life of vision impairment and perhaps blindness. Here are the ingredients of the miracle: ophthalmic technologies and ophthalmic practitioners.

Major advances permit cataract removal

A critical factor in the success of cataract surgery is preserving the capsule, the clear sac that surrounds the human lens like the skin on a grape. Even when cataract formation causes the lens to become cloudy, the capsule around the lens is still clear. Until the mid-1980s, surgeons did not have a way of extracting the cataract without also damaging or removing the capsule. Today, technology enables surgeons to implant an IOL into a capsule that remains in place after the cataract is removed.

Prior to the advent of sophisticated devices for cataract removal, surgeons were forced to sacrifice the capsule, either by removing it entirely or damaging it during surgery. This contributed to long recovery times. Because it was impossible to implant the IOL in the capsule, surgeons had to either place an IOL in front of the iris or not implant one at all.

Ultrasonic tools permit lens removal

A major advance took place when technology evolved to allow removal of the cataract without damage to the delicate capsule surrounding it. Ultrasonic devices enabled a technique known as phacoemulsification, which permits removal of the cataract without removing the capsule.

Once phacoemulsification became the standard for cataract removal, patients benefited from intact capsules. On top of that, surgeons were able to implant IOLs into the capsule behind the iris instead of in front of it, leading to far greater stability of the IOL within the patient's eye. This reduced recovery time and post-surgical restrictions on the patient's lifestyle.

Equipment and device advances result in less-trauma, better outcomes

Phacoemulsification requires the use of expensive capital equipment as well as numerous single-use devices. Phacoemulsification devices have undergone dramatic technological improvements since their introduction in the 1970s. The ophthalmic device industry has invested substantially in

> Dr. David Maberley (et al.) estimates the annual cost of blindness in Canada as close to $1 billion, based on CNIB registry data, disability benefits, and tax exemptions.
>
> *The National Coalition for Vision Health, 2005*

improved phacoemulsification technologies so that cataract surgery is less traumatic to the eye, resulting in improved outcomes. Advances in cataract removal continue. The latest devices offer benefits such as preservation of surrounding ocular tissues and reduction in complications.

Specialized tools ensure precise incisions

Although today's cataract incision is less than three millimeters, the surgeon must create the micro-incision with supreme precision. Two incisions are made during most cataract procedures, and they must be created using specific angles, lengths, and widths. To construct the proper incision architecture, surgeons rely on highly specialized cutting devices.

Unique devices protect the cornea during surgery

An important adjunct to the procedure is a clear, viscous gel called a viscoelastic. Viscoelastics were introduced in the early 1980s because, during cataract surgery, the underside of the cornea was often damaged by contact with instruments, devices, fluid bubbles, and IOLs. Because the cells in this region cannot regrow, there is a need to protect them. Viscoelastics provide a coating to protect the cornea from damage, resulting in clearer corneas after surgery. Viscoelastics also gently inflate spaces inside the eye, making it easier to maneuver various tools inside the eye and implant IOLs.

Viscoelastic devices have evolved and newer ones have been introduced. Today's cataract surgeon uses viscoelastics to protect the cornea, insert IOLs, lubricate insertion devices, manage intraoperative complications, and gently manipulate the delicate tissues within the eye.

Foldable IOLs reduce complications, speed recovery

After the cataract has been removed, the IOL is implanted. Prior to the introduction of IOLs, post-surgery vision was extremely poor and could be only partially corrected with extremely thick spectacles. Earlier IOLs were made of a rigid material known as polymethyl methacrylate (PMMA). These required the surgeon to make a very large incision for inserting the IOL.

Large incisions were associated with numerous drawbacks, including greater risk of infection, greater risk of retinal detachment, and a lengthy post-operative healing and recovery period. In addition, sutures were required to close these large incisions, sometimes resulting in surgically induced astigmatism, discomfort, and other problems. The patient was required to return to the physician's office to have the sutures removed.

The advent of foldable IOL technology in the early 1990s revolutionized cataract surgery. Surgeons could fold IOLs in half and thus implant them through incisions that were half the size required

for PMMA lenses. The dramatic benefit to patients' surgical outcomes fueled demand for even smaller incisions. The IOL industry responded with improved materials that met this need. Industry continues to work toward IOLs that can be inserted through even smaller incisions.

Advances in biometry improve safety

Improvements in ophthalmic biometry use safer, non-invasive and non-contact methods to precisely measure corneal curvature and anterior chamber depth and the axial length of the eye to determine the IOL power calculation. Though rarely necessary, the primary reason for IOL explant is an error in biometry.

Insertion devices permit optimal implantation

A crucial step in the evolution of today's micro-incisions was the development of IOL insertion devices. In the absence of an insertion device, the surgeon must fold and insert the IOL with forceps by hand. IOL insertion devices add a greater degree of control and predictability to this surgical step.

IOLs made of later-generation materials are carefully placed in the insertion device. The surgeon is trained to properly activate the insertion device so that it folds the IOL into the optimal shape for insertion through the smallest possible incision. Insertion devices are designed with disposable, single-use cartridges that minimize the amount of contact the IOL has with the exterior surface of the patient's eye, thereby reducing the risk of intraocular infection.

Microsurgery techniques also aid quality in non-ophthalmic care

Improvements in ophthalmic technologies have also spurred the development of microsurgery techniques that can be applied in other treatment areas. For example, microminiaturization, first pioneered in eye care, is now a critical component in intricate brain procedures, neurology care, and heart treatment, among others. The improvements in patient care and greater efficiencies in delivery are significant — quicker procedures, reduced recovery times, shorter hospitals stays, and less invasive care.

FROM OUTCOMES TO OUTPUT: CREATING NEW ECONOMIC VALUE

Better sight is only part of the story of advances in cataract technology. Better economics and productivity are also important. People who can see enjoy an improved quality of life. They can go to work, drive their cars, mow their lawns, live independently, and generally enjoy their lives. In addition to quality gains, better ophthalmic technologies mean greater efficiencies in the health care system, since lengthy surgeries, hospital stays and recovery times are a thing of the past. The economists call this "productivity." And they are beginning to calculate the value of these paybacks to individuals, institutions, and the Canadian economy. Here are some samples:

- A seven-year study demonstrated patients who underwent cataract surgery had a 50 percent lower rate of automobile crashes than patients who chose not to have surgery (Figure 1). Reductions in automobile crashes significantly reduce health care and economic costs.[7]

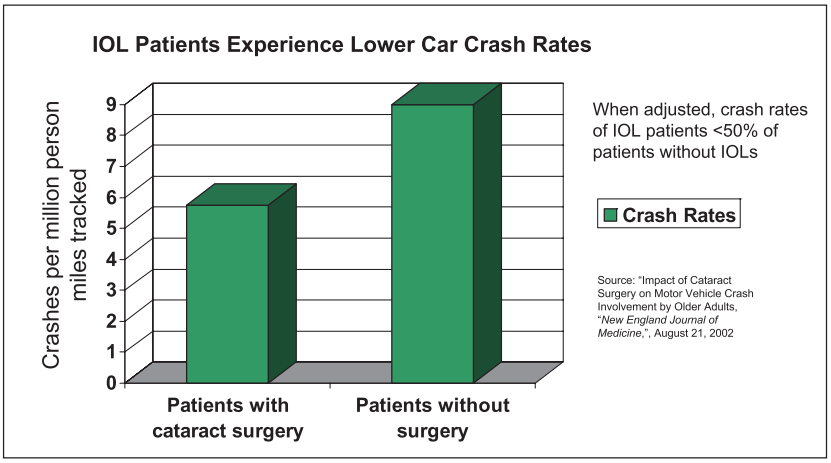

Figure 1: Shows lower rate of car crashes among cataract patients who received IOLs vs. untreated patients.

- A prospective study examined the impact on patients' I.Q. (intelligence quotient) following implantation of a late-generation IOL. The study demonstrated patients experienced a diminished IQ prior to cataract surgery. Following surgery with IOL implantation, average I.Q. was restored to a level equivalent to these same patients' level at ages 18-30 years. Post-surgical I.Q. improvement increased up to 14 points in this population.[8]

- A paper examined whether technological advances in cataract surgery were worth their higher costs. The study analysis concluded clinical benefits (improved visual outcomes, lower complications) of these technologies measurably exceed their costs.[9]

- In the same study, investigators further described the economic contribution of modern cataract surgery. They noted the enhancements to cataract patients' qualify of life enable

each patient to contribute $95,000 more in economic productivity than they would have without surgery.[10]

- A study of 384 patients confirmed that persons with cataract have a statistically significant increased risk of death (Figure 2). This seven-year study further found the increase in mortality risk was greatest in those patients who had cataracts but chose not to be surgically treated. When subjects with cataracts had surgery, their mortality risk declined by nearly 4 percent. After treatment, people with cataracts had a risk of mortality statistically equivalent to people without cataracts.[11]

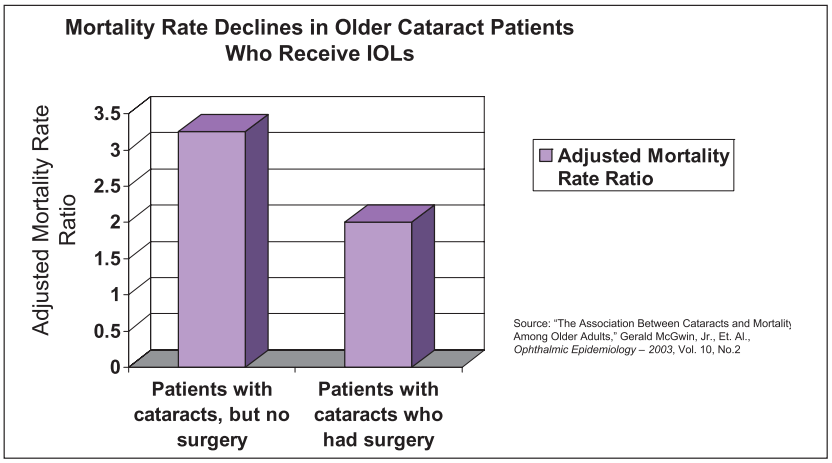

Figure 2: Mortality rate declines in older cataract patients who receive IOLs.

- Moderate to severe non-corrected unilateral visual impairment, caused by eye diseases such as cataracts, has been shown to have a measurable impact on patients' quality of life (Figure 3). The *Blue Mountains Eye Study*, examining over 3,000 patients, found significantly poorer scores on quality of life questionnaires for patients with visual impairment, such as caused by cataracts.[12]

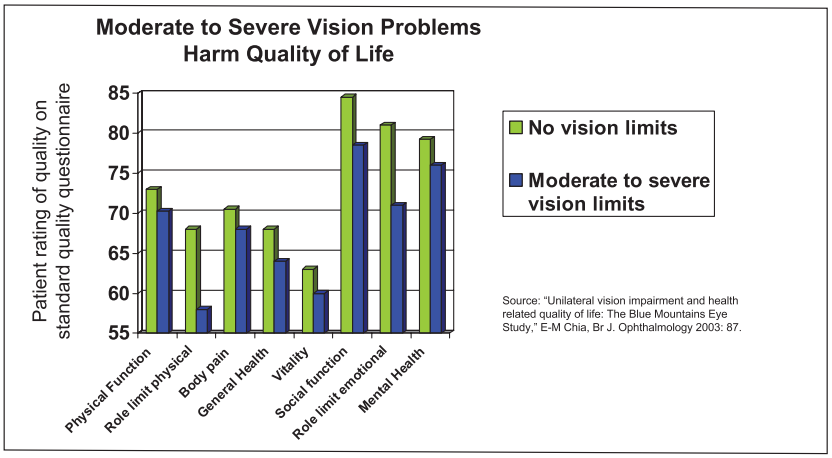

Figure 3: Moderate to severe vision problems harm quality of life.

The costs of modern cataract surgery are more than justified by its substantial benefits to patients and to society. Dramatic technological improvements in cataract surgery have translated into better vision, fewer complications and improved rehabilitation for patients.

They have also saved money. When savings due to shorter hospital stays and fewer complications are calculated, the total costs for cataract replacement today, in real terms, is no more than it was 30 years ago.

LOOKING TOWARD THE FUTURE: INNOVATIONS IN OPHTHALMIC TECHNOLOGIES CAN IMPROVE CARE EVEN MORE

While significant progress has been made in treating patients with cataracts, much work remains. Advances now under study would permit even clearer vision, reduce complications further, and increase convenience for patients. Such advances are particularly important in light of the graying of Canada. As the population ages, more and more Canadians will face the challenges of cataracts. Here is a sampling of some of current research that has the potential to help these people:

Correcting power errors without surgery

Just as patients sometimes receive eyeglasses that are not the correct power, implanted IOLs are sometimes of the incorrect power. Today, an additional surgical procedure is needed to exchange such an IOL for one of correct power. Technology is being developed to allow a non-surgical method to alter the power of the implanted IOL—thus eliminating surgery entirely in such circumstances.

Preventing unwanted tissue damage during surgery

A rare, but serious complication during cataract surgery is when a clear membrane, called the capsule, ruptures. When this happens, it may prevent the successful implantation of an IOL. It may also lead to further sight-threatening complications such as retinal detachment, inflammation, and macular swelling. Current developments in cataract equipment and devices further reduce the risk of capsular rupture and other complications.

Injecting liquid IOLs through ultra-miniature incisions

Today's cataract surgery is performed through a micro-incision typically less than three millimeters in size. This permits surgeons to implant a solid, foldable intraocular lens. Industry is now working to develop IOLs that can be injected in liquid form through an ultra-miniature incision. Once inside the eye, they will solidify — thus further reducing complications.

Automating surgical incisions

A critical factor for successful cataract surgery is making the proper incision. Poor incisions can impede proper healing, leading to greater infection rates and intraocular pressure instability. Today's 2-3 millimeter cataract incisions are created by hand. Even the most highly skilled surgeon can create an imperfect incision. Device companies are developing new devices to permit automated creation of consistently constructed incisions.

Customizing IOLs for patients

Today's IOLs correct for only the imperfections that are measurable with standard ophthalmic tools. The emergence of wave-front measurement technology is enabling doctors to measure visual aberrations that were previously impossible to detect. Using this technology, customized, patient-specific IOLs may be possible, allowing visual acuity better than 20/20. For many patients, such devices would not only treat the cataract, but also correct other visual problems.

Eliminating the need for glasses after surgery

Many cataract surgery patients are disappointed to learn that they must endure the expense and awkwardness of reading glasses following conventional, monofocal cataract surgery. Advances in the field of multi-focal correction are starting to provide patients with alternatives that may eliminate or reduce dependency on spectacles following cataract surgery. In addition to the current development underway in support of multi-focal IOL technology, IOL technology now in development will mimic the youthful eye's ability to see images both near and far.

Protecting against future retinal disease

Many cataract patients live long enough to develop retinal disease. Cataract implants have been recently introduced that may protect the retina from harmful light rays that contribute to retinal disease.

Improving refractive outcomes

Anatomical eye measurements, or biometry, are required for each eye prior to cataract surgery in order to calculate the proper IOL power for surgical implantation. Accurate biometry and IOL power calculation results in desired postoperative vision that minimize patient dependence on spectacles and enhance quality of life. Inaccurate biometry and IOL power calculation leads to after-care complications and costs ranging from spectacle dependence to correctional surgical intervention.

Optical biometry, a new technological advancement, is five times more accurate than ultrasound biometry, leading to enhanced outcomes, patient satisfaction, and lower complication costs. Compared with ultrasound biometry, optical biometry is a quick procedure that does not require touching the eye with the instrument. In addition, it decreases the potential for human error in measurement results.

Reducing the likelihood of secondary cataracts

Today's procedures, technologies and devices have reduced the incidence of secondary cataract, also called PCO (posterior capsule opacification). Secondary cataract occurs after cataract surgery when the back of the capsule becomes opaque. Improvements in technique and in IOL material and design are demonstrating that a dramatic reduction of this post-operative complication is possible.

SEEING INTO THE FUTURE TOGETHER: AN ONTARIO FOCUS

Until fairly recently, patients with cataracts had to undergo invasive surgery, followed by several days of in-hospital recovery to correct the disorder. After the procedure, most patients still had to wear glasses or contacts to correct any other vision problem they might have. Now, because of a steady stream of technological advances, patients are treated effectively with minimally invasive techniques, and many never need glasses or contacts again.

Beyond savings to medicare, successful cataract surgery results in improved economic output from employees. According to a recent U.S. study, cataract patients contributed $95,000 more in economic productivity from improved quality of life than if they had not had the surgery.[13]

New technologies developed by MEDEC members are responsible for dramatically improving outcomes for cataract patients. As such, the outlook for patients who have or will develop cataracts has never been better. Surgery time is shorter, recovery time is faster and vision is better after today's cataract procedures.

In November 2004, the Ontario government announced its Wait Time Strategy to shorten wait times for five key selected services, with cataract surgery identified as one of the five. The provincial government's goal is to have a comprehensive system that monitors wait times and that works toward ensuring Ontarians receive timely and appropriate access to selected services. In Ontario, wait times are measured from when the procedure is formally booked until it is actually carried out.

On the positive side, the government's Wait Time Strategy is underway and wait times are improving. On May 27th, 2005, the government announced it would provide additional operational funding for 14,000 cataract surgeries - an increase of 13 per cent over 2004/2005.[14] Implementation of the strategy and additional funding is anticipated to reduce cataract surgery wait times to 4 months in Ontario.

At present, the median wait time for cataract surgery within the Local Health Integration Networks (LIHN), of which there are 14, is being reported at a median wait time of 19 weeks.[15] Although a seeming improvement, the time does not take into account the time a patient waits to see their optometrist and then the wait timing inevitable in the referral process to see the ophthalmologist. In essence, it is reasonable to assess that at this time, wait times can essentially and easily be double to what is currently reported.

After cataracts, Macular Degeneration is the leading cause of blindness in people over 50.

Interview with waiting cataract patient Arlene Silver, CTV TV, April 2005

Advances in cataract care, as well as those introduced to treat other age-related eye disorders, come just as Canada's Baby Boom generation is reaching the critical age for developing these diseases. While cataracts are the most prevalent disorder, and will be in the coming years, other eye disorders such as age related macular degeneration, glaucoma and diabetic retinopathy are expected to affect millions of Canadians. Advances in medical technology have kept pace with these diseases as well.

In addition to the huge potential savings for Medicare from prevention of eye disease, improvements in treatment that are available but not yet fully funded or accessible to all Canadians are expected to yield millions of dollars in savings to the government and health programs for the elderly by reducing the recovery period, eliminating the need for an overnight hospital stay and reducing the complications that require further medical intervention.

MEDEC members see themselves as actively working with the Government of Ontario to be part of the vision solution. Together, industry, government and other healthcare stakeholders can create greater efficiencies and improve health outcomes. Through access to safe medical device technology and with medical device innovations on the horizon, the future for patients with age-related eye disorders has never been brighter.

SOURCES

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[15] Institute of Clinical Evaluative Sciences (ICES), Access to Health Services in Ontario reporting

** Credit goes to AdvaMed for the work they have done on the vision risk of older Americans, "Vision For The Future."

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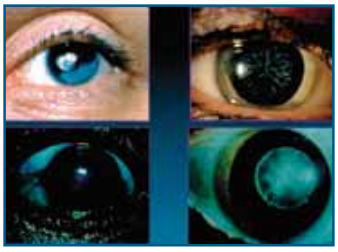

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