CONSUMERS' ASSOCIATION OF CANADA

Who's Minding the Store?

Emerging Consumer Issues in New Private Medical Markets

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Executive Summary

Over the past decade, more and more Canadians have been choosing to undergo laser eye surgery, an invasive, discretionary medical procedure, as an alternative to wearing contact lenses or glasses. Media coverage of life changing outcomes, both good and bad, has been extensive, adding to a polarized debate between service providers, who argue there is little risk when the surgery is done correctly and consumer advocates, who argue that the risks are being whitewashed. This debate, while worthy of study in and of itself, given that approximately one-half of Canadians will need some sort of visual aid during their lives, is of even greater importance as a test case of the implications of greater privatization and commercialization of medical services in Canada. What lessons can be learned from ten years of experience in this sector?

To that end, a three tiered research initiative was undertaken on behalf of the Consumers' Association of Canada, which targetted: consumers' experiences with laser eye surgery; service provider perspectives on the nature and challenges in the sector; and, an overview of federal and provincial regulatory bodies that impact on the way in which laser surgery is marketed and performed in Canada. Key issues were identified based on concerns expressed by all sides and then explored in the context of interviews and a cross-national survey of Canadians who have undergone laser eye surgery.

Among the many service providers (ophthalmologists, clinics) contacted, relatively few were willing to be interviewed, perhaps because of a perception that consumers associations and indeed the media have been unfairly targetting the sector. Among those who did agree to speak with the interviewer, there was a marked consistency in the way in which consumers were attracted, educated and then offered surgery. Service providers emphasized the need for careful assessment, as well as greater consumer education and awareness with regard to value for money. They stressed the benefit of having pre and post-operative exposure with the surgeon, which inevitably raises the cost of the procedure. Clinics believed their clientele came primarily from word-of-mouth advertising, and did dismiss claims that large numbers of patients were suffering from side-effects, particularly night vision problems.

Of the approximately one hundred consumers interviewed or surveyed, 90% were satisfied with service and outcome, some suggesting it was the best thing that ever happened to them. Of the ten per cent who were not happy, many had several lingering side effects and in one case, the individual appeared to be severely limited as a result of the surgery. It was not feasible to draw any firm conclusions about the relationship between price, contract terms and satisfaction because of major changes to the sector over the ten years. Consumers today face a much wider choice in terms of price for surgery, which remains a major factor in deciding whether to proceed. There was a significant difference in satisfaction with information received from clinics between those for whom the outcome was successful and those for whom it was not, suggesting the latter were not well prepared for the worst. Consumers indicated their first awareness of

laser eye was through newspaper advertisements, highlighting the need for fair and balanced advertising. On the whole, consumers were not aware of what they could do should something go wrong, making it clear that transparent redress procedures are needed, both to correct poor surgical outcomes and to channel complaints for poor service. The fact that a number of individuals with poor outcomes wound up being treated by provincial Medicare, while others seeking follow-up consultations found their clinics had closed, suggests a need for greater regulation to protect consumer interests after surgery.

Only two provincial Colleges of Physicians and Surgeons have guidelines specifically for laser eye surgery, although a third is preparing a set. Two key issues were highlighted as a result of the review of regulatory bodies. The first is that in some provinces the regulations (guidelines, standards) regarding advertising and business practices apply only to the physician and not necessarily to the clinic offering the service. This provides for a disjunct between professional ethics and values and business practices and values. While physicians are subject to an investigation based on complaints from a patient related to professional ethics, the clinics offering the service may be free of oversight. The second concern centres on the federal process of approval for lasers, which appears to allow lasers into clinics on an investigational basis much more quickly than in the US without this experimental nature of the technique being made clear to the consumers.

This research suggested several problems have arisen as Canadians face moving to commercial markets and private payment for medical services. The key issues and possible remedies are outlined below:

- There is a genuine lack of awareness of the difference between privatized and socialized medical care. Consumers tended to trust information provided by a clinic, some did no further research. Few sought second opinions. Those whose outcomes were poor genuinely felt let down by the system. If more medical services are to be delivered privately, much effort will be needed to educate consumers to learn to ‘shop’ wisely in the health care market.

- There is a lack of regulation that ensures that consumers are protected in the face of business failure. Health services are not like car maintenance. If one dealer goes out of business there is another, but without patient records and, in some cases, financial means to fund necessary post-operative care, some consumers are left with no where to turn. Private delivery of medical care must be structured so that consumer health does not fall victim to the vagaries of the market.

- In the case of laser eye surgery (or, by extension, any surgical procedure that carries with it the risk of catastrophic results, however rare), there is no mechanism to look after the needs of those who wind up “a statistic”. These needs extend well beyond maximizing eyesight in light of uncorrectable vision deficits, to psychological counselling,

retraining, support and financial assistance. Those firms profiting from positive outcomes should be held at least in part financially responsible for poor outcomes.

- At least a portion of consumers felt they were not fully aware of the risks and consequences of laser eye surgery. The remedy needs to go beyond the provision of information verbally or orally to more graphic presentation of just what a poor outcome can mean. While some suggest this may be fear-mongering, an awareness of the worst-case scenario is the only way in which a decision to proceed can be said to be truly informed.

- There is a patchwork of regulations with many loopholes and inconsistencies across Canada. Cross-national standards and enforceable and enforced regulations are needed, which will involve co-ordination and co-operation at an inter-provincial level given provincial responsibility for health care.

Sommaire

Au cours de la dernière décennie, un nombre croissant de Canadiens ont choisi d'avoir recours à la chirurgie oculaire au laser, une intervention médicale discrétionnaire agressive, plutôt que d'avoir à porter des lentilles cornéennes ou des lunettes. L'impact des résultats sur la qualité de la vie, tant positifs que négatifs, a fait l'objet d'une large couverture médiatique, attisant ainsi le débat qui sépare les fournisseurs de services, qui déclarent que les risques liés à l'intervention sont minimes lorsque celle-ci est menée correctement, et les défenseurs des consommateurs, qui prétendent qu'on étouffe les risques. Ce débat, qu'il serait d'ailleurs important d'étudier en soi puisque la moitié des Canadiens auront besoin de corriger leur vue d'une façon ou d'une autre au cours de leur vie, est d'autant plus important qu'il sert d'exemple pour les implications de la privatisation et de la commercialisation accrues des services médicaux au Canada. Quelles sont les leçons qu'on peut tirer des dix années d'expérience dans ce secteur?

Afin de répondre à cette question, une initiative de recherche sur trois volets a été lancée pour le compte de l'Association des consommateurs du Canada. L'étude a ciblé : les expériences des consommateurs de la chirurgie oculaire au laser; le point de vue des fournisseurs de services sur la nature et les difficultés du secteur; et une vue d'ensemble des organes de réglementation fédéraux et provinciaux qui affectent les moyens par lesquels la chirurgie au laser est commercialisée et effectuée au Canada. Des questions-clés ont été formulées en fonction des préoccupations que toutes les parties ont exprimées. Ces questions ont ensuite été explorées dans le cadre d'entretiens et d'un sondage à l'échelle nationale auprès de Canadiens qui ont subi une intervention oculaire au laser.

Parmi la multitude de fournisseurs de services (ophtalmologistes, cliniques) contactés, très peu ont accepté un entretien, peut-être à cause de l'impression que les associations des consommateurs et même les médias ciblent ce secteur de façon injuste. Parmi ceux qui ont bien voulu parler avec l'enquêteur, une uniformité marquée est ressortie quant aux moyens d'attirer et d'informer le consommateur pour ensuite lui offrir l'intervention. Les fournisseurs de services ont souligné le besoin de faire une évaluation approfondie, ainsi que d'informer et de sensibiliser davantage le consommateur sur le rapport qualité-prix. Ils ont insisté sur les avantages d'assurer un contact avec le chirurgien avant et après l'intervention, ce qui augmente forcément les frais de l'opération. Les cliniques étaient d'avis que leur clientèle s'était établie principalement de bouche à oreille et elles ont rejeté les allégations que de nombreux patients souffraient d'effets secondaires, particulièrement de problèmes de vision nocturne.

Sur la centaine de consommateurs qui ont passé l'entretien ou répondu au sondage, 90 % étaient satisfaits du service et des résultats. Certains ont même dit que c'était une des meilleures choses qu'il leur était jamais arrivée. Sur les 10 % qui n'étaient pas satisfaits, beaucoup ont éprouvé plusieurs effets secondaires persistants et dans un cas, la personne atteinte semblait gravement limitée à cause de l'intervention. En raison des grands changements que le secteur a connu au cours des dix dernières années, il n'était guère possible de tirer des conclusions

définitives sur le rapport entre le coût de l'intervention, les modalités du contrat et la satisfaction du consommateur, bien qu'aujourd'hui on offre à celui-ci un plus vaste choix sur le plan du prix de l'intervention, qui est d'ailleurs un facteur important dans la décision d'avoir ou non recours à ce service. Quant à la satisfaction des consommateurs à propos des renseignements obtenus des cliniques, une différence considérable est ressortie entre ceux dont le résultat était une réussite et ceux pour qui cela n'a pas été le cas, laissant entendre que ces derniers n'étaient pas bien préparés à affronter le pire. Les consommateurs ont indiqué que c'est dans des annonces de journal qu'ils ont d'abord pris connaissance de la chirurgie au laser, ce qui souligne la nécessité d'une publicité juste et équilibrée. Dans l'ensemble, les consommateurs n'étaient pas au courant des démarches qu'ils pouvaient entreprendre en cas de problèmes, ce qui indique clairement que des procédures transparentes de redressement sont nécessaires, tant pour réparer les mauvais résultats chirurgicaux que pour diriger les plaintes sur les mauvais services. Le fait qu'un certain nombre de personnes pour qui le résultat était mauvais ont dû subir des traitements pris en charge par le régime d'assurance maladie provincial, et que d'autres personnes, qui voulaient des consultations de suivi, ont trouvé que leur clinique avait fermé boutique, indique qu'une réglementation rigoureuse est nécessaire afin de protéger les intérêts des consommateurs après l'intervention.

Dans les provinces, seuls deux collèges des médecins et chirurgiens ont des directives régissant spécifiquement la chirurgie oculaire au laser, bien qu'un troisième soit en voie d'en préparer un ensemble. Deux problèmes-clés se sont dégagés de l'enquête sur les organes de réglementation. Le premier, c'est que dans certaines provinces la réglementation (directives, normes) en matière de publicité et de pratiques commerciales ne vise que le médecin et pas nécessairement la clinique qui offre le service. Cela crée une faille entre la déontologie et les valeurs professionnelles d'une part, et les pratiques et les valeurs commerciales d'autre part. Alors que les médecins sont susceptibles de faire l'objet d'enquêtes fondées sur les plaintes d'un patient mettant en cause la déontologie professionnelle, il se peut que les cliniques qui offrent le service ne soient sous aucune surveillance. La deuxième préoccupation concerne le processus fédéral d'approbation des lasers, qui semble permettre aux cliniques d'obtenir à la suite d'une enquête des lasers beaucoup plus rapidement qu'elles ne le pourraient aux États-Unis, sans toutefois bien faire comprendre aux consommateurs la nature expérimentale de cette technique.

Cette étude a révélé l'émergence de plusieurs problèmes sur lesquels les Canadiens doivent se pencher dans la perspective de la commercialisation et du paiement privé des services médicaux. Voici les problèmes saillants et leur solution possible :

- un véritable manque de connaissance sur la différence entre les soins de santé privés et les soins de santé sociaux. Les consommateurs tendaient à faire confiance aux renseignements fournis par les cliniques, et certains n'ont pas poussé plus loin leur recherche. Peu d'entre eux ont cherché à obtenir un deuxième avis. Ceux pour qui le résultat a été décevant ont jugé réellement avoir été trahis par le système. Si l'on

envisage de fournir davantage de services médicaux dans le secteur privé, il faudra consacrer beaucoup d'efforts pour apprendre aux consommateurs à être des acheteurs avertis dans le marché des soins de santé.

- le manque de réglementation pour assurer que les consommateurs seront protégés en cas de faillite commerciale. On n'entretient pas sa santé comme on le fait sa voiture. Certes, si un fournisseur fait faillite il y en a d'autres, mais sans le dossier du patient et, dans certains cas, les moyens pour financer les traitements postopératoires nécessaires, certains consommateurs n'ont aucun recours. La prestation de services médicaux dans le privé doit être encadrée de façon à ce que la santé du consommateur ne soit pas abandonnée aux caprices du marché.

- dans le cas de la chirurgie oculaire au laser (et, par extension, toute intervention chirurgicale impliquant un risque de résultats catastrophiques, si rares soient-ils), le manque de dispositions pour répondre aux besoins de ceux qui finissent parmi les « statistiques ». Ces besoins vont bien au-delà de la maximisation de la vue dans une situation de déficience visuelle irréparable, et touchent à la consultation psychologique, au réapprentissage, au soutien et à l'appui financier. Les sociétés qui font des bénéfices des résultats positifs devraient être tenues au moins en partie responsables financièrement des mauvais résultats.

- au moins une partie des consommateurs ont jugé qu'ils ne comprenaient pas toute l'ampleur des risques et des conséquences liés à la chirurgie oculaire au laser. La solution doit aller au-delà de l'offre d'information orale et inclure une présentation plus graphique de ce qu'un mauvais résultat implique. Même si certains diront que cette solution sert d'épouvantail, il n'en demeure pas moins que comprendre la pire des hypothèses est le seul moyen pour prendre une décision en toute connaissance de cause.

- des réglementations sans uniformité qui contiennent plusieurs lacunes et incohérences d'une province à l'autre du Canada. Il faut des normes nationales et des réglementations applicables et appliquées. Pour cela, il faut une coordination et une coopération au niveau interprovincial, étant donné que les soins de santé relèvent de la responsabilité provinciale.

1 Introduction: Laser Eye Surgery in Canada

1.1 Report Rationale

This report has three purposes:

- To provide an overview of Canadian consumer[1] experiences with laser eye surgery with a view to:
- identifying the factors that consumers consider in making decisions regarding this controversial procedure;
- clarifying how satisfied they are with various aspects of the procedure, including the information received prior to the surgery, surgical outcomes, pricing and contract arrangements;
- ascertaining the level of awareness among consumers regarding follow-up and redress options, should surgery not be successful.
- To highlight issues that have been raised by consumers, sellers and critics of the sector and to investigate in the light of data collected whether these concerns are justified and to what extent.
- To place these results in the context of emerging medical markets and the privatization and commercialization of discretionary medical procedures. What lessons can be learned from the case of laser eye surgery?

In order to better understand the context of laser eye surgery in Canada, sections 1.2 and 1.3 outline briefly what refractive laser eye surgery is and how it has become an accepted option for eye problems in Canada since its introduction twelve years ago. Section 1.4 sets out the main consumer issues that have been raised by those familiar with the sector.

1.2 What is Laser Eye Surgery?

Laser eye surgery can be traced back to the work of Dr. Jose Ignacio Barraquer of Colombia, who in the 1950s developed a method of altering the shape of the cornea of the eye to correct refractive problems such as nearsightedness (myopia) or farsightedness (hyperopia) and more recently astigmatism. His work led to developments in Russia in the 1960s and the first

[1] This report uses the terms 'consumer', 'client' and 'patient' interchangeably to refer to the individual receiving treatment. The fact that three terms were required highlights the complexity of the role of the individual seeking this service. They are a consumer of a service, an active seeker of that service (client) and a passive recipient of treatment (patient). Successful interaction with the system might be seena s a function of assuming the right role at the right time.

accepted laser eye surgical procedure which is still practised today, although rarely, radial keratotomy (RK). Laser eye surgery was viewed as highly experimental for many years, gradually gaining acceptance in Europe in the 1980s and in North America since the beginnings of the 1990s, at which time clinical tests were showing positive short term outcomes for many patients with specific eye problems. Because it is such a new procedure and developments are continually being made in the field, such as the introduction of new lasers and new surgical techniques[2] (see below), the long term effects of surgery remain unknown.

1.2.1 Common Types of Laser Eye Surgery

Laser eye surgery is an invasive procedure which reshapes the cornea using a variety of methods, of which only RK, photorefractive keratectomy (PRK) and laser in situ keratumileusis (LASIK) are outlined below. PRK and LASIK are the most widely used procedures in Canada[3], while RK is still used with certain patients (two in our sample underwent RK)[4].

PRK

In photorefractive keratectomy (PRK), first performed in Germany in 1987, the surgeon removes the outer layer of the cornea and polishes the underlying portion, the stroma, which is then reshaped using a computer-programmed laser. The laser typically removes 50 - 70 microns (about 10%) of the thickness of the cornea. PRK is generally acknowledged to be more painful post-operatively than LASIK and clients are usually required to wear protective contact lens and use eye drops for a period following the surgery as the cornea develops a new outer layer.

LASIK

LASIK is a hybrid surgical procedure developed from PRK and the less common automated lamellar keratoplasy (ALK) procedure. Instead of removing the outer layer of the eye, a corneal flap is cut open and the underlying tissue shaped with an excimer laser. With the replacement of the outer flap the newly cut tissue is not exposed thus cutting down on the risk of infection and reducing post-operative discomfort.

RK

Radial keratotomy (RK) involves making several surgical incisions around the periphery of the cornea, which changes the overall shape of the cornea and thus reduces myopia. Since it is much harder to judge the outcome of this surgery in terms of specific improvements in vision, it

[2] For instance the introduction of scanning spot lasers allowing the treatment of the entire cornea or the development of LASEK, a hybrid technique comprising aspects of both PRK and LASIK surgery (see Wilson, S.E. (2001) LASEK: The Next great procedure? *Review of Ophthalmology*, 8 (11), 3 - 6.)

[3] Health Canada, www.hc-sc.gc.ca

[4] For a more detailed description of the surgery, see www.fda.gov/cdrh/lasik.

is less likely to fully correct myopia and may led to scarring. For that reason it is much less commonly used.

1.2.2 Common complications and side-effects

Hard data on success rates and side-effects for Canada are not readily available, given the provincial responsibility for medicine and the largely unregulated nature of the sector in Canada (see section 5). Ophthalmologists, clinics and clinical studies all cite different success rates, depending on the procedure in question, the particular laser used, the presenting eye problem and its severity and what one considers "successful surgery", i.e., patient satisfaction or post-operative vision (20/20 vs. 20/40, etc.). Overall there seems to be agreement, though, that between .01 and 5 per cent of those undergoing the surgery will have complications, which may include anything from under or over correction resulting in the need to wear corrective lens to more severe cases of corneal decomposition or permanent eye damage, with the latter being relatively rare. In late 1999, Dr. Patricia Teal, former president of the Canadian Ophthalmological Society was quoted as estimating over 100,000 Canadians underwent the procedure since its introduction in 1990[5], suggesting that between one hundred and five thousand Canadians are now suffering the effects of poor surgical outcome in the 1990s.

Recently, however, studies have suggested that a much higher percentage of LASIK patients may suffer from reduced night vision, prompting the RCMP to advise its members against surgery and the Fitness to Drive Committee of the Canadian Medical Association to warn that laser eye surgery is a risk factor in driving at night[6]. Halos, dry eye, glare and cloudiness may also persist, although these may often be viewed as acceptable trade-offs for otherwise much improved sight. The American Academy of Ophthalmology recently published a meta-analysis spanning three-decades of LASIK results which suggested minor side-effects, such as these, were more common than previously reported[7].

For the purposes of this report, the key issues with regard to the nature of laser eye surgery are that:

- It is a relatively new procedure;
- It is constantly being adapted and modified in an attempt to increase success and decrease discomfort;
- Most clients are satisfied and, in the majority of cases, the results are satisfactory by any standard;

[5] Hawalesha, D. (1999). Laser visionaries. *MacLean's*, 112 (7), p 58-60.
[6] Health Briefs (2000) in *MacLean's*, 113 (37), p 49.
[7] Sugar, A., Rapuano, C., Culbertson, W.W., Huang, D., Varley, G.A., Agapitos, P.J., de Luise, V.P. & Koch, D.D., (2002). Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy. *Ophthalmology, 109*, 175-187.

- Long-term consequences of the surgery are still under study at this time; and,
- When the surgery is unsuccessful, the results can be devastating for the individual.

1.3 A brief history of Laser Eye Surgery in Canada

Just as there no clear statistics on surgeries and success rates in Canada, there is no definitive history of the sector in this country, although it is generally agreed that the first PRK surgery was conducted by Dr. John van Westenbrugge in Calgary in 1990. The first half of the decade showed a gradual rise in the number of surgeries from year to year, although totals are confounded to a certain extent by the large numbers of US residents who made the trip across the border for treatment. Initially the same surgery was not available in the US because it was not until 1995 that the excimer laser was approved by the US Food and Drug Administration for use outside of university research facilities. More recently a favourable dollar and extensive competition in price setting have made Canada an attractive option.

By 1999 approximately 40,000 individuals had undergone this treatment[8] in British Columbia alone. By 2000, 13 clinics were operating in the lower mainland of B.C. Part of this growth is due to an aggressive advertising campaign which has used techniques such as 'package deals' 'two-for-one specials' and celebrity endorsements[9] that are more reflective of winter vacation marketing than anything Canadians have seen previously in the context of a surgical procedure. This commodification of surgery is one of the major concerns of those who follow the sector. They argue that marketing the procedure as a commodity encourages Canadians to make impulse decisions as they would in buying many other commodities, that is, without careful thought about the risks and implications of invasive surgery. Also responsible for the growth in the market on the positive side, are improvements in the procedure, which originally was only suitable for mild to moderate myopia, but now can be used successfully most of the time with more severe myopia and combinations of astigmatism and myopia or hyperopia[10].

With the increasing competition and the growing market came more competitive pricing, which has driven the price down to as low as $450.00 per eye from a high of $2250.00. Laser surgery critics claim that such price cutting comes at the cost of patient care and, particularly in the case of individuals whose surgery does not go that well, adequate follow up treatment. At the same time patients who want the procedure are clamouring for reasonable rates, arguing that this should not be a procedure only for the rich. Canadians are used to equal access to medical

[8] Kent, H. (1999). Huge declines in price as competition heats up in Vancouver's booming laser-surgery market. *Canadian Medical Association Journal*, *161* (7), 857-859.

[9] One of the most notable being Tiger Woods. See Morgan, J. (2000). LASIK surgery gives Tiger eagle eyes. *USA Today*, March 15.

[10] Just how successfully is contentious, with the same meta analysis noted above suggesting there is a much greater likelihood of problems with individuals presenting with particularly poor eyesight. Since the study does include data from early surgeries, it is not clear whether this is still a major concern.

services regardless of wealth, at least more so than in many countries, and this 'right' colours the way in which discretionary medical practices are viewed.

By the end of the decade, the popularity of laser eye surgery was growing exponentially. In the US, the market grew from one half a million procedures in 1998 to nearly a million in 1999 and close to 1.5 million in 2000, with a similar growth rate in Canada. With the increase in absolute numbers of surgeries, however, came an increase in the absolute number of problem cases. In the US there has been a marked upswing in the number of lawsuits related to laser surgery, largely due to the exponential increase in number of surgeries performed. In 2001, the Review of Ophthalmology reported that the Ophthalamic Mutual Insurance Company had seen a 100% increase in LASIK-related lawsuits between 1999 and 2000 as a function of their overall case load[11]. Cases often allege improper assessment or evaluation, but sometimes inappropriate techniques or downright errors, such as the case of Sheryl Sullivan who alleges her doctors used the measurements from another patient's eye in programming the laser for her surgery[12].

Canada has been affected by awsuits in the US, as well as some at home,[13] and by the extensive media coverage, which has often focussed on horror stories and things gone very wrong. Clinics reported a drop in business in 2001 and into 2002 and some, in the wake of drastic price cuts, such as Canada's LASIK Vision Corp and Icon Laser Eye Centres have gone bankrupt. Others such as the premium service, Mississauga-based TLC Laser Eye Centre, which refused to drop prices in the price wars, have reported major losses and a 35% drop in procedures, although have been able to weather the economic downturn and the loss of consumer confidence[14]. The closing of some clinics has created yet another worry for the laser eye consumer: uncertainty over the availability of follow up care, even if promised as a part of the service package.

The very rapid development of this sector, far outstripping traditional conservative time frames for the introduction of new medical procedures and techniques has given rise to a tension between commercial values and practices and professional medical values and practices. The growth of this market presents some new and unique challenges for the Canadian public, the profession and regulators, which are outlined in the following section.

1.4 Key Consumer Issues

Over the dozen years since laser eye surgery was first introduced into Canada, thousands of individuals have undergone this medical procedure with varying results. Along the way,

[11] Anonymous, (2001). Popular Media Pound LASIK, *Review of Ophthalmology*, *8*, (10), 11-13.

[12] Sullivan vs. Slade & Baker, Texas District Court, 1998

[13] See Capen, K & Kothari, A. (1997). Lawsuits over laser patients raise serious issues for physicians, patients. *Canadian Medical Association Journal*, *157* (6), 737-739.

[14] Havardsrud, P. (2001). Downturn hits demand for laser eye surgery. *Financial Post*, December 11.

consumers, consumer 'watchdogs', the media and some in the medical profession have raised concerns about a wide range of issues relating to consumer protection, consumer awareness and regulatory and fair marketing practices. In this section we identify some of the issues that have been raised to provide a context for the survey of consumers and service providers, the results of which are set out in sections three and four. The consumer survey is intended to clarify which issues appear warranted based on consumer experiences, while research into service provider practices will provide insight into the potential for problems that may not have been captured in the necessarily limited sample of consumer responses.

The range of issues identified in the media and the consumer protection literature is considerable and the scope of a small, targetted survey report such as this precludes an in-depth inquiry into all facets of the sector. The focus of the report is on issues that have been raised on several occasions in different forums and thus are deemed to be key issues for consumers; issues that are relevant not only to the laser eye surgery sector, but may extend to many discretionary medical procedures that are being marketed currently or may be in the future; and, particularly, issues that have been raised by laser eye clients themselves over the past decade of Canadian consumer experiences[15].

Issue 1: Advertising

One of the major concerns levied against this industry by consumer advocates is in the area of marketing practices. More specifically, in the past laser eye surgery clinics have advertised "two-for-one" specials and other types of advertising 'gimmicks' to encourage patients to seek out this service. Sector supporters maintain this is a standard business practice and that it only brings potential clients to the door where they can make an informed decision about the process based on extensive information provided. Critics argue that such marketing gives the appearance that surgery is a commodity little different from a "2-for-1" dry cleaning service or pizza purchase. The advertising used to attract clients through the door, it is argued, thus minimizes perceived risks and consequences of a surgical procedure. Clients are simply not used to thinking of two-for-one and surgical risk in the same context; no other product marketed in this fashion carries the risk of outcomes that can be devastatingly life-changing if unsuccessful. In section 3 service provider perspectives on this sort of advertising are explored, while in section 4 we examine the extent to which clients are attracted by such advertisement.

Issue 2: Cost Cutting

In a similar vein the recent price slashing by as much as 75 - 80% is often criticized as it is seen as discount pricing of a sort that can only be offered when corners are being cut and essential safety and follow up procedures ignored or excluded. Sector supporters argue that such pricing

[15] We are indebted to Wendy Armstrong of the Alberta Office of the Consumers' Association of Canada for providing background material and substantive input into the elaboration of consumer issues based on her years of research and interest in this sector.

offers individuals who are not wealthy the opportunity to enjoy a popular alternative to cumbersome contacts and glasses[16]. In both sections 3 and 4 we explore the extent to which pricing is perceived to reflect quality of service. Do service providers link the two? Is there any evidence that consumers who have paid more have got better service or are more satisfied?

Critics also argue that the practices of some laser eye surgery clinics, which require potential clients to pay for their suitability assessment, is flawed in that it seriously impedes their ability to get a second opinion. Service providers are asked about this practice in section 3, while consumers are polled with regard to how often and why (or why not) they seek second opinions on their suitability.

Issue 3: Risk Awareness

There has been considerable attention paid to the issue of consent and client awareness of the impacts of the procedure. Although patients are generally required to sign informed consent forms, several critics argue that the risks of the procedure are not clearly delineated and that these are generally found in the smaller print near the end of a multi-page document. It has also been reported that some centres do not present the patient this consent form until just prior to the surgery, which gives the consumer very little time to review the contents and their implications. In section 3 we examine what procedures service providers have in place to ensure consent is informed and in section 4, results explore just how informed clients feel they were, both from their own research efforts and directly from the clinic.

As a specific example, one of the most widely publicized clinical issues surrounding laser eye surgery is the potential difficulty with night vision. There appears to be considerable debate on this issue as service providers claim the incidence of night vision problems is widely exaggerated and the studies done to support this claim are methodologically flawed and based on older technology and that with proper screening, this risk is non-existent. In section 4 we ask clients to report on their own experiences with night vision and other commonly cited side-effects of laser eye surgery to ascertain if these have seriously impacted satisfaction with the surgery and thus need to be more clearly spelled out for potential patients.

Issue 4: Follow Up and Redress

One of the more poignant issues surrounding laser eye surgery is the fate of self-proclaimed "survivors" of this surgery. These individuals argue that success rates and statistics are essentially meaningless if you are one of the unfortunate few who have a negative surgical outcome. The dire consequences of failed laser eye surgery, no matter how rare, given its impact, can have far-reaching effects on everyday life and can truly be a life-altering experience.

[16] It is noteworthy that similar arguments are not advanced by dentists, who maintain a price structure that is meant to reflect a consistent level of professional care, but that may result in some having to go without that care.

What redress does a consumer have if things go wrong? How have individuals who fall into this category coped and what should be done to help them readjust to a permanently altered life?

Relatedly, we explore in section 4 who bears the cost of eye repair surgery? Many clinics offer unlimited follow ups and will perform several surgeries if necessary to ensure poor surgical outcomes are minimized, but is this always the case? Who bears the cost of things gone wrong if the clinic does not? Critics argue that taxpayers, through the provincial Medicare plans, are the ones who have to shoulder the financial burden of poor surgical performance (or poor candidate selection). In section 4 we ask any clients who needed such care who paid for their surgery?

A more recent issue relates to the high-profile bankruptcy cases that have occurred in this sector. Critics argue that consumers are drawn in by promises of a "lifetime guarantee", but fail to recognize that the lifetime may refer to that of the clinic and not of the individual. How aware are consumers of this issue and how concerned are they about the reliability of their clinic to provide follow-up? How can consumers protect themselves in such cases? Are service providers taking precautions to ensure the well-being of their clientele should they go out of business and are those measures adequate?

Issue 5: Regulation of the Sector

Another major consumer issue for Canadians is the fact that there is currently no federal regulation of the industry or national standards for performing the surgery or pre-operative assessments. The impact of this lack of standardization on consumer protection becomes readily apparent when one considers the different screening procedures used to identify "suitable" clients for laser eye surgery. If there are no universally accepted guidelines, especially in a privatized industry where profit margins are critical, the question must be asked whether everything is being done to weed out unsuitable candidates who may be at a slightly higher risk of poor outcome. Does the industry 'take chances' to make an extra dollar? Critics argue they do and point to many reports of unsuitable candidates undergoing surgery. Sector supporters argue the numbers are in fact very small, stressing that this was much more common early on when the surgical procedures were new and ophthalmologist less experienced, but is rarer today. In section 3 we ask service providers to outline the procedures and criteria used to select candidates and in section 4 we explore on what basis they make their decision to proceed.

As set out in section 5.2, the only federal involvement in this sector comes from the Medical Devices Bureau of Health Canada, which certifies the lasers used within Canada. Currently eight lasers are certified in Canada, but only two in the US, with certification coming much earlier in Canada, albeit on an investigational basis. Why is this so and what are the implications for consumers and service providers both of a relatively unregulated practice? Relatedly, sector critics have accused clinics of using clients as 'guinea pigs' to try out new surgeries and new lasers without clearly informing them that they are part of clinical trials. In section 4 we explore

whether clients have had this experience or to what extent they are aware that they may or may not have been used to help identify problems with procedures and devices.

1.5 Concluding remark

Perhaps the key issue that this research addresses is what can consumers do to maximize a positive outcome with regard to their involvement with this sector, whether that positive outcome is defined as a good surgical outcome or a well thought out decision not to proceed. Based on the information garnered in the course of this research, a checklist has been developed to help consumers make the right personal decision (see Appendix D).

2 Methodology

2.1 Methodological Framework

The Action Group was contracted in December 2001 by the Consumers' Association of Canada to conduct research to help identify the scope and extent of consumer problems and issues relating to professional conflicts of interest, advertising and marketing, access to relevant information and redress (remedies) in the new and growing private marketplace for discretionary medical procedures such as LASIK and photo refractive (PRK) eye surgery. To this end three research themes were developed, each focussing on a distinct aspect of the laser eye surgery market: service provider perspectives, including both clinic staff and surgeons; laser eye client perspectives, including both written survey responses and interviews with satisfied and dissatisfied customers; and, a review of regulatory and oversight bodies that govern this sector. Each of these segments are dealt with in chapters 3, 4 and 5, respectively, with common themes and issues that need addressing developed in chapter 6, where the lessons learned from this research are put into the context of emerging private medical markets.

The work of the Consumers' Association of Canada is to both inform and educate consumers as well as to advocate on their behalf with government[17]. This report attempts to address both roles, by setting out information that may be useful to consumers in making an informed decision on laser eye surgery, as well as by identifying issues that require action by government, concerned citizens and consumer advocates with regard to laser eye surgery and in the larger context of the privatization of medical services. To this end, Chapter 7 offers a series of recommendations stemming from this research for players in the sector and a practical checklist is to be found in Appendix D which may serve as a useful guide to help Canadian consumes who are considering laser eye surgery.

It should be noted that The Action Group has had no previous involvement with the laser eye sector, although it has been involved with health-related research projects. The choice of a neutral consultant for the data collection and analysis was intended to allow for an impartial exploration of the issues that have been raised by consumer advocates in this sector in the context of service provider and laser surgery consumer experiences.

2.2 Research Design

2.2.1 Service Provider Perspectives

In order to provide a maximally comprehensive overview of the state-of-the-art in laser eye surgery in Canada, service provider clinics from across the country were contacted to elicit their

[17] See www.consumers.ca

support in participating in a semi-structured interview exploring several critical questions regarding this industry. Details of the sampling and interview approach are presented below as well as problematic areas that emerged during data collection.

2.2.1.1 Sample selection

A comprehensive list of laser eye surgery clinics across Canada was compiled through several sources including lists of laser eye clinics provided by the provincial branches of the Consumer Association of Canada, as well as additional research conducted via the Internet and newspapers by associates of The Action Group. The final list included clinic representation from each province, with the exception of PEI and the Territories. Having decided to interview ten laser eye clinics, several clinics from each province were contacted to determine whether they would be interested in participating. In the end, only eight laser eye clinics agreed to participate but there was representation from each region of Canada. Table 1 below provides the geographical location of these clinics. The distribution mirrors the results of the client survey (see section 4.1) in which the majority of respondents were from Ontario or the Prairie provinces.

Table 2.2.1
Geographical locations of service provider clinics agreeing to participate in the survey

Location	Number of clinics
Atlantic	1
Quebec	1
Ontario	3
Prairies	2
B.C.	1

There were several reasons why the number of laser eye clinics interviewed fell slightly short of the projected target. First and foremost, several laser eye clinics identified in our list had closed, as noted in Section 1.3. This trend was especially noticeable in British Columbia. Furthermore, although several of the clinics agreed to review an outline of the interview protocol for consideration, many declined to participate stating that they did not see the added value to either their clinic or their clients while others noted that they felt they did not have time to participate. More specifically, it was readily apparent that the administrators/surgeons were uncomfortable when it was mentioned during the initial phone call that this research was being sponsored by the Consumers' Association of Canada. Although it was not directly stated, it seemed that these individuals viewed a consumers association, by default, as adversarial and this may have

resulted in a reluctance to participate[18]. This indicates that more work needs to be done in bridging the gap between the Consumers' Association of Canada, patient groups and service providers, particularly if a trend towards privatization of health care in Canada continues.

Finally, several messages were left at many doctor's offices and private surgery clinics but these phone calls were never returned. It should be noted that a smaller number of doctor's offices referred us to the parent company or mentioned that the surgeon worked out of a larger private surgery clinic specifically for laser eye surgery, which was not part of their regular eye care practice (e.g., optometry clinic). Also, several other clinics either offered only cosmetic or cataract surgery, which would make them ineligible for this study, or some no longer offered laser eye/refractive surgery at all.

Forty-four surgeons and/or clinics were contacted for participation and only eight agreed to be interviewed. This raises serious questions regarding the non-participatory clinics. For example, it could be argued that this lack of participation indicates that these other clinics were not as concerned with the well-being of their patients, deeming it of little financial or practical value for the clinic if they participated. This is unfortunate, as many client responses identified customer "service" as one of the key variables in this sector and is arguably the first thing mentioned when it comes to dissatisfied consumers. Clinics may also be apprehensive about sharing details of their business practices with their competitors in the context of the current highly competitive market for laser eye surgery in Canada.

Another point that needs to be raised is regarding how concerned laser eye clinics are with educating consumers. Although it will be seen in this section that the vast majority of laser eye clinics who agreed to be interviewed felt this to be of paramount importance, it is difficult to understand why setting aside an hour of time to be interviewed to answer some relatively non-intrusive, but fair questions (e.g., please tell us a bit about your practice, see Appendix B) would engender such strong opposition or relative disinterest by various clinics. Furthermore, as many of these clinics have clinic directors or other administrative personnel to handle these requests, the argument cannot be made that it would interfere with service delivery to the clients because the surgeon is needed elsewhere. In this regard, one of the interviewees for this project agreed to be interviewed at home, despite the fact he was for all intents and purposes an independent practitioner and was the head surgeon who delivered most of the surgeries in his clinic. It is clear that there may be motivational or other differences between clinics who agreed to participate in this research and those who refused.

[18]As an ancillary but related point, when service providers interviewed for this project were asked to comment on the challenges and unfair criticisms of the industry, the vast majority expressed the extreme negative reporting bias present in the media and the need for more balanced representation of the sector.

2.2.1.2 Limitations of sample

As participation in this research project was voluntary, randomization of clinic selection was not possible given the self-selected nature of the sample. This has several implications when interpreting the results. These clinics should not be seen as representative of laser eye clinics across Canada. Furthermore, and important for consumers, it is entirely possible that the clinics that were interviewed are those who adhere to ethical and high level market practices as they are more transparent about the nature and extent of their services. Thus, the self-selected and limited sample of clinics suggest clients need to be very aware when choosing laser eye clinics and should contact multiple agencies (a point of view that was endorsed by several of the laser eye clinics that participated in this research)[19].

2.2.1.3 Procedure

When a service provider was contacted, a representative from The Action Group introduced themselves with the following preamble:

"My name is…… I work with the Action Group, an Ottawa-based consulting firm. We are conducting a study on behalf of the Consumer's Association of Canada on laser/refractive eye surgery. We're interested in the practices and experiences of refractive eye surgery service providers and would like to know whom I could talk to in your organization about the issues that are emerging in the context of new private medical markets. This is NOT market research, but information that will be used to inform a position paper being developed by CAC on Canadian consumers' experiences with laser eye surgery in the context of privatization of health services in Canada. We are very much interested in ensuring the views of laser eye surgery clinics are appropriately represented in this study and would very much value your participation. Who could we talk to in this regard?"

Once the appropriate individual was identified, he/she was contacted and was sent the interview protocol via fax or email to review while considering whether their clinic would be interested in participating. This approach was used to ensure the interview content was as transparent as possible and in order for the clinics to be aware of what they were agreeing to in advance. It was also intended to increase clinic participation. If no response was received within a week, a follow-up call was made to ensure there were no additional questions, or to ascertain, if further clarification was needed. If the individual agreed to be interviewed, a mutually acceptable time was selected and the interviewee was told that the interview would last approximately 45 minutes to one hour. Finally, the interviewee was informed that if he/she wanted to raise or discuss other points related to laser eye surgery in Canada that were not covered in the interview protocol, they were encouraged to do so. This would allow additional items to be

[19] For reasons of confidentiality and anonymity guaranteed to all participants in this study, the Consumers' Association of Canada is not able to provide any information on which clinics were interviewed. Guidelines for researching options and choosing a laser eye clinic are provided in Appendix D.

tabled that were felt to be relevant to service providers while also confirming to the clinics that their concerns were a valuable component in shaping the final document.

2.2.2 Consumer Perspectives

Focussing on those who were both satisfied and dissatisfied with the outcome of their surgery and their laser eye experience in general[20], this report examines consumer experiences, attitudes and beliefs surrounding various aspects of laser eye surgery, including:

- perceptions of the quality and availability of information;
- influence of marketing strategies, prices;
- extent and nature of deliberations leading to a decision to proceed;
- awareness of and perceived availability of redress when things go wrong; and,
- positive and negative experiences throughout the process.

Data were collected simultaneously using three media: the Internet, newspaper advertisements, and a limited number of detailed semi-structured interviews. Ideally, these three data collection initiatives would have been conducted consecutively, tailoring the questionnaires to reflect concerns raised in the interviews; however the limited time-frame for data collection made this impossible. Instead a triangulation based on three different data sources was expected to go a long way to providing some reassurance that the field was 'covered' and key consumer input was not being overlooked. The three approaches adopted were as follows.

2.2.2.1 Semi-structured Interviews

Thirty individuals were contacted to participate in a phone interview and virtually everyone agreed, although several individuals had to drop out because of busy schedules. Participants were contacted from across Canada and offered several optional times for the interview[21]. Potential interviewees were drawn from an extant list of interested participants (collected last summer via a notice posted on the CAC website), referrals from CAC volunteers, and by asking respondents to the email and newspaper surveys (below) if they would be willing to participate in an interview instead of completing the survey. These hour long interviews covered the same basic material included in the written surveys, but allowed more opportunity for consumers to "tell their story" and provide indications of the impact of laser eye surgery on their

[20] In the original proposal consumers who had considered laser eye surgery but had decided against proceeding were also to be targeted. In the course of the time-limited research associated with this project, only one such individual was found. He did complete a survey. Possible reasons for a paucity of such individuals are discussed in section 4.1.

[21] We had hoped to include five interviews targeted at that group addressed in the previous footnote, that is, individuals who had decided against laser eye surgery (for a total of 25) but no one contacted for an interview was in this situation.

life. The hope was that issues that may have been missed in the survey might surface in this less structured format (see Appendix C for the interview protocol).

2.2.2.2 Email Survey

To complement the interview data by allowing some extrapolation in terms of the frequency of consumer concerns, demographic variation and overall level of satisfaction with service in the country, an email survey was conducted which involved posting notices to listserves, newsgroups and soliciting responses over the Internet. The original intention was to post a short survey directly on the Internet, but based on feedback from the CAC volunteer advisory board, the shorter survey became too long to post conveniently. Instead notices were posted which described the research and provided an email address that individuals could contact for a survey, if they wished to complete one. A separate email address was set up and the full survey was emailed in ASCII or PDF format, depending on the consumer preference. Consumers who completed the survey (which is provided in Appendix A) were given the option to return it via email or print it off and return it by regular mail[22].

2.2.2.3 Newspaper solicitation of participants

Since the Internet is only accessible to some, data collection was supplemented by a series of advertisements in newspapers across Canada in or close to cities where laser eye clinics are located. One province (Manitoba) was selected to include rural participation and advertisements placed in 47 rural community newspapers. Interested participants were asked either to email and request a copy of the survey or to phone a 1-800 number at The Action Group and to leave their mailing address and name. Surveys were emailed or sent out and respondents were asked to complete them before the end of February 2002. Stamped self-addressed envelopes were provided. The questionnaire was similar to the semi-structured interview protocol, with ample room for individual experiences, but emphasized basic quantitative questions. Only five weeks were available for data collection, so a modest target of 100 responses was set.

All participants were entered in a lottery draw for $250.00 and the winner, a Saskatchewan resident, was chosen using a computer-generated random selection feature from all those who returned their completed surveys. He was notified by phone at the end of March, 2002[23]. Participants were assured that any information they provided would be kept confidential and not shared without their written consent. Names and contact information were collected for the draw and were kept separate from the questionnaire. Individuals were also informed that a copy

[22] Because of this overlap and because the survey questions were the same, no distinction was made in the analyses between surveys that were received by mail or those that were received by email.

[23] The use of a draw also encouraged those who have no "axe to grind" to participate. Often it is those who have had problems who are intrinsically motivated to report on those difficulties, given the inherent benefit to telling one's story. Those for whom everything went well have no such incentive.

of this final report would be available through the Consumers' Association of Canada as of April, 2002.

2.2.3 Regulatory Bodies

Regulatory practices were initially investigated by conducting a web-based research project. Information published by each provincial college, the Royal College of Physicians and Surgeons, and any other professional medical association was reviewed to determine the guidelines and standards that apply to laser eye surgery. Based on this research, a list of interviewees, and an interview guideline was developed.

Regulatory bodies and professional associations[24] at both the national and provincial level were interviewed to determine what standards exist with regards to the practice of laser eye surgery. The list of interviewees began with each provincial college, and grew to include other associations as indicated by the service providers.

Each regulatory body was approached by phone, and the purpose of the study, and the information desired was explained. We were then directed to the person whom the organization felt most appropriate to handle the questions. The success of this method varied from province to province. For example, in Ontario, the first attempt resulted in being directed to the complaints department after being told that the college was not required to divulge information regarding their decision making processes, or their guidelines for physicians to the public. The mandate of the college is to respond to complaints from the public. A second attempt at gathering information from the media relations contact was more successful.

The following questions were used as a guide for discussion with each regulatory body interviewee, as appropriate:

- How is Laser Eye Surgery currently regulated in Canada/in your province?
- What aspects of this health car service are regulated both in Canada and in your province? (e.g. technology used, patient education/information, marketing and business practices, health care standards, other)
- What purposes do the regulations/standards serve?
- How would a consumer report a concern?
- Have complaints been received with respect to LES? How many? How are they resolved?

[24] Regulatory bodies govern the profession and can bring sanctions (e.g., suspensions, etc.) against its members whereas professional associations are organizations for the members whose mandate is professional development and facilitating communication between members.

2.3 Methodological Review

An expert in research methodology was retained by CAC to ensure the study's methodology was sound within the constraints imposed by the limited time frame and funds. The evaluator also ensured that interpretation of the results was warranted, based on the methodology chosen.

2.4 Limitations of the design

The major limitation with the methodological design set out above is the limited time frame for data collection. Using the various media selected, a wide range of patients, rural, urban, younger, older, newer clients and older clients were expected to respond, but this sort of research often benefits greatly from word of mouth and protracted media exposure. This was not an option in this case and, indeed, response rates appeared to be steadily increasing just as the cutoff for responses was reached. With a final sample of around 100 clients the study cannot purport to be fully representative. The responses received therefore must be viewed as a useful contribution to the debate on laser eye surgery from an interested consumer perspective, but there were insufficient numbers to allow for inferential statistical analyses by meaningful demographic subgroups (by region, gender, age, etc.).

Although the use of a lotto to encourage participation was adopted in part to ensure that individuals who had a good experience with the procedure would be motivated to reply, it is still likely that more people with problem outcomes responded than would be predicted based on standard success rates. Individuals who have had difficulties are in greater need of 'telling their story' and often feel much more motivated to respond to this sort of research than those whose expectations were met. Extrapolation of satisfaction rates to the wider population is therefore not warranted, although rates found were commensurate with media reports.

A further limitation involves the non-representative nature of the service providers interviews as noted in section 2.2.1.2. As detailed in section 3, few service providers were willing to discuss their business practices, so the eight who did agree are, by that very fact, not representative of the many contacted. This, combined with a paucity of dedicated consumer research on marketing practices in this sector, results in a sketchy picture of the sector against which to compare consumer perceptions. The nature of the research required to develop a comprehensive view of this sector would have gone well beyond the scope of the methodology set out for this report and the time frames indicated. This remains a project for the future.

3 The Provision of Laser Eye Surgery Services: Cutting to the Chase

As mentioned in the methodology section, service providers were faxed or emailed a list of general questions as a framework for the interview. However, during the interview interviewers also probed for additional information. In the vast majority of cases, interviewees provided answers to all of the questions asked, but in a very few cases, time constraints and/or unavailability of information left some gaps. Follow-up questions were asked when a clinic mentioned a unique or innovative approach. Given the small sample of clinics that were interviewed and the lack of randomization in interviewee selection, the results are presented in qualitative form as aggregating the results from a quantitative perspective would be inappropriate.

3.1 Background on participating clinics

The surgeons and clinic managers interviewed tended to be involved in the laser eye surgery industry for several years. More specifically, clinics and/or surgeons reported being involved in this sector for between 8-12 years, a possible testament to their ability to survive in an industry that was hard hit with many high-profile bankruptcies over the past several years, as noted in Section 1.3. Once again, this artifact adds more credence to our suspicion that those clinics who volunteered to participate are those that offer higher end service. Unfortunately, however, there is no way to test this hypothesis, as clinics were unwilling to quote prices for surgery over the phone.

Clinics tended to operate with one or two surgeons on staff, with a couple of clinics stating that they allowed some other surgeons to come in on an as-needed basis to use the facilities for their clients. However, very few clinics worked with this arrangement. In those cases where outside surgeons would come in, internal checks were conducted to ensure these individuals met the operating requirements of the clinic and were appropriately trained in laser eye surgery. It should also be noted that the laser eye surgeons were also regular eye doctors in every case. For most clinics, laser eye surgery was only a portion of their regular eye practice, while other individual surgeons were employed on an external basis to private parent firms (e.g., LASIK or Gimbel Eye Centre). The most commonly reported form of laser eye surgery performed was LASIK and PRK (reported by all clinics), while others were involved in PTK, Clear lensectomy, or Phalic Intraocular Lens (IOL). This is consistent with the results of the consumer survey (see section 4.2) in which 98% of respondents underwent LASIK or PRK procedures.

3.2 What happens to clients who pursue laser eye surgery?

As one would expect, there is some variability among clinics with regard to the process followed, but there are also substantial areas of overlap and these will be presented below. In cases where there are potentially problematic or innovative practices used, these will be highlighted.

Once an individual states an interest in getting laser eye surgery, an initial meeting is set up with the clinic. Some clinics break this pre-operative assessment into two separate meetings while in the vast majority of cases the assessment occurs in a single day. Clinics doing two assessment segments pre-operatively believe it gives the client a greater opportunity to digest all the information provided and to make a more informed choice. The orientation/assessment takes approximately 2-2 ½ hours and the client is brought through a series of different stages. In most cases, clients have the option of receiving information to review beforehand to see whether they are interested in pursuing laser eye surgery.

In terms of client screening, the client is given an appointment at the clinic where the details of laser eye surgery are discussed and the potential clients are asked if they have any further questions based on the information they received or what they have heard. The clients receive a complete eye exam and a series of tests are conducted (e.g., corneal topography, etc.) to determine whether the client is indeed suitable for the procedure. The advantages and disadvantages of the surgery are presented to the client and this information is also provided in written form for them to take home to review. In each case, there is also a 'psychological' assessment conducted to ensure the client is appropriate for the surgery. Although this is not a psychological assessment in the formal sense of the term, it does probe the reasons the clients provide for wanting the surgery and also their expected outcome. If the expectations are too high (e.g., the client expects perfect vision after surgery or to never wear glasses for the rest of their life), the clients are often told they are ineligible for the surgery. According to those clinics we interviewed, on average between 70-90% of the clients were found suitable for laser eye surgery, with a variety reasons found for unsuitability, such as unrealistic expectations, medical background or eye-related difficulties (e.g., cornea is too thin)[25].

Several individuals may be involved in providing this information to the clients at this stage. However, in all but one clinic interviewed, the actual laser eye surgeon was involved in at least one part of the pre-operative procedure. As mentioned by one clinic representative, this "chair-time" with the surgeon is critical as it allows the client to feel comfortable with the surgeon and, arguably more important, allows the surgeon to familiarize him/herself with the client. This ensures that on the day of surgery the client, who is normally somewhat apprehensive, will not

[25]Some pre-operative assessments are conducted by the client's regular ophthalmologist or optometrist. These cases tend to occur for practical reasons (e.g., distance) or at the request of the client. However, according to those clinics interviewed, the surgeon (or technician/optometrist) of the clinic always reviews these assessments and follows through on the psychological evaluation.

meet the surgeon for the first time. In addition, the surgeons tended to be involved in conducting at least the complete eye exam during the pre-operative assessment to determine client suitability. Surgeons were less frequently engaged in discussions surrounding the details of the procedure as well as its risks and advantages. However, in roughly half the clinics interviewed, the surgeons were even involved in these areas. It should be noted that in cases where the surgeon is not involved in a specific aspect of the pre-operative process, the staff members who are involved (e.g., technician or optometrist[26]) are reportedly extensively trained and certified in the procedures employed by clinic.

Consumers should note that involvement by the surgeon can have a significant impact on the cost of the procedure. More specifically, given the high level of training involved, having a surgeon conduct the pre-operative eye examination will cost the clinic more than using an optometrist or technical support individual. Therefore, consumers should be aware when price shopping that, in most cases and certainly for the clinics that were interviewed for this project, many price fluctuations can be accounted for by the quality and extent of services provided by the actual clinic and may not be directly related to the business model (e.g., profit-taking) employed by the clinic.

If the client is found a suitable candidate for laser eye surgery, a surgery date is scheduled and the surgery performed.

3.3 Follow-up process

The follow-up procedures used by each of these clinics were identical in every case. Following the surgery, the patient was assessed immediately by the surgeon before the client left the clinic. The normal follow-up schedule was one day, one week, one month, three months, six months, and in most cases, 12 months. One clinic mentioned that a nurse would contact the patient the night of the surgery to see how well he/she was adjusting and whether he/she had any questions.

There is some variability in terms of who conducts the follow-up assessments. In one case, the laser eye surgeon conducts each of these assessments, while in most other clinics, the surgeon conducts the first few follow-up appointments (e.g., 1 day and 1 week) and then hands the rest over to either a technician or an optometrist specializing in laser eye surgery. As mentioned by one interviewee, having the surgeons extensively involved in the follow-up appointments was not an effective use of the surgeon's time or expertise as it introduced unnecessary costs into the system as the follow-up appointments were quite basic to administer. However, that said, this individual noted that the surgeon was always available should complications arise or discrepancies occur during the examinations. In those cases where the surgeon does not

[26] Optometrists are health care practitioners who diagnose, treat, manage, and prevent diseases of the eye and visual system and related structures. Ophthalmologists, on the other hand, are physicians (e.g., doctors of medicine) who specialize in the medical and surgical care of the eyes and the visual system in the prevention of eye disease and injury and are licensed by the Royal College of Physicians and Surgeons.

conduct the follow-up appointments, the surgeon may be consulted and brought back in should complications arise or if explicitly requested by the patient. Patients are also generally given access to a pager number or hotline number that they can contact 24 hours a day should they have any questions.

In only one of the clinics interviewed was the surgeon not involved in any of the follow-up appointments. In this case, a trained optometrist was involved and only consulted the surgeon and brought him/her in when it was required. Patients have the options to have their follow-up care performed by their own eye care specialist and there are many reasons given for this choice (e.g., patient lives in a remote location and cost and commuting time makes it expensive and exhausting).

In terms of most commonly occurring questions asked during the follow-up appointments, patients tend to want to know what types of activities they are allowed to engage in following surgery. Although this information is always provided in writing before surgery, according to the clinics that were interviewed, patients take advantage of the opportunity to discuss this with their surgeon/specialist following surgery. There are also several questions asked about the side effects experienced and the length of those (e.g., dry eyes, swelling, etc.), although the clinics interviewed mentioned that this information is discussed in-person before the procedure and is commonly included in their clinic brochures.

3.4 Fee payments

For each clinic that was interviewed, clients had to pay for the surgical procedure on the day of surgery. In only one case were clients asked to pay for pre-operative assessment, but this was deducted from the cost of the surgery should the client be deemed suitable and choose to proceed. Consumers need to keep payment scheduling and arrangements in mind when visiting different clinics as there is a wide variety of payment practices. For example, in the case where the pre-operative assessment costs money up-front, this may restrict a client's ability to "window shop" at various other locations as this money would be lost at the outset. Another clinic mentioned a similar practice of receiving payment for initial assessment, but noted that this money was refunded should the client not proceed with the surgery. The lesson to be learned from this segment is that payment arrangements and the consequences of different types of assessment outcome should be clarified by the consumer *before* undergoing the assessment.

There are many payment options. Consumers must be aware of these arrangements and actively investigate what services (e.g., follow-up) these payments cover. For example, several clinics include the cost of the procedure in one lump sum payment that is due on the day of the surgery. This cost will cover the pre-operative assessment, surgical procedure, as well as follow-up care. Others will provide a tiered payment structure which allows clients the option of paying for the surgery alone, as well as a "deluxe" option that includes follow-up care, which is obviously more expensive. Consumers should think about their own expectations and desires when

considering payment options as these have an ultimate impact on what is covered by the cost. For example, an important question for consumers to ask themselves is how well they feel they are prepared to handle the outcome should they have post-operative complications but decided against purchasing follow-up services at the time of surgery. Follow-up appointments and "touch-ups" can be very expensive so consumers should balance their desire for being financially responsible with the burden of ensuring appropriate care for their eyes[27]. As stated previously, cost is invariably tied to features surrounding the delivery of the service. For example, clinics that use technicians or other eye care professionals (e.g., optometrists) to conduct pre-operative assessments and follow-up care will be able to charge a lower fee than those providing all of these services by the surgeon. Thus, consumers should educate themselves about what is exactly covered in the cost of surgery and what the implications are of these choices and their comfort with the potential risks involved.

Many of the clinics make explicit what additional costs the clients will incur following surgery. These tend to include eye drops (to moisten dry eyes) as well as the steroid medication patients may need to take to quicken the healing process. In addition, follow-up care may cost extra if clients choose to separate the two at the outset. Consumers should note that although some clinics provide payment options and delivery schedules within a written contract, others do not include such information. It is to the advantage of the consumer that the services covered be set out in clear terms in a written contract.

As mentioned previously, in the vast majority of cases according to the clinics we interviewed, the price of the surgery is directly related to the quality of services provided. More specifically, more "chair time" with the surgeon inevitably increases the cost of the surgery. As one interviewee noted, it is amazing what consumers will put up with to save a couple of hundred dollars. Are consumers willing to put their trust in someone other than the surgeon to conduct the pre-operative assessment as this is a critical stage in determining client suitability? This is an important question for consumers to consider.

It should be noted that according to most of the clinics interviewed, if the client chooses that their eye care specialist conduct follow-up care and if the client paid for this service up-front, those follow-up fees would be reimbursed to the client.

3.5 Sources of clients

Each of the clinics was asked how they advertised and marketed their services and which source provided most of their present clients. Overall, clinics reported using a variety of methods including television advertisements, newspaper advertisements, billboards, yellow pages, flyers, and attending various community events such as wellness fares, etc. The most

[27] As will be discussed in section 4.7, the lack of follow-up treatment arrangements can have implications for provincial health care costs, especially as the number of surgeries conducted grows.

commonly mentioned marketing approaches listed were given by each clinic and included word-of-mouth advertising and referrals from local eye care specialists. In fact, in several cases, clinic directors and surgeons mentioned the importance of advertising, but stressed that the majority of their cases came either from referral or through word-of-mouth promotion. The most successful alternate approach to this was found to be face-to-face meetings at booths set up at local fares or shopping centres where questions could be answered "on-the-spot".

An additional concern for clients relates to optometrist referrals to laser eye clinics. More specifically, some optometrists have co-managing partnerships with laser eye surgery clinics whereby if they refer clients to a particular clinic and conduct the pre-operative assessment or post-operative follow-ups, they will receive payment for services rendered. Therefore, if consumers are referred by their optometrists to laser eye surgery clinics, they should ask for clarification of the relationship between the optometrist and the clinic. Although the majority of these cases may be more beneficial for the consumer due to continuity of care and increased trust in their regular optometrist, there can be potential for concern where optometrists are earning commissions as a function of their clients' involvement in laser eye surgery.

3.6 Standards/regulations governing their practices

Each of the clinics mentioned that there were currently no federal standards or regulations that governed their industry. In fact, the only federal agency that was involved in any capacity in terms of guidelines was the Medical Devices Bureau of Health Canada and their role is to officially licence the lasers that can be used. It should be mentioned that one interviewee noted that the number of lasers certified in Canada far exceeds the number of certified lasers in the United States. Another interviewee critically stated that Health Canada does not even have a list of certified laser eye surgeons in Canada.

The clinics acknowledged that they were governed by their own provincial College of Physicians and Surgeons. However, there is a great deal of variability reported across each of these bodies, with some such as Manitoba and Alberta[28] having or developing specific standards and guidelines whereas others having more roundabout or global guidelines or standards[29]. Each interviewee made it clear that surgeons were bound by their medical code of ethics and that absent ongoing regulation, these clinics closely police themselves. However, this lack of federal regulation and provincial control should make consumers wary, as the provision of laser eye surgery services does not fall within the traditional auspices of the Canadian health care system.

[28]Alberta recently began an extensive consultation process to develop specific standards for the laser eye surgery industry

[29]See section 5 on regulatory bodies for an examination of these differences

This point was raised by one of the interviewees as well. More specifically, he mentioned that consumers tend to feel that since laser eye surgery is, in fact, a health care service, it is tightly regulated by the federal government in the way that other health care services are. Individuals are often shocked when informed to the contrary. For example, one individual who called The Action Group to request a survey mentioned how he was appalled that there was no federal governance of this industry and stressed how he never would have proceeded (despite the fact his surgery was successful), if he had known. In this age of increasing privatization of health care services, consumers must arm themselves with adequate information and not trust implicitly in the inner workings of the system (see Section 6).

3.7 Professional development practices

Interviewees were also asked to discuss the professional development protocols they had in place for both their clinic and their surgeons/support staff. There was a wide range of procedures used, and all of the clinics used some combination of the following:

For the surgeons, clinics reported that:

- the surgeon regularly attended academic and professional conferences, both national and international that focussed on laser eye surgery and its delivery;
- they subscribed to relevant academic journals and professional publications which were circulated to staff;
- they have arrangements for laser company representatives to conduct skills seminars on site; and,
- they possess video/audio material relating to equipment usage and maintenance.

All support staff, including technical support specialists, nurses, and/or optometrists were all trained in laser eye surgery techniques and procedures and were mandated to attend professional development seminars and conferences as well as part of their employment contracts. These individuals also had access to the reference material (e.g., journals, videos, etc.) that were used by the surgeon.

According to the clinics that we interviewed, although there are no federal regulations regarding the maintenance and upkeep of equipment, the clinics closely police themselves on this issue. Each interviewee noted that the microkeratome blade was replaced following each surgery, and several individuals mentioned that this is not always the case in the industry, a potential concern for consumers as noted in section 1.3. Some clinics also tested their lasers on a random basis, while others performed tests and recalibrations following each procedure. Again, consumers should be prepared to ask clinics about quality assurance procedures that are used to ensure maximum client safety and equipment performance. One clinic noted that it sends in various readings from the laser to the parent company in order to have quality assurance conducted

there while still another mentioned that a laser company representative would be scheduled to come in regularly to check the status of the equipment. Again, consumers should be cautious and ask clinics to describe their internal quality control mechanisms in detail and not be afraid to voice their concerns or demands.

3.8 Major challenges facing the industry:

Interviewees were also asked to comment on what they felt were the major challenges facing the laser eye surgery industry in Canada[30]. As the responses received to this question were necessarily limited, these will be rank-ordered in frequency of reporting by the interviewees. Numbers in parentheses indicate the number of clinics raising the issue:

(4) Patient education - Although this is certainly related to managing unrealistic consumer expectations from advertising (see below), it is a little broader in scope as clinics emphasized consumers need to be more aware of laser eye surgery in terms of the procedure, the risks/advantages, and the probable outcomes. As one interviewee noted, "this is a surgical procedure and there are inherent risks involved. Clients need to be more aware of those and understand their implications." Similar cautions are widely posted on web sites regarding laser eye surgery.

(3) Manage unrealistic consumer expectations from advertising. It was mentioned that many advertisements for laser eye surgery provide unrealistic expectations for clients and clinics always struggle with how to lower client expectations to a reasonable level so they will not be disappointed. Another example provided by an interviewee was that some consumers are better candidates for the procedure than others yet both have the same expectations. A counter example also classified under this category was the case of the consumer who has unrealistic fears and concerns about the procedure given negative press.

(3) Improved performance/safety - This was stressed in terms of the technological/equipment side of things as well as procedural aspects of service delivery.

(1) Re-establishing reputation and trust with clients - One interviewee mentioned that the current downturn in the laser eye surgery industry was due to several "greedy" individuals who infiltrated the market during the early stages and "cut corners" in order to maximize profits. Although these companies are now, for the most part, out of business, the effects of these experiences continue to negatively impact the industry. As he mentioned, the biggest complaint generally received from consumers related to the customer service side of things, and not the procedure or its effects.

(1) Developing a set of national standards - Although this was only explicitly mentioned in this section by one interviewee, the majority of interviewee candidates lamented the lack of federal

[30] It should be noted that one interviewee was not asked this set of questions given time constraints.

guidelines in the industry throughout the interview. The interview candidate who did discuss this under this section said not only are standards required but they also need to be enforced. This individual suggested the development of a quality control protocol similar to that used for optometrists where there is substantial in-field monitoring. More specifically, teams of optometrists visit neighbouring clinics and conduct audits of patient charts and files. This state of affairs would be invaluable for the laser eye surgery industry to ensure it is maximally effective for clients. These standards would also provide tremendous benefit to the service providers themselves as they would ensure the ethical and professional treatment of consumers within the industry, which would reduce negative outcomes so commonly reported in the media and increase client willingness to participate.

(1) Economics - This concern was mentioned by one clinic, but ironically, it was the first one mentioned in that clinic's list and may reflect the profit-driven nature of the laser eye business or the intense competition found in the region. The interviewee stated that given the recent downswing in the economy, people are more nervous about spending money on a more cosmetic procedure than they were previously.

3.8.1 Problems with night vision

Considering the amount of attention given to night vision problems encountered by clients of laser eye surgery following the procedure (as noted in Section 1.2), the interviewees were asked to comment on this question. There was unanimous agreement that the primary problem that contributed to this outcome was inappropriate client screening. Although several clinics acknowledged that night vision problems may occur, they were seen as a very small percentage of clients, and becoming rarer given more modern techniques. Each clinic felt that the problem had been exaggerated and when night vision problems do occur, they can be addressed by further surgery, for the most part. One interviewee also linked this problem with the quality of the laser used to perform the procedure.

Despite this level of agreement, the interviewees took a variety of different stances to support their contentions, including:

- One interviewee did acknowledge that limited night vision is a potential problem, but argued that there needs to be balanced coverage regarding the extent of such cases;
- One interviewee stressed the importance of the actual surgeon performing the pre-operative exam. He argued this type of inappropriate screening would be significantly reduced if the surgeon were to conduct the assessment;
- Two clinics presented statistics concerning night vision problems, with one interviewee stating 0.8% experience night vision problems while the other claimed 2%. However, the veracity of these claims must be seriously questioned given the large numbers of consumers who reported night vision problems in the present survey and other clinical reports (see sections 1.2 and 4.3.2.)

Reports claiming that a high percentage of patients suffer from this side-effect were, however, attacked as methodologically flawed by the interviewees, who stated that they were based on surgeries that had used old technology. In addition, one interviewee mentioned that although there were statistically significant reductions in night vision quality as measured by highly sensitive assessment tools, she argued these differences would not be noticeable for the consumer.

3.8.2 Unfair criticisms of the laser eye surgery industry

Interviewees were also asked to provide the single most unfair criticism they had heard lodged against the laser eye surgery industry. Once again, as the number of responses generated this question were necessarily limited given the small number of clinics, the results are rank-ordered by frequency:

(2) Procedure is unsafe - One interviewee in particular took exception to this claim and argued that Health Canada recognizes laser eye surgery as a safe, effective, permanent procedure.

(1) One interviewee replied that although he did not necessarily feel that the criticism of laser eye surgery (e.g., night vision concerns, itchy eyes, etc.) was unfair, he felt what was unfair was the biased coverage given to the topic in terms of negative press. He strongly felt what was needed was a more balanced approach where both positive and negative experiences were presented.

(1) Lumping all surgeons under the same umbrella - One interviewee noted that it is grossly unfair that problem cases are interpreted as a procedural problem as opposed to a surgeon problem. This individual stressed that individual surgeons engage in very distinct practices and the vast majority of problems should be attributed to the surgeon and not the procedure.

(1) Night vision/glare - Interviewees felt this was unfair as conclusions are based on outdated studies that tested old procedures. Furthermore, it was pointed out that these studies had several significant methodological flaws.

(1) Unfair criticism by fellow eye care specialists - One interviewee stressed that laser eye surgery is unfortunately seen as a "cash cow" by many professionals in the industry (e.g., optometrists and ophthalmologists). This individual noted that surgeons make a very small percentage, much less than they do for performing cataract surgery. This state of affairs is compounded by the fact that there are tremendous overhead costs for equipment purchasing, maintenance and facility acquisition.

(1) Clients feel laser eye surgery is too expensive as there are several "discount" centres that offer the service at a considerably lower rate. However, this individual stressed that in order to make the business profitable or even stay 'afloat', the volume of clients that must be processed under this "discount" model is significant. Thus, if a surgeon is conducting twenty surgeries in an afternoon, corners necessarily need to be cut and pre-operative assessment and post-operative

care will have to be compromised to compensate for this significantly reduced rate. This individual noted that many clinics have closed as a result of offering "bargain basement" prices to consumers, and have left consumers "in the lurch".

3.9 Consumer Issues from the Service Providers Perspective

As set out in Section 1.4, there are several key consumer protection issues facing the sector today. However, given that this was a nonrandom sample of clinics that are clearly not representative of laser eye clinics across Canada, an in depth exploration of these issues was not possible. However, in the vast majority of cases, the clinics we interviewed did not engage in questionable business practices. A review of the marketing material for several of these clinics (both hard copy and Internet-related) showed that there did not appear to be any potentially unethical marketing practices (e.g., 2-for-1 deals and the like).

The most problematic consumer issue uncovered in this section was bankruptcy protection. When clinics were asked what measures were in place to protect consumers from such an event, either procedures were non-existent or the clinic would state that they were on solid enough footing financially not to worry about that, although recognizing the limitations of this stance. Another clinic mentioned that although formal procedures were not in place to deal with such an event, the surgeon made a pledge to clients (as he had a private practice himself offering services other than laser eye surgery), that he would take care of them should anything occur. Notwithstanding, consumers should ask potential clinics to discuss their contingency plans frankly and how they will be protected in case of clinic closure. This is essential to long-term client care and given the costs and risks associated with the surgery, as well as the uncertainty of long-term effects, clients should ensure that they know to what extent they are covered by the clinic. They should not settle for something until they are satisfied and have in writing a clear statement of the coverage they will receive. Some provincial or federal regulation is likely necessary to ensure contingency plans are in place. Consumers should also be encourage to ensure they have adequate disability insurance (see section 4.7).

4 Client Perspectives on Laser Eye Surgery: Insight from under the Laser

Sections 4.1 and 4.2 outline the characteristics of the individuals surveyed or interviewed, while subsequent sections address substantive issues raised in section 1.4

4.1 Sample characteristics: demographics

In all, 82 surveys were received in response to email requests for participation, Internet postings and newspaper advertisements across Canada in the five-week data collection. Of these, four surveys (5%) were discarded as unusable because the respondent indicated the laser surgery was to remove cataracts or to repair an injury. The ineligibility of these responses was clear in that respondents indicated the work done was covered by provincial medicare and therefore cannot be considered to qualify as a discretionary medical procedure[31]. Approximately 30 additional respondents to the newspaper advertisements were contacted for potential interviews, of which 20 were eventually conducted. Others either demurred, preferring to complete the written survey, or finally withdrew after having had to cancel several scheduled interview times. Two individuals contacted indicated they had undergone cataract surgery and thus were deemed ineligible. Consumer perspectives in this report therefore reflect the views of just under one hundred (98) Canadian clients of laser eye surgery.

Only one individual among all those responding to the advertisements indicated that he had signed up for, but had not yet undergone, the surgery and only one other indicated that she had thought about but decided against laser eye surgery. There are a variety of reasons why both groups might be so under-represented[32]. Given the sharp decrease in popularity of laser eye surgery in the past year noted in section 1.3, the waiting time for surgery has been reduced significantly so that the window of opportunity to garner input from the former group has shrunk. Psychologically, it may also stem from a reluctance to participate in a survey which may raise questions about the safety or advisability of the procedure once the individual has committed to that procedure[33]. In the case of those having decided against the procedure, it is possible that the advertisements as worded did not catch their attention or they thought they might be

[31] This was in spite of clear instructions regarding who was eligible on the first page of the survey, see Appendix A.

[32] The two isolated responses were considered qualitatively, but excluded from the quantitative analysis, leaving 96 respondents for most analyses

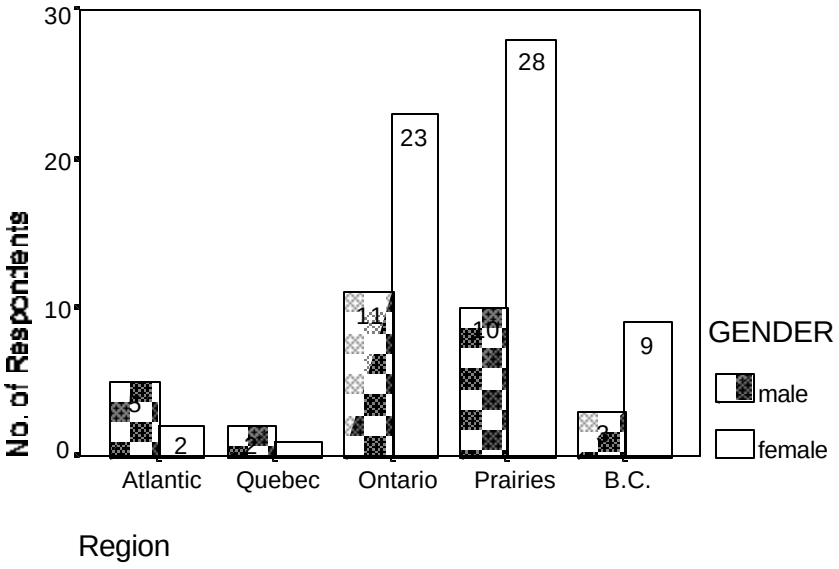
[33] German action researchers have shown that individuals enter into a project initially with a deliberative mind set in which all factors, good and bad are weighed, but that once a decision has been made to proceed (moving to an implemental mind-set) the tendency is to avoid disconfirming evidence and focus on the positive aspects. (See Gollwitzer, P.M., Heckhausen, H & Steller, B. (1990). Deliberative and implemental mind sets: Cognitive tuning toward congruous thoughts and information. *Journal of Personality and Social Psychology*, *59*, 1119-1127.)

ineligible. Likely it stems from the fact that having definitively decided against the procedure, it no longer registered as topic of interest and thus they were not motivated to enquire about participation. Such a sample would likely have to be targeted in a separate data collection using different methods of access.

For the sample as a whole, gender, age and education are set out in Table 4.1., while regional representation (by gender and age) is graphically represented in figures 4.1.1. and 4.1.2. The preponderance of female respondents is very typical of written surveys, with women very often more willing to take the time to respond. The lack of any participants under 20 reflects the fact that, from the outset, laser eye surgery has not been recommended for those under 18, given the probability of prescription change[34]. Similarly the paucity of individuals over 60 is likely a reflection of conservatism in the face of new, discretionary procedures among the elderly as well as the fact that fewer individuals of that age are or were considered in the past to be good candidates for laser eye surgery.

Figure 4.1.1.

Regional Representation (by Gender)



[34] Although there are some indications this may be about to change. See Davidoff, J.M. (2000) *Journal of Cataract and Refractive Surgery, 26*, 1567-1568.

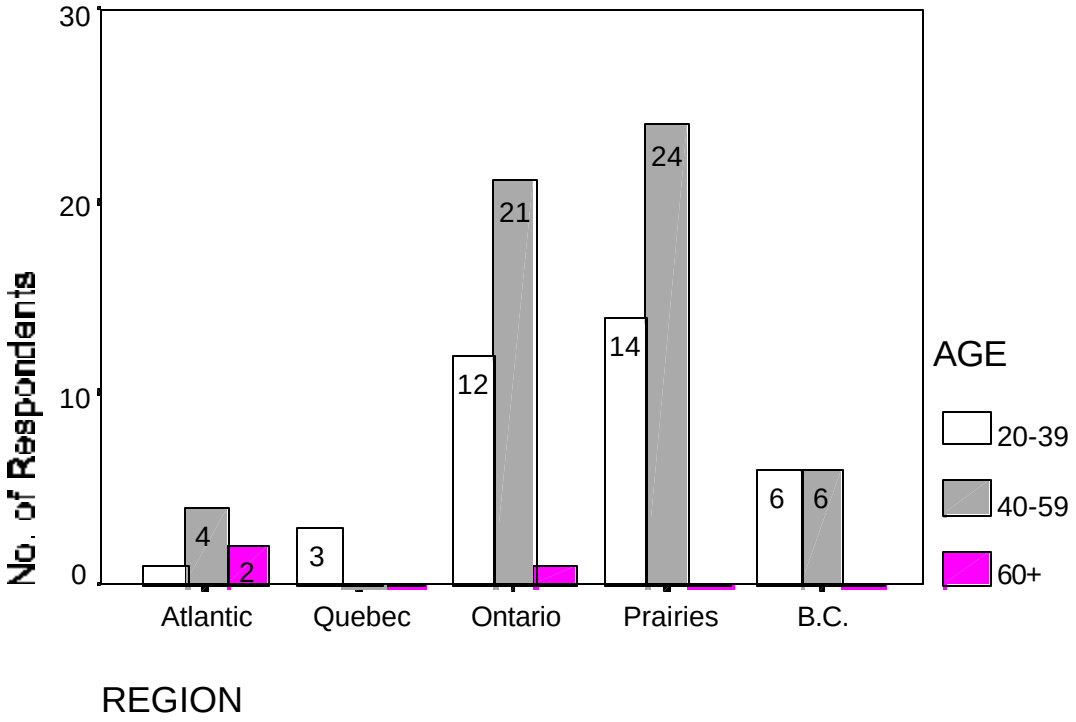
Table 4.1.
Client sample demographics

	Survey Sample		Interview Sample		Total	
Gender		*%*		*%*		*%*
Male	22	29	9	45	31	32
Female	52	68	11	55	63	66
Unspecified	2	3	0	0	2	2
Age						
20-39	27	36	0	0	36	38
40-59	44	58	9	45	55	57
60 and over	3	4	11	55	3	3
Unspecified	2	3	0	0	2	2
Education						
Grade school	2	3	1	5	3	3
High school	28	37	2	10	30	31
College/ Vocational School	10	13	4	20	14	15
University	20	26	10	50	30	31
Graduate/ Professional	13	17	3	15	16	17
Unspecified	3	4	0	0	3	3

Careers among the respondents were diverse, including several farmers, accountants, homemakers, secretaries, nurses, tradesmen, civil servants, journalists, as well as a family physician, a lawyer, a fisherman, and a TV cameraman, to name a few. In general, from a socio-economic perspective, the sample seemed to tap a wide range of Canadian consumers.

Figure 4.1.2.

Regional Representation (by Age)



4.2 Sample characteristics: what, when and how?

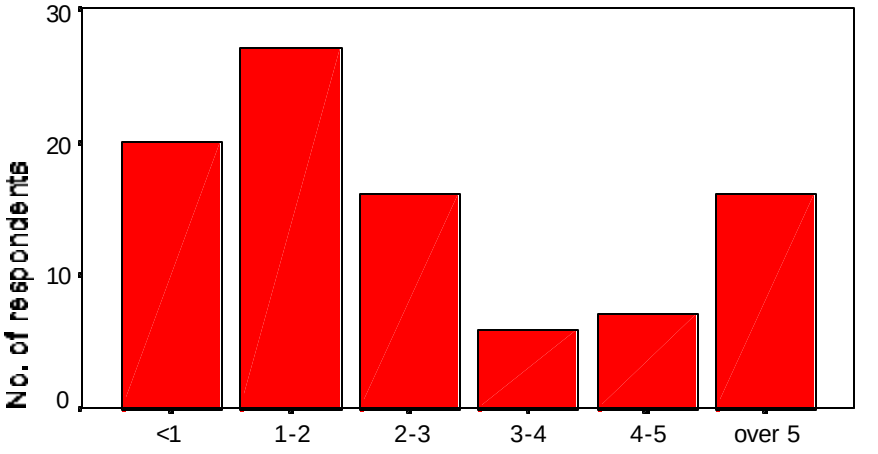
By far the majority of respondents underwent surgery because of myopia (63%) or myopia and astigmatism combined (27%). The remainder were treated for hyperopia, astigmatism or a combination of both. Two did not indicate the presenting problem. Of the 96 respondents, 66% and 26% were treated using LASIK surgery or PRK surgery, respectively. 2 individuals (2%) had RK surgery and the remaining 6% either did not know or did not specify the type of surgery they underwent. Figure 4.2.1 shows that respondents in this survey included individuals who had surgery relatively early[35] right up to the month prior to the survey. The majority, though, were in the past three years. Clearly, individuals who had just had surgery would be more cued to the issue and thus more likely to respond to the advertisements. Year of surgery is an important factor to consider in interpreting the results as the sector has grown and changed and practices that were common early in the 1990s may no longer be the norm.

[35] As early as 1992, in fact.

Figure 4.2.1

When was Surgery Performed?

92 responses



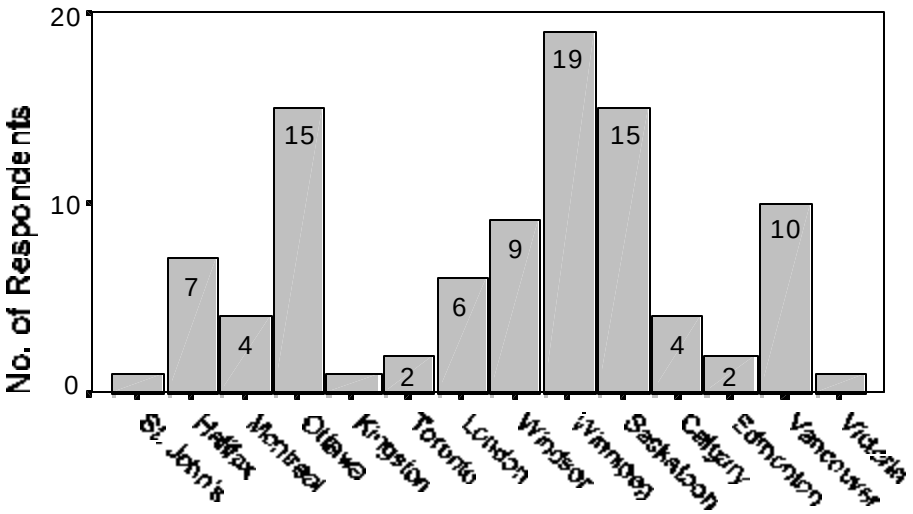
Respondents indicated that surgery was performed in 14 different cities across Canada, with the majority undergoing surgery in Ottawa, Winnipeg, Saskatoon and Vancouver. This distribution is a reflection of the necessarily limited advertising that was done across the country. The fact that the largest number of respondents were from Manitoba (and therefore had their surgery done in Winnipeg) reflects the fact that Manitoba was selected to also provide rural input into the survey (see section 2.3). It is not clear why so many Saskatoon residents responded, given that advertisements there were run for only two weeks, less than in many other cities. What is central for the purposes of this study is that respondents underwent surgery in variety of locales (see Figure 4.2.2.)[36]. Nine laser eye service providers across Canada did 64% of the surgeries reported by participants, with 31% performed at one of two well-known clinics.

[36] Toronto was not targeted due the very high cost of advertising in that region.

Figure 4.2.2.

Where was Surgery Performed?

96 responses



4.3 General Satisfaction with Laser Eye Surgery

Of the 93 participants answering the question, 83 (89%) said they would have the surgery again. This is very close rates reported in the media, of between 90 - 95% satisfaction[37]. Among the laudatory comments were such endorsements as:

- laser eye surgery is one of the best things people can have to enhance their quality of life (Ontario respondent)
- best money I ever spent (B.C. respondent, Ontario respondent)
- best thing I ever did. Should have done it sooner. 100% satisfied (Manitoba respondent)
- would tell anyone to have this. Definitely would do it again (Saskatchewan respondent).

Of the other ten participants, eight indicated they had had problems post-operatively or with service from the clinic. These problems stretched from a lack of satisfaction over the results prompting secondary surgery to significant loss of vision.

[37] For instance, Kent, D.G. (2001). How successful is refractive surgery? See http://xtra.co.nz/health.

- since the surgery, I can only see enough to get by. I have chronic headaches and eye irritation. My night vision is poor. It is hard to read and my activities are limited.
- [I was] bullied by the surgeon...staff were uncaring and was not told the truth about complications.
- would never have elective eye surgery done again.

While the number of dissatisfied clients was too small to derive statistically significant differences relating to cost of procedure or time of surgery, there did seem to be a trend towards fewer dissatisfied clients in more recent years. This may reflect improvements in the sector, with less reputable clinics going out of business, or, improved techniques, as some supporters of laser eye surgery maintain, but it may also reflect the fact that those who had surgery more recently and who are still experiencing side-effects may be more hopeful that they will abate soon.

Not all 83 respondents who would have the procedure again would do so in the same clinic. Seven individuals said they would go elsewhere, noting that they were having problems given the clinic they chose had subsequently gone out of business and they could not get their records. One said there had been 'bad press' on the surgeon involved. Another noted that the surgeon "treated his customers like numbers and did a poor job of explaining why one eye had poorer vision."

Even among those who would go back to the same clinic, there was some dissatisfaction expressed: "poor, sloppy, insincere service from staff"; "took three surgeries, a bit disappointing"; "shortly after my surgery, the clinic dropped the price by 50% but did not compensate me." "Both eye clinics in town have closed. A bit unsettling.". Overall then, experiences run the gamut from exhilaratingly life enhancing to tragically life changing.

Figure 4.3.1

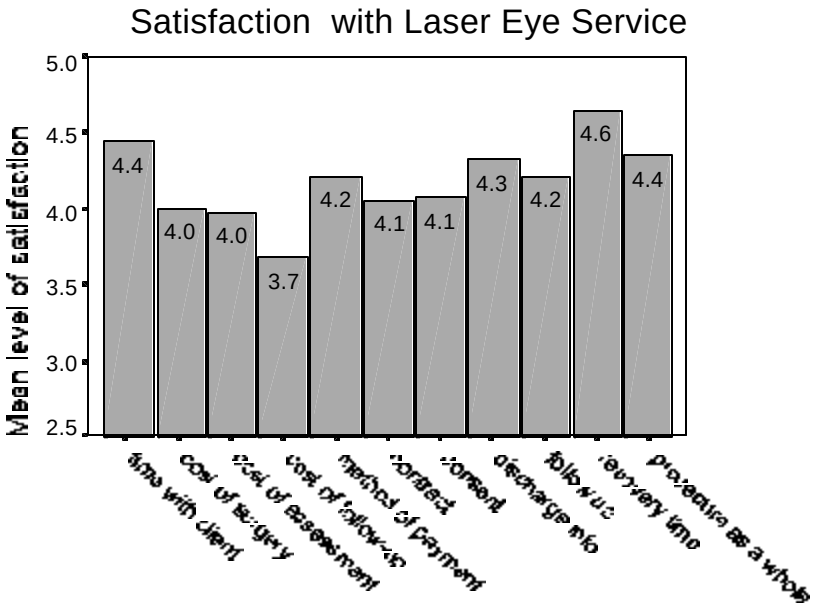


Figure 4.3.1 presents graphically levels of satisfaction with various aspects of the laser eye surgery experience. Again it is clear that most respondents were very satisfied with most aspects of the process; satisfaction with follow-up cost was the only item noticeably less enthusiastically endorsed. This may be as a result of lower satisfaction among those who paid separately for follow-up.

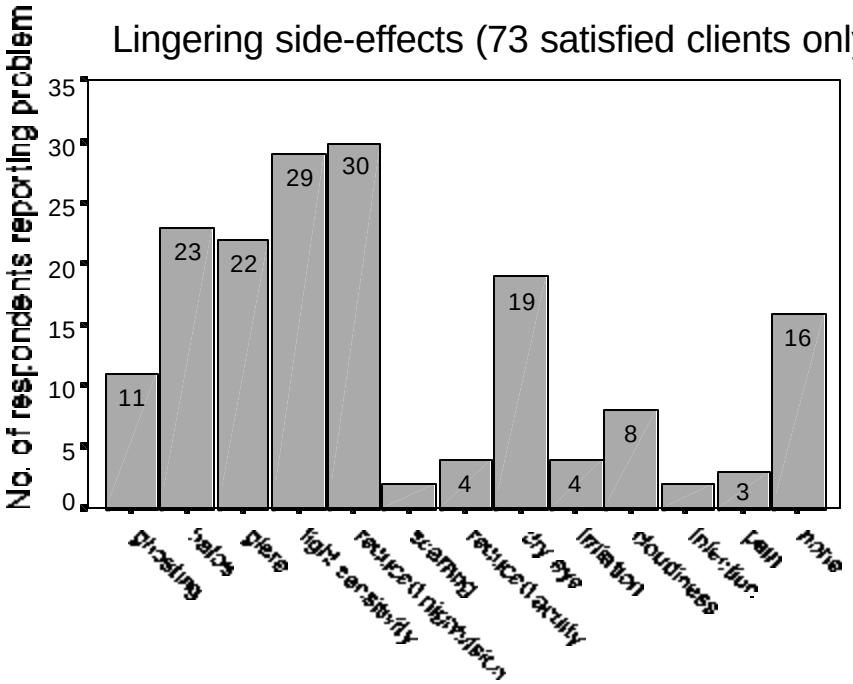
Taking the both comments and ratings of respondents into consideration, it seems clear that laser eye surgery is meeting the needs of many Canadian consumers, who are happy with the service, the results and procedure involved. However, even if we describe the consumer view as approximately a 90% satisfaction rating based on a stated willingness to have the procedure again, is this adequate when even some of the remaining 10% have had their lives severely limited, by their own account? The consequences of an unsatisfactory outcome can be so devastating that everything that can be done to minimize the chances of such an outcome must be done, by the consumer, by the clinic and by the government overseeing the process.

Perhaps most surprising to the researchers on this project was the extent of the symptoms that individuals reported three months (+) post-operatively. In figure 4.3.2 (next page) we see that only 16 of the 73 satisfied clients, who would do the surgery again (and who had their surgery more then 3 months earlier[38]) reported no lingering symptoms or side-effects. Among the

[38] Any laser eye surgery patient who indicated their surgery was 3 months or less was excluded from this analysis, given that most clinical reports suggest that side-effects are to be expected during this period.

remaining 78% of satisfied clients, the most common side effects still occurring were night vision problems, a finding supported in the clinical literature[39], and sensitivity to light. Many reported three or more side-effects after three months[40]. No significant differences were found in overall number of symptoms reported between PRK and LASIK surgeries or as a function of when the surgery was done[41].

Figure 4.3.2



This is not a clinical study, so we will not comment on the implications of such side-effect reporting other than to highlight the care with which high satisfaction ratings must be interpreted, particularly by individuals considering surgery. While one consumer may believe that lingering

[39] Jory, W. (2000). Findings presented at the May conference of the American Society of Cataract and Refractive Surgeons. Recently this has led the RCMP advising its members against undergoing this surgery, following the lead of many UK police and fire departments.

[40] It should be noted that while some indicated the severity of the symptom, many did not, so no information is provided in the body of this report with regard to how severe the side effects are perceived to be. Some individuals did indicate on a scale of 0 - 5, that some lingering side-effects were 3 or 4. Many indicated just a 1 or 2.

[41] A larger sample size would be required for an adequate test.

side effects such as these are a small price to pay for liberation from glasses or contact lenses, others may not agree. Consumers who ask simply 'Are you satisfied?' 'Would you do it again?' may not realize that there are trade-offs that must be judged on a case-by-case basis.

4.4 Cost

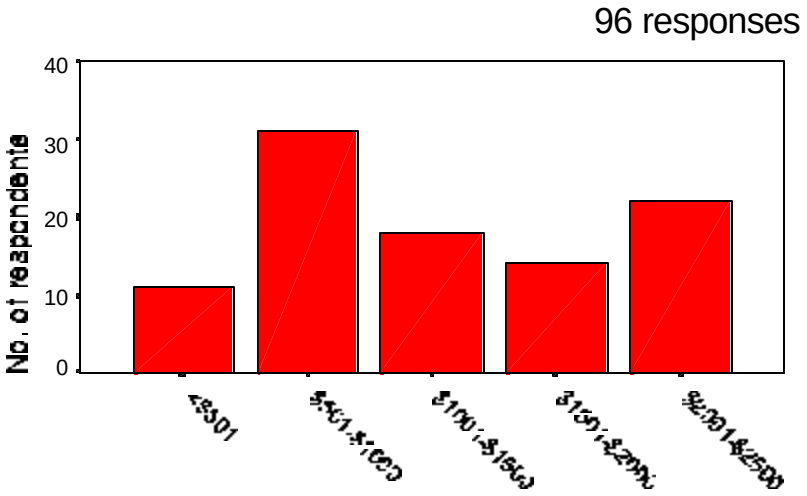
Confirming media reports that price is a major concern among prospective laser eye client, 50% of those interviewed mentioned price as one of the two or three major factors that were at the heart of their deliberations over whether to proceed or not with the surgery. Among those who indicated they felt they had no options in terms of choosing a clinic, 33% indicted the limitation stemmed from financial constraints. Clearly price *is* a major concern with many who consider laser eye surgery, but Canadian consumers are not at all used to shopping for medical procedures based on cost considerations. Are they aware of what they should be considering?

The costs of the surgery reported varied widely, from $445.00 to $2500.00 per eye (see Figure 4.4.1). However a major factor in this variation is the time of surgery[42]. As Figure 4.4.2 shows the majority of individuals who have had surgery over the past 36 months (3 years) have paid $1000.00 or less per eye, while virtually no one who had surgery earlier paid less than $1,500.00 per eye. As the graph shows; however, it is not matter of an even decline in prices, rather there has been a steady increase in the variability of price over the years. In the early and mid 1990s, prices varied by no more than $1000.00 per eye, whereas now they can vary up to as much as $1800.00. Consumers now have a greater choice, but with that choice comes the need for ensuring value for money: what exactly is included in the cost?

[42] $r = .59$, $p < .001$

Figure 4.4.1

Cost of Surgery



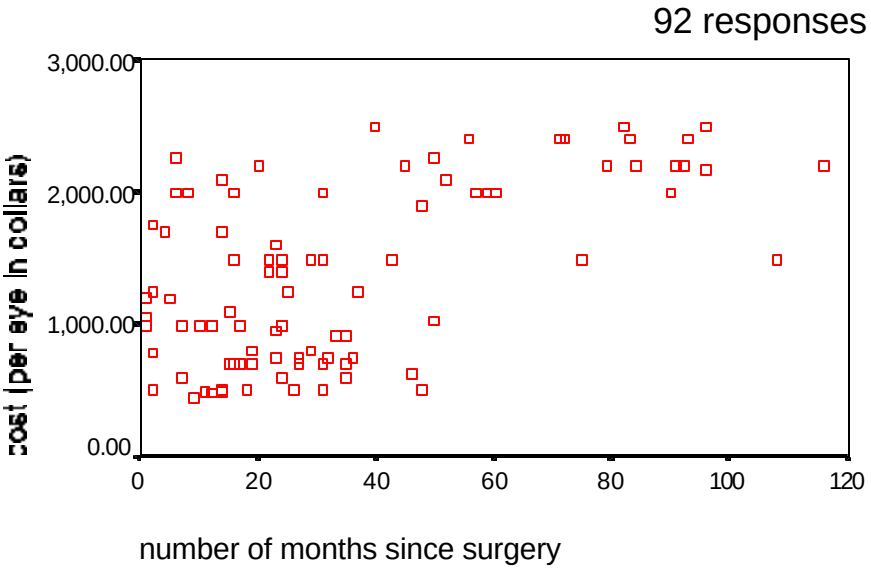
For most respondents (72%), the price they paid did include the initial assessment. Only 17% indicated it did not, with the remaining 11% not indicating either way. The overall reported cost per eye of the surgery did not change as a function of whether the initial assessment was included or excluded in the price, nor was the exclusion of assessment in the overall cost a function of when the surgery was done. Of the 17% who indicated they did need to pay extra for assessment, only ten indicated a price, which ranged from $30.00 to $400.00, with an average payment of $130.00[43].

Similarly, only 4 respondents (4%) indicted that some sort of follow-up was not included in the cost of the surgery. The extent of the follow up did vary considerably, from 2 months to an unlimited time-frame and from 1 “touch-up” to an unlimited number. The variation did not seem to be a function of cost, however, as many $2,000+ surgeries included only one free touch up or 1-2 years follow up, while many surgeries of less than $1000.00 per eye included unlimited touch-ups or indefinite follow-ups. What was not specified in the responses was who did the follow up,

[43] It is possible that some respondents confused making an initial payment on the total price at the time of assessment with actually paying for an assessment separately. These figures should therefore be interpreted cautiously both because of possible misunderstandings of the process and because of the small number of cases reported.

Figure 4.4.2

Cost as a function of time of surgery



the local optometrist or the surgeon at the clinic. There was a small but not statistically significant relationship between time of surgery and extent of follow up, with more recent surgeries more likely to offer unlimited follow-ups.

It would seem then that consumers should not assume, based on price, that they are getting more extensive follow up care. However, in deciding on where to get laser surgery, the prospective client needs to inquire not only about the extent of follow up treatments, but also who is doing those follow ups. A local optometrist is likely well suited to managing the usual post-operative symptoms and is qualified to identify problems that may develop, but if a follow up with the clinic surgeon is not included, treatment for those extraordinary problems can be expensive, both in terms of professional costs and, for many individuals who may not live in the city where the clinic is located, in terms of travel and living expenses. Twenty-one percent of this sample considered that they did have post-surgical problems with their eyes that required intervention by the clinic (not an optometrist). In only four cases was the cost covered by the clinic and in the one of those four cases where the individual had to travel out of province for the follow-up care, he was not reimbursed for travel or living expenses. In five cases the cost was borne completely by the client or the client's private insurer.

Provincial governments also need to be concerned about how follow-up treatment is managed for discretionary medical procedures, given that five respondents (24% of those indicating a problem) noted that it was provincial medicare that covered the cost of correcting their post-surgical problems. Clinics may wish to offer lower cost services for their clients (or improve

profit margins) by excluding extensive post-operative follow up guarantees and in many cases such guarantees may not be necessary; however, when the worst happens[44], is it appropriate for the taxpayer to have to bear the cost?

Given the current lack of clarity regarding responsibility for poor surgical outcome, consumers should also be careful to ensure that their disability insurance will cover their losses should they become one of the unlucky few. A spokesperson for the Life and Health Insurance Association (of Canada, LHIA) when asked to comment on whether disability insurance would normally cover such an eventuality, suggested that in most cases disability insurance would cover the losses incurred. Individual consumers should check their policies and speak to their insurance agents to determine if indeed this is the case and the extent of their coverage[45].

There appeared to be no concern among clients that they were not adequately informed about what was or was not included in the price, however, it was clear that some clients were caught off guard at the costs associated with post-surgical problems, when such arose. To a large extent guaranteed follow-up treatment with the surgeon is an insurance policy. It may not be necessary, but is it worth the risk of assuming you will not have any problems when the impact of those problems (job loss, costs of remedial surgery) can be so great? The client's ability to deal with a worst case scenario in terms of money and time off work etc., must be made clear so that their decision to go for a 'no frills package' can be informed. Alternatively some government regulation is required to ensure taxpayers are not held responsible for undue thrift on the part of consumers seeking treatment.

4.5 Contracts

Among the 96 respondents, 72% (69) indicated they did sign a contract, 25% (24) did not and the remaining 3% (3) either could not recall or did not respond. Whether or not a contract was signed was not related to time of surgery or to the cost of the surgery, nor did consumers who did not sign a contract find their laser surgery experience any less satisfying. It is striking, though, that 25% of those contacted would enter into a major financial investment without any legally binding contract. This may reflect the fact that consumers are not used to signing contracts (as opposed to consent forms) in the context of medical procedures, but it would clearly be to the benefit of all concerned if the contract spelled out the responsibilities of both parties and inclusions and exclusions. For instance, 74% of individuals who signed a contract indicated that provisions for follow-up treatment were set out in the contract they had signed. 26% indicated follow up treatment was not addressed in the contract.

[44] Among a few of the specific problems that were identified by respondents as requiring more specialized follow up were a need for cauterization of tear ducts, re-lasering due to poor vision, pain from a swollen cornea, and infections, among others.

[45] Insurance was not discussed with service providers interviewed, but consumers may wish to verify if the clinic itself has insurance to cover a poor surgical outcome and in what cases would it apply.

Most respondents who signed a contract, did so at time of surgery (56%), with the remainder signing at the time of the assessment (38%) and few at a specified time in between, once they had decided to go ahead (one month or two weeks prior to surgery, for example). Although there has been some concern expressed among those following this sector about individuals signing contracts before having had sufficient time to consider their options or decide whether they really wished to proceed, none of the laser eye clientele interviewed or surveyed indicated they felt pressured into signing or committing to the procedure. For many, the major deliberation seemed to occur before they actually approached the clinic for assessment as a suitable candidate.

4.6 Consumer Awareness: Shopping for Surgery

As noted in section 1.4, although Canadian consumers are used to shopping for cars, for houses and for a variety of services, medical procedures have traditionally been delivered through government run and therefore highly regulated avenues; for the most part diagnoses not specific services are sought. Canadians therefore have very little experience with smart shopping in this area or the complexity of issues that need to be considered. We were interested in how long they deliberated before deciding; what were the major factors that went into that deliberation; how did they research the pros and cons of laser surgery; and, once they decided to proceed, on what basis did they choose a clinic.

4.6.1 Laser Surgery as an Option for me

Respondents were asked how they came to hear about laser eye surgery. The majority indicated through newspaper ads or articles about the surgery[46], although almost as many indicted that they had heard about it from a friend or relative. Indeed, many added "friend, co-worker, relative" in the "other" column as a secondary source, along with their first choice (see Figure 4.6.1). There were many comments to the effect that individuals went ahead with the procedure because of someone close who had had it done successfully.

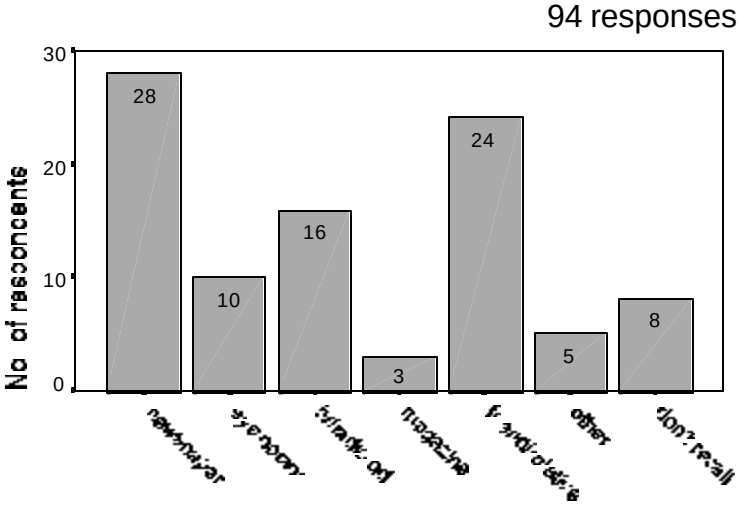
This raises the concern mentioned previously that, unlike buying a car or even most services, a medical procedure may produce very different results from one individual to the next, so consumers need to be careful in assuming that full restoration of vision for a brother or co-worker, whose vision problems may be quite different, is any indication of how things will work out for them. The industry recognizes that word of mouth is one of the major avenues for attracting customers and while it makes sense that individuals may want to go to a clinic where someone they trust has had a good experience, once they walk in the door, they need to focus

[46] Despite claims from the clinics that all press is bad, it is not difficult to find stories in the media of very satisfied clients, for example, McGrath, A. (2001). An Autumn blessing: Surgery offers second sight, without glasses and with renewed wonder at the world, *St. John's Telegram*, October 26; Strelieff, J. (2002). 'New' eyes worth few days of discomfort, *The Star Phoenix* (Saskatoon), March 19; and Knapp, S. (2001). Teen now wants to share her vision, *Calgary Herald*, December 15.

on how the procedure will affect *them*, not rely on previous success stories to increase their comfort level. In other words relying on a referral in the context of how clinic staff and surgeons treat an individual is sensible. Relying on a referral as an indication of potential success is not. These need to be clearly differentiated in the mind of the consumer.

Figure 4.6.1

Becoming aware of laser eye surgery



Among those interviewed who said they did not seek a second opinion on their suitability for surgery, several mentioned the reason was because they trusted the referring individual. “The only reason I did it was because I knew three people who were very happy with their results”. This suggests that more weight may be placed on others’ experiences than may always be wise.

The fact that so many individuals are attracted to laser eye surgery by newspaper advertisements highlights the importance of having clear regulations regarding what is and is not appropriate in advertising. Canadians are not used to seeing advertisements for medical services and are likely to judge those advertisements by different standards, given the medical context. For instance a full page advertisement in the 29 December edition of the Ottawa Citizen ran under the banner “Public Notice”. That, taken together with the average Canadian consumer’s view of medicine as highly regulated at all levels by the provincial government, is misleading. It implies official government involvement and sanction of what follows and is not consistent with the spirit of the guidelines as set out by the Canadian Ophthalmological Society, which state, among other provisions, that “advertising, promotional, and marketing activities must be truthful, verifiable, accurate, and ethical. Special care must be taken to ensure that these materials do not

mislead the public."[47] The implications of current advertising and marketing practices are discussed in greater length in section 3.

4.6.2 Deciding to proceed

Figure 4.6.2.1

Deliberating Laser Eye Surgery

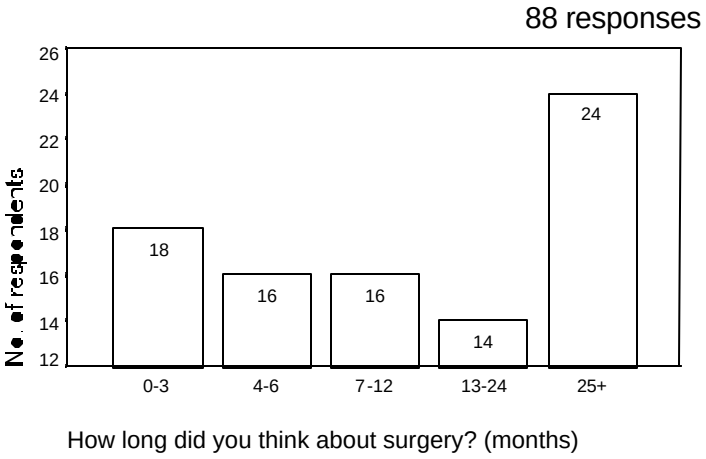
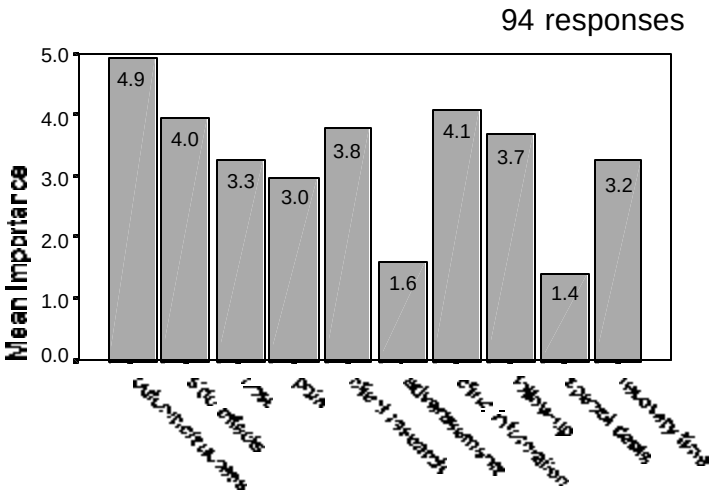


Figure 4.6.2.2

Major considerations in proceeding with surgery



[47] New Advertising Guidelines, approved by COS Board of Directors, 1994, but in Ontario, clinics are not

Data from this survey show that most consumers do not make the decision to go ahead with laser eye surgery overnight. As Figure 4.6.2.1 indicates, over one quarter of respondents actually thought about laser surgery for more than two years prior to deciding to proceed[48]. This raises the question: what do individuals consider the most important factors in making this decision? Among those interviewed, price considerations, that is value for money, was a major issue as was concern over the potential outcome. In rating how important eleven factors were in making the decision, survey respondents were clear that the likelihood of a successful outcome was the most important consideration. Indeed it was statistically significantly more important than any other consideration, including price[49]. Least important were any special deals, two for one packages or group pricing promotions and the clinic's advertising, both of which were statistically significantly less important than any other considerations (see Figure 4.6.2.2.). This is encouraging as there has been considerable concern among consumer advocates regarding such marketing practices, as noted in section 1.4., which are viewed as encouraging consumers to think that choosing laser eye surgery is little different than buying a new outfit or a new gadget. This finding does not mean, however, that such deals have no impact on consume decisions, since such deals directly influence price and price is a major factor in the decision process.

Consumers were also asked what sort of research they did when thinking about proceeding and how much time they spent researching information on the procedure and the clinic they were considering. On the whole consumers indicated they consulted on average 4 sources as they deliberated the procedure involved, with the experiences and opinions of others and information provided by the clinic being the most commonly cited (see Figure 4.6.2.3.). Least common sources of information were Health Canada or the family physician. Of concern are the few who indicated they relied exclusively on information provided by the clinic or exclusively on the recommendation of others or both. While clinics are likely to be well informed on the latest procedures and success rates, they are not an impartial source, given that they are competing for business, particularly in the recent competitive market. In terms of others' perceptions of the procedure, as noted above, these can be coloured by their own success, which may well not be relevant to the individual seeking reassurance that the procedure is right for them. As noted in section 1.3, LASIK lawsuits in the United States frequently cite inappropriate candidacy for surgery as one of the leading causes of post-surgical problems[50].

The most useful information that respondents found in their research was overwhelmingly that provided by the clinic where they were to have the surgery. Undoubtedly many clinics are entirely ethical and provide excellent information; however, even from this small sample we see

obliged to follow the guidelines set out by the COS, only the surgeons (see section 5).

[48] Unfortunately, only one person came forward who had thought about and decided against laser eye surgery, so no formal comparison can be made. That individual, who worked in a medical setting, decided against proceeding primarily because she was fearful of the risk involved.

[49] Statistical significance here is defined as likely by chance only one time in a thousand ($p < .001$)

[50] Some LASIK patients seeing lawyers, *American Ophthalmology Association News*, Dec. 18, 2000.

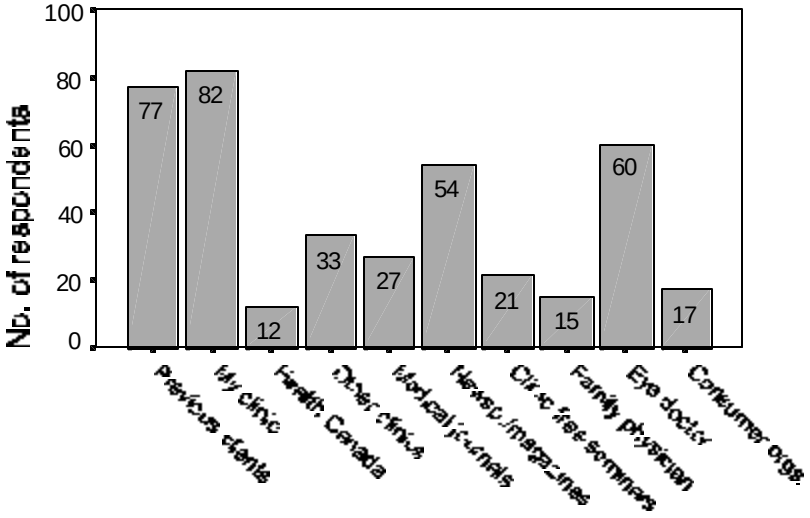
that in some cases clients feel they were not given all the information they should have had to make an informed decision:

- I was not told the truth about complications;
- I was not aware that my vision would take 1 - 3 months to stabilize after surgery;
- My recovery is taking longer than I was told.

Figure 4.6.2.3

Sources of information consulted

in deliberating on laser eye surgery



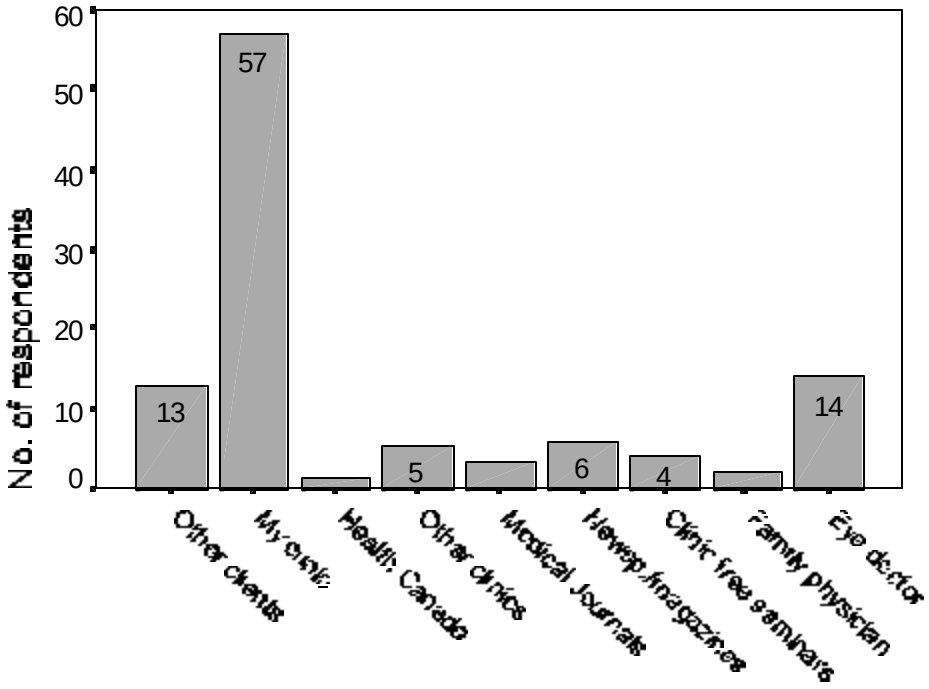
This puts a great onus on clients to go a step further in their research beyond the often extensive details provided by their chosen clinic. Even then, literature that a client may think is impartial, such as a recent best seller regarding laser eye surgery, *The Laser Vision Breakthrough*[51], may not be. In this case the author works for one of the major U.S. laser eye clinics, as did most of the doctors quoted in the book. Governments and consumer organizations need to develop and to distribute information that offers a fair and balanced view of the procedure which can be accessed by consumers for a second opinion. Such information does exist, for instance, Health Canada has a short but informative cyber-pamphlet on laser eye surgery as part of their *It's Your Health* series. The U.S. Federal Drug Administration has an extensive cite that

[51] Brint, S., Kennedy, B. & Kuypers-Denlinger, C. (2000). *The Laser Vision Breakthrough*. Prima Publishing.

deals with all types of laser eye surgery and provides extensive information regarding the risks and benefits[52]. Even some independent websites are offering unbiased advice, although it may not always be that easy to distinguish these from clinic-sponsored sites[53]. From those surveyed, however, it seems few people are aware of these and for many, the Internet is still not an accessible avenue for garnering information. For that reason the promulgation of alternative sources of information is key.

Figure 4.6.2.4

The most useful information (by source)



Some potential clients confuse regulatory bodies, such as provincial colleges of physicians and surgeons with impartial sources of information. In general these regulatory bodies do not have and do not provide such information. Some but not all will indicate if a complaint has been acted upon and a surgeon has been found to act unethically. The role of regulatory bodies is addressed below in section 5.

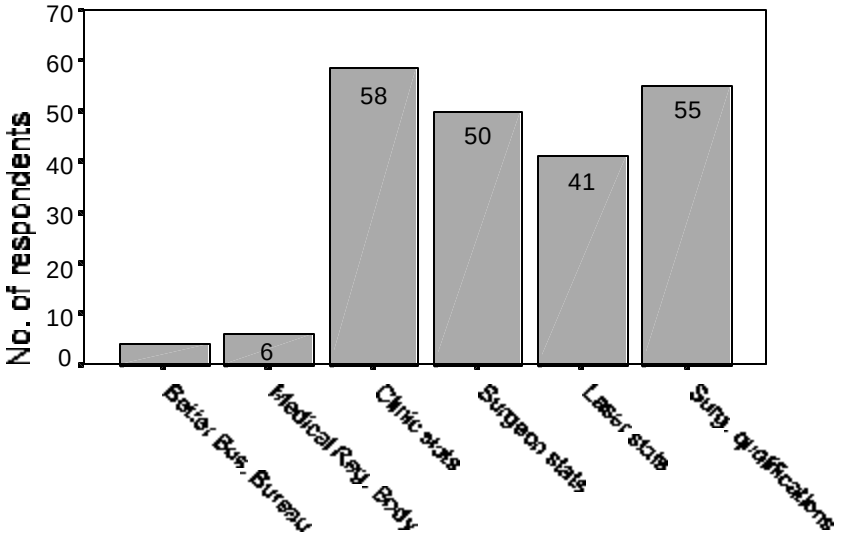
[52] www.fda.gov/cdrh/lasik.

[53] E.g. www.surgicaleyes.com, www.soyouwanna.com

Figure 4.6.2.5

Choosing a clinic and a surgeon

Information sought by prospective clients



In researching the clinic itself, the vast majority of consumers relied most heavily on information provided by the clinic. In Figure 4.6.2.5, the last four bars reflect information provided by the clinic on success and complication rates for the surgeon, the procedure and the clinic as a whole. Some respondents indicated, in the words of one, that "these were all provided without me having to ask for it", which is clearly what would be expected of a reputable clinic. That individuals ask for and get this information is laudable and should be encouraged. Nonetheless, the fact remains that except for a very few individuals who contacted the Better Business Bureau, the College of Physicians and Surgeons or their optometrist (indicated in an open "other" column not reflected in the graph), virtually all the information obtained by the consumer in order to help them decide where to have the laser surgery done was provided by the clinic wooing the individual. This is not a situation that inspires confidence in that human nature dictates that despite even the best intentions, with no oversight, slips are much more likely to happen.

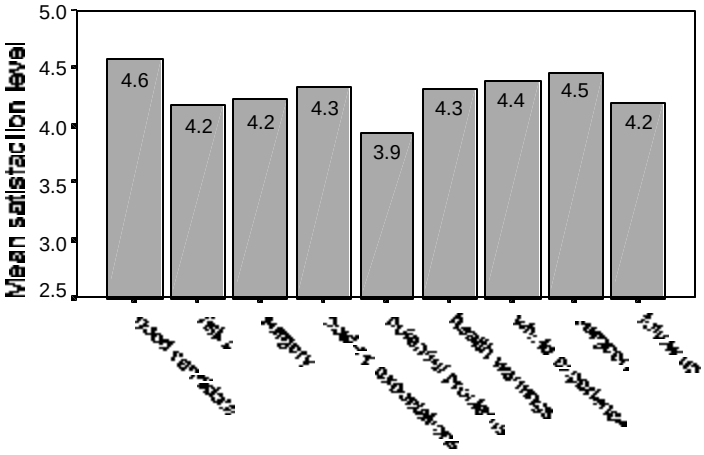
There were several unsolicited comments among survey respondents that suggest this is recognized by at least some consumers:

- unlike a garage and body shop, laser eye surgery isn't well regulated at a federal or provincial level;
- I hope [this survey] enables someone to bring in controls;
- happy to see a survey like this. [The industry] needs government regulation;

g glad to hear the Consumers' Association of Canada is interested in laser eye surgery.

Figure 4.6.2.6

Client satisfaction with information provided by clinic



Respondents were also asked to comment on how satisfied they were with the information they received from the clinic. For the most part clients were very satisfied with information pertaining to all aspects of the process, although they were significantly more satisfied with information regarding their suitability for the surgery than some other items. Clients were least satisfied with the information they received regarding what they should do if the surgery does not work out. Not surprisingly, individuals who had gone through the surgery and had problems, that is, those indicating they would not have the surgery over again if they had the choice, rated almost all categories of information provided by the clinic as significantly less satisfactory than those who would repeat the process. The three exceptions (rated similarly by both groups) were regarding information on how appropriate a candidate they were, information on specific health warnings prior to surgery and information on the follow-up procedures with the optometrist. What this suggests is that the information provided is fine as long as you don't have problems, but is not designed or geared towards those (few) who may encounter difficulties. Perhaps clinics do not wish to frighten the majority of their clients who will likely have no problems, but it does suggest that full disclosure of risks and how to deal with those risks is not perceived to be adequately addressed (see section 4.7).

Laser eye surgery clients surveyed were also asked retrospectively how much time they spent researching their options. Responses varied widely and are not easily reported given that some reported the actual amount of time spent (in hours or days) while other reported the period over which they conducted aperiodic research (in weeks, months or years). Forty-four per cent

spent less than a week researching their options, with ten percent indicting less than a day. Some (5%) indicated they did no research at all. More accessible and better known access points to independent information would help consumers spend less time and get more relevant information.

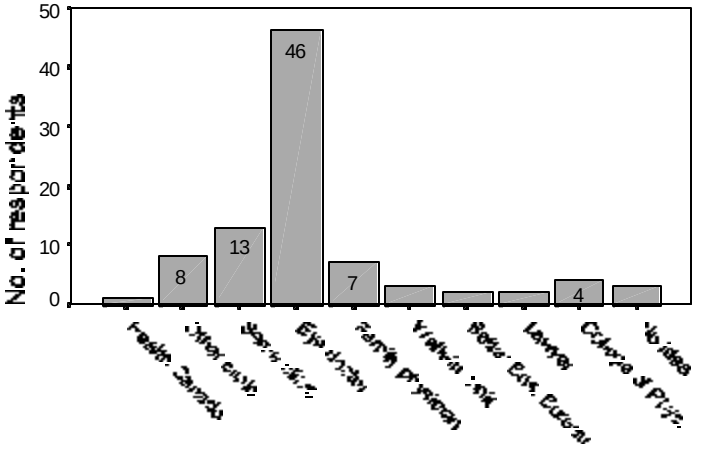
In sum, consumers need to be encouraged to seek out independent sources of information regarding both the procedure and the service provider and should be cautious in accepting all information provided by clinics as complete or comprehensive. Governments, regulatory bodies and consumer associations need to make such information more accessible and promulgate checklists and recommended procedures for researching and choosing the type of surgery and the clinic. Guidelines for exactly what sort of statistics must be provided by clinics are needed that include provisions regarding the context and 'spin' put on the data. As noted above much of the needed information does exist, but the lack of consumer awareness suggests it is not doing the good it could and should be.

4.7 What to do if something goes wrong?

Figure 4.7.1

Where would I turn if things go wrong?

89 responses



At the end of section 4.6, we noted the information given to clients about what to do if something goes wrong was rated as significantly less satisfactory than many other types of information provided. Survey respondents were asked to indicate where they would turn if they found they did have problems *and were unsatisfied with the response of their clinic*. This question was asked in an open format, but responses were easily coded into a few categories. By far most respondents interpreted the question to mean where would I go to 'fix' the problem (see Figure 4.7.1). Only very few considered where they would turn for help in taking the clinic

to task for perceived poor service. This is likely the case. If something has gone wrong medically, the immediate and overarching need is to get the problem fixed and, if serious, it is doubtful the individual may have the resources (time, energy) to both address the problem and fight the original clinic. Consumers need clear information on where to turn on both accounts: for remedial medical help and for support in making their case if the service provider was at fault.

Of concern is the fact that 15% of individuals would still go back to the same clinic even if not satisfied with the response to date. In some cases this may stem from a lack of choice, with individuals in smaller places where only a single clinic exists (four respondents noted this as a factor in choosing the clinic). In other cases it likely means that the individual does not know where else to turn. Also of concern is the fact that many of these options, as discussed in section 4.3, involve treatment that may cost either the client or provincial medicare.

In this context too, it is important to highlight the need for comprehensive follow-up care for those whose lives are seriously impacted by a poor outcome. This can involve not only medical care or remedial procedures, but psychological counselling, retraining in some cases and financial aid to offset what can be a devastating change in life circumstances. Given the profit-based nature of this sector, it seems only fair that clinics who are profiting from the successful delivery of this service should be in some manner held accountable for the minority of cases that do not go well. Impromptu support groups are developing in response to these needs[54], but in reading the stories of individual cases that have gone wrong it is clear that society as a whole is not providing the support needed in this still small but ever growing population. The alternative is to make it devastatingly clear to all clients signing up for surgery that if anything goes wrong (with graphic illustrations of just what can happen) then they are on their own. That is certainly not currently being done. As noted, in the U.S. the response has been a rise in litigation with awards as high as $1.2 million. As yet in Canada, the less litigious nature of the population has prevailed, although consumer advocates note that the 'deck is stacked against litigants' here in Canada, which may dissuade dissatisfied clients from taking legal action.

4.8 Clinical Trials

There is a fear among some consumers, waning as this surgery grows more accepted, that they may be serving as "guinea-pigs" in what some view may still be variations on this experimental procedure. It is a fact that new lasers have been introduced into Canada several years before they are approved by the FDA. Of the fifty-three individuals who answered the question relating to this issue, just over half (52%) indicted they were not part of a clinical trial, another 43% had no idea and only 4% (2 individuals) indicated they had been a part of a clinical trial, but both noted they had signed a consent form relating to the experiment. Perhaps most instructive here is the fact that most respondents did not seem to know one way or the other. New procedures and devices are continually coming on the market and clinical trials are an accepted and vital

[54] E.g. www.surgicaleyes.com.

part of medical advances, but consumers must be made aware or take the initiative to find out whether they are still experimental and if they have been approved for the procedure for which they are being used.

5 Regulatory bodies: Who is minding the store?

5.1 Federal Regulations and Guidelines

The purpose of the **Canadian Ophthalmological Society** (COS) is to assure the provision of optimal eye care to all Canadians by promoting excellence in ophthalmology and providing services to support its members in practice. The COS is recognized as the authority on eye care in Canada[55].

The COS has published a set of practice guidelines for refractive surgery which were developed by a working group of experts in the area, and approved in June of 2000 to address the clear absence of guidelines in the industry in this regard. These include suggested standards of practice for the suitability of candidates, preoperative testing, informed consent, postoperative care, training requirements for surgeons, maintenance of equipment, and reporting of adverse reactions. These guidelines are comparable with those published by provincial colleges of physicians and surgeons.

The COS suggests that suitable patients should be 18 years of age or older, have a stable refractive error, and have healthy eyes. The COS also states that suitable candidates for refractive surgery must have a reasonable expectation of success, although reasonable is not defined. They mention the success rate depends on the suitability of the candidate as well as the individual's specific reasons for considering refractive surgery. That is, success from the perspective of the surgeon, may not be the same as success as defined by the patient.

A series of pre and post-ophthalmic testing that must be completed are also outlined. The COS mandates that the patients must sign a detailed informed consent form, written in simple language, and includes the name and telephone number of the operating surgeon, the nature of the procedure to be performed as explained by the operating surgeon or investigator, the current status of the procedures as well as any possible adverse reactions.

Especially of interest is that the guidelines state that the surgery *should* be performed by a surgeon registered in the province in which they practice. Although we did not find any instances where persons other than registered surgeons perform refractive eye surgery, the guidelines do not appear to prohibit such occurrences.

Health Canada is responsible for regulating the use of medical devices, such as the lasers used for refractive surgery. However, service providers have indicated that the technology changes very quickly, and that the lasers are usually classed as 'experimental'. The technology is out of date by the time the technology meets the requirements of the regulations.

[55] http://www.eyesite.ca/english/the_society/index.htm

The **Royal College of Physicians and Surgeons** has standard guidelines and registration requirements for physicians who choose to specialize (e.g. ophthalmology). These requirements are quite prescriptive, and while they do not focus on laser eye surgery specifically, address the qualifications and continuing education of surgeons who perform laser eye surgery.

The **Canadian Society of Cataract and Refractive Surgery** is a professional association which provides continuing education for surgeons. The society holds an annual conference and publishes a newsletter to inform surgeons of recent practices and issues affecting refractive surgery. Attendance at the conference qualifies as professional development and surgeons can earn credits to be used for recertification.

Conclusions

Overall, governance at the national level is focused on certifying, providing guidance to and professional development for surgeons who perform laser eye surgery. That is, the sharing of information to improve the profession and body of medical knowledge, not to regulate the specific procedures performed by surgeons. This is consistent with the regulatory framework of the health care system in Canada which places responsibility for regulating health care practices at the provincial level.

5.2 Provincial Regulations and Standards by Provincial Colleges of Physicians and Surgeons

Regulations vary widely across the provinces. The provinces of Newfoundland and Prince Edward Island and the three Territories do not have provincial/territorial colleges to govern laser eye surgery. In the Territories and Prince Edward Island, this is not a major concern because there are currently no clinics operating there. In Newfoundland, however, there is one laser eye clinic and an associate with The Action Group was unable to find any documentation regarding how the industry was regulated by the province, although it is assumed that they would fall under the provincial department of Health and Community Services. This appears to be a major gap that should be addressed by the provincial government as soon as possible.

There are also differences in the level of rigour in which the practice of laser eye surgery is regulated. In some provinces, the college has established specific standards, statements or regulations by which surgeons and clinics must abide in order to practice in the province. Other provinces have established guidelines as suggestions for practice, but these are not specifically required. All surgeons are required to abide by the general regulations, standards or guidelines for any registered member of the college, and include abiding by a code of ethics. It should be noted that the only redress the college has is to discipline the doctor, based on a lengthy complaint process.

The authority of the colleges to establish these regulations, standards, policies or guidelines are set out in the respective provincial medical/health acts. The level of authority granted to each provincial college varies from province to province, and may account for some of the differences in the level of rigour in monitoring the practice of laser eye surgery. For example, many provinces regulate not only registered physicians, but also clinics that offer medical services. However, it is unclear if this authority is granted in all provinces, for example in Ontario, where policies and guidelines seem to apply only to the surgeons themselves, the actual clinics, whether privately or corporately owned, are not bound by the guidelines restricting advertising and marketing practices published by the Ontario College of Physicians and Surgeons. In contrast, the Collège des médecins du québec issued a warning to prospective patients of the LASIK VISION clinic in December of 1998 following an advertisement that laser eye surgery could be obtained for $500 per eye. The college also investigated the quality of the medical care provided by the clinic with regard to the procedure advertised.

Each provincial college has a standard complaint and redress procedure to track and investigate patient complaints. In most cases, the results from these procedures are made accessible to the public. The colleges report very low numbers of complaints regarding refractive laser eye surgery, and the few complaints (single digits) registered, relate mostly to the billing procedures of clinics and surgeons.

An overview comparison of the guidelines in each of the provinces can be seen in Table 5.2 below.

Table 5.2

Comparison of the availability of provincial guidelines and standards for laser eye surgery

Provincial Colleges of Physicians and Surgeons	Guidelines and Standards			
	Refractive Eye Surgery	Marketing and Advertising	Billing Practices	Clinic Certification (General)
Nova Scotia		Standard	-	-
New Brunswick	-	Regulation	Guidelines	-
Quebec	Guideline	Standard	Standard	-
Ontario	-	Regulation	Policy	-
Manitoba	Guideline	Statement	Statement	Regulation (By-law)
Saskatchewan	-	Regulations	- [56]	Regulations
Alberta	Standard under development	Standard	Standard	Standard
British Columbia	-	Regulation	Policy	Standard

DEFINITIONS:

Standards and Statements – clinics and surgeons are required (in order to maintain membership in the college) to abide by these standards

Guidelines and Policies – strongly suggested standards of practice for which the level of monitoring and enforcement can vary

Regulations – surgeons and/or clinics are required by law to abide by the published regulations

5.2.1 Highlights of Regulations and Guidelines, by Province

The following is a detailed description of the regulations or guidelines governing laser eye surgery developed by each of the provincial colleges of physicians and surgeons.

[56] Only to the extent that physicians in general must take into account the ability of a patient to pay fees, something not relevant to a discretionary medical procedure.

5.2.1.1 Nova Scotia

The College of Physicians and Surgeons of Nova Scotia (CPSNS) does not have specific guidelines or regulations governing the practice of laser eye surgery. Surgeons are required to abide by the code of ethics as stated in the regulations, as well as a regulation governing communications with the public. The guiding principle of communicating with the public shall be to serve and to inform the public. There are no guidelines or regulations specifically related to fees, although the code of ethics has a brief, general statement for communicating fees to patients.

5.2.1.2 New Brunswick

The College of Physicians and Surgeons of New Brunswick (CPSNB) does not have guidelines or regulations specifically addressing standards of practice for laser eye surgery. However, guidelines for charging for uninsured services include allowing for a deposit, as long as the circumstances for forfeiture of such deposits are made clear to the patients. The college has regulations which restrict advertising and marketing practices of surgeons such that patients and clients are provided with truthful and accurate information in a manner that will not damage the integrity of the profession.

5.2.1.3 Quebec

The Collège des médecins du Québec has published a set of guidelines for laser eye surgery in Québec which are very similar to those of the Canadian ophthalmologic society. The college also has guidelines regarding advertising practices, and billing procedures for surgeons. However, of special interest, is that the college has also published a policy on the collaboration between optometrists and ophthalmologists which addresses issues such as separate patient records, shared office space, payment for services, honorariums for referrals, guidelines for follow-up care, etc... The college has made very clear that honorariums for referrals, or payment for services should never be provided regardless of the nature of the collaboration. Should the care of the patient be shared, the preferred medical services provider should be chosen by the patient, and payment should be remitted from the patient directly to the respective professionals.

5.2.1.4 Ontario

The College of Physicians and Surgeons of Ontario has established a number of policies which affect the practice of laser eye surgery in Ontario. These policies include charging for uninsured services (September 2000), and consent to medical treatment (February 2001). There is a regulation in the Medicine Act of 1991 relating to advertising practices of physicians (Ontario Regulation 114/94, Part II Advertising). In general, the regulation requires that information advertised by physicians must not be false or misleading. Advertisements cannot contain testimonials, or comparative or superlative statements and should not contain references to specific equipment. Of importance, is the fact that these policies and regulations do not apply to

the clinics or corporations, only the surgeons themselves. Therefore, while a surgeon may not make claims or provide client testimonials about his service for his own benefit, the clinics who employ the services of the surgeon can use whatever advertising or marketing methods they choose.

There are no policies or guidelines published by the college specific to laser eye surgery. The media relations branch of the college has indicated that many of the College's policies are under review, and it is possible that a policy relating to laser eye surgery is under development, however they were unwilling to confirm this.

One Ontario service provider interviewed indicated that their clinic would be much more comfortable operating in a more heavily regulated environment. They were concerned with the lack of standards and monitoring regarding the practice in Ontario, as well as the questionable business practices of some of the clinics that employ their colleagues. There was an acknowledgement that perhaps this was becoming less of a concern as word of mouth spread, however, better regulation could only protect the consumer, as well as the service providers.

5.2.1.5 Manitoba

The College of Physicians and Surgeons of Manitoba (CPSM) governs the practice of laser eye surgery extensively, from a variety of perspectives. Guidelines relating to the specific procedures (PRK and LASIK) are provided in detail and include background information on the procedure, guidelines for assessing patient suitability (or indications and contraindications for undergoing the procedure), preoperative assessment, intra operative care, postoperative assessment, possible complications, and areas of caution.

The college has also issued a statement (a formal position of the College with which members shall comply) outlining the necessary qualifications for refractive eye surgery, as well as other requirements in order to perform the procedure in the province of Manitoba. For example, the procedure may be performed only in a College approved facility; the preoperative record must include certain documentation; postoperative documentation must include follow-up examinations and records at times acceptable to the College and must be available for College inspection.

The college has published a statement for advertising that states that it is unethical:

- To advertise in a manner designed to promote one physician as being better in any sense that his/her colleagues.
- To have direct contact with any person in an attempt to solicit or invite patronage.

The basic principle of ethics is that the public be served and this should be the guiding principle in any decision to advertise. A statement of ethics also provides strong guidance with respect to the billing practices of surgeons. Unless there are significant up-front costs to any procedure

(such as the purchase of supplies or equipment specifically for the patient's procedure) no payment should be collected until after the procedure has been completed.

5.2.1.6 Saskatchewan

The College of Physicians and Surgeons of Saskatchewan does not have any guidelines or policies which specifically address laser eye surgery, however there are general by-laws pursuant to the Medical Profession Act, 1981, which apply to the clinics and surgeons. Advertising guidelines are very specific and require that advertising, promotion and other marketing activities must be in good taste, accurate, and not capable of misleading the public. The by-law also specifies the criteria under which a physician may place his name, address and telephone number in the white and yellow pages, clinic and office signs, and statements to and interviews with the Media. Clinics must also be certified under the Bylaw for Approval of Procedures Conducted in Non-Hospital Medical/Surgical Facilities. A clinic director must be appointed by the clinic and assumes overall responsibility for the standard of medical care and medical records in the facility. The director, who must be a member of the college, must apply for permission to perform procedures in the facility. Clinics, just as registered physicians and surgeons are required to adhere to the by-laws and Code of Ethics of the College.

5.2.1.7 Alberta

The College of Physicians and Surgeons of Alberta (CPSM) requires that each clinic that offers surgical procedures outside of a hospital setting be accredited, according to specific standards outlined in the "Non-Hospital Surgical Facilities Standards and Guidelines, February 2001". In approximately 6 months to one year, specific standards for Laser Eye Surgery Clinics will also be published, and all facilities will be required to become accredited, and renew accreditation every four years in order to operate in Alberta. The CPSM has also published policies relating to charging for uninsured services, advertising by physicians and the performance of laser surgery. The policy regarding laser surgery (not specific to laser eye surgery) was established in June of 1992, and requires that surgeons receive formal instruction recognized by the CPSM.

5.2.1.8 British Columbia

The College of Physicians and Surgeons of British Columbia (CPSBC) does not have specific guidelines regarding the practice of refractive eye surgery. However, clinics who perform refractive eye surgery must be certified by the College as stated under the Medical Practitioners Act (BC) Part XV – Non-Hospital Medical/Surgical Facilities. Clinics are also subject to compliance inspections and re-certification requirements of the CPSBC.

The CPSBC does have a policy regarding billing for professional services; however the policy does not address the timing of billing and payment. It appears to be at the discretion of the surgeon to bill a patient before or after a procedure. An advertising policy exists which is taken directly from the Medical Practitioners Act. Surgeons are required to respect these rules

regarding publication or communication of information about their practice or qualifications. The rules also address placing signs at or about an office location.

6 A Synthesis

6.1 Key Issues in the Sector: What the data say.

Issue 1: Advertising

Service providers interviewed do not believe that most of their clients come into the clinic as a result of media advertising, but are rather referrals, either from former dients or referring optometrists. Data from the consumer survey suggest that newspaper advertisements often are the first source of information on laser eye surgery that a client sees, although many note secondary sources are indeed word-of-mouth references for a given clinic. This fact suggests that close monitoring of how laser eye surgery is being advertised is warranted.

From a regulatory perspective, surgeons are required to meet certain standards/regulations across all the provincial regulatory bodies and ophthalmologists are expected to adhere to the guidelines set out by the Canadian Ophthalmological Society. What appears to be of greatest concern is that in some jurisdictions, such as Ontario, the clinics are not bound by the same regulations that apply to ophthalmologists working in them. In this case then, market-driven advertising can occur in the absence of the counterbalance offered by professional standards.

While a more precise and consistent regulatory framework for advertising across all provinces may help avoid marketing practices that are not consistent with professional values, thereby avoiding the promotion of surgery as a commodity, it is still not a panacea. We live in a global village in terms of the media and much information Canadian consumers hear is from our southern neighbour, whether second hand in terms of US media reports about laser eye surgery or first hand from the Internet. Consumer awareness and education with regard to the perils of buying into advertising gimmicks is thus essential. This can be promoted by consumer groups, government publications and clinics themselves, who can redouble their efforts to disabuse clients upon first contact of the wisdom of viewing surgery as an impulse buy. Certainly the majority of clinics interviewed in this survey suggested they do just that, but many others, not interviewed may not.

Issue 2: Cost Cutting

The limited sample of consumers that participated in this survey does not allow any clear cut conclusions to be drawn about the relationship between price and service. In fact this is a question that is only brought into relief when things go wrong and since only 10% of the sample was unsatisfied, no inferential statistical analyses were possible. On the surface there seemed to be little relationship between price and service according to consumers, who reported unlimited follow ups with some lower priced deals and few follow ups with more costly surgeries, however the fact that the surgeries occurred over a ten year span makes it difficult to compare, as does the fact that the nature of the follow up was not explored in the survey data.

From the service provider perspective, however, cost was directly linked to the amount of time the client spends with the ophthalmologist, that is, with the real expert in the surgery, both pre and post surgery. The benefits are clear. The ophthalmologist is regulated by his profession and, as a physician, must provide a balanced view of the risks and benefits of the surgery. He is also the best qualified individual to make the determination regarding how suitable a candidate the prospective client is. Post-operatively, he is best qualified to identify early signs of problems or address side-effects. Thus time spent with the specialist is an insurance policy and would seem to be a good investment. Again we see the risk of looking at this as a 'business deal' in which it might seem logical to surmise that with a 95% success rate (by most standards) the extra 100-200% cost involved in more premium service is not warranted. Yet what is at stake in most business transactions is not as vital as one's eyesight and by extension one's entire well-being.

Again consumer awareness seems to be a central factor in this issue. If clinics persist in offering discount prices that impact the level of service they can give, consumers must be aware of what they will face when things do go wrong, even if chances are unlikely that they will. This must be done in a way that hits home, that is, graphic indications of what could happen in rare cases. As those who have found themselves in this state have made clear, statistics are simply not an accurate way to reflect the surgery, not when you wind up in the small percentage for whom things have gone very wrong. Alternatively provincial governments, who may be called on to absorb the cost of problems associated with poor surgical outcomes should consider legislating clinic responsibility for at least some of these costs. This would likely end in fewer discounted surgeries, as that cost would be passed along to the consumer. Clinics would also be forced to carry insurance to address this contincency.

With regard to the payment process, considerable variability exists. Service providers sometimes ask for payment at time of assessment, although most who agreed to be interviewed for this research, indicated the money would be returned if the client did not proceed. Many do not ask until the time of surgery. Consumers did not seem to consider this a major issue, but that may reflect the relatively low number that sought out a second opinion. Of those, too, the second opinion may have reflected an optometrist's or another clinic's view of the safety and advisability of the procedure, not a full assessment on the suitability of the individual for laser eye surgery. Given the very frequent comment both in media reports and among those in the laser eye sector themselves that the major problem with poor outcomes is inappropriate assessment, anyone considering this type of surgery should think very hard about proceeding based on a single assessment. At the same time, clinics need to ensure their pricing structure allows clients to be assessed without locking them into the full procedure at that clinic. If profits must be made from surgery, they should not be made on initial assessments.

Issue 3: Risk awareness

Although all service providers indicated they do provide consent forms and extensive information to clients before the latter commit themselves to surgery, it is not clear in all cases whether clients can be said to be to be fully informed. Is this the responsibility of the clinic?

Certainly from a regulatory standpoint it is the responsibility of a surgeon doing surgery to insure that the consent for that surgery is fully informed and in some provinces this extends to the clinic. What is not clear is what is meant by 'informed consent' or how that consent is to be demonstrated[57]. Does it mean simply providing the information or should it go further to prompting and quizzing the client on what a poor outcome would mean to him or her?

Not surprisingly, clients whose surgeries went well tended to think they had lots of good information from the clinic, while those whose outcomes were worse than expected reported significantly less satisfaction with the information. In situations where there is a small chance of such a bad outcome, clearly it is morally and ethically important to ensure that consent is based on the highest degree of risk awareness. This does not currently seem to be the case, given consumer feedback. The responsibility is not all with the clinics, though. Consumers need to be made aware and reminded that they too must seriously weigh the information provided and actively think through 'as if' scenarios in which their own outcome is less than they expect. Only in that way will they be able to agree to surgery with full confidence that they understand the risks.

While many consumers do seem to consult various sources of information before surgery, most found the information provided by the clinic to be the most useful and some did no research before making up their minds to proceed. In both the case where no research was done and the case where all the information received was from the clinic itself, consumers are running the risk of not being fully informed about aspects of the surgery. That is not to say that a clinic would necessarily knowingly omit information, but information can be provided in various ways and what may be very salient to one consumer in one form may be much better understood by another consumer in a different form. The more information the better is likely a good motto for potential laser eye clients.

A good example is the one addressed in both the service provider and consumer perspective sections: that of night vision. Service providers contacted for this study were almost unanimous in their view that night vision problems were rare and that studies arguing the contrary are methodologically flawed. Clearly not believing the conclusions are valid, they would not refer to them in their information packages and may even dismiss such concerns, as they did with the interviewer. Yet others in the field, notably the authors of these reports, many of whom are very reputable ophthalmologists disagree. Consumers need to be aware that at least some in the field are saying that 50 to 60% of LASIK patients experience night vision problems. In our sample 47% reported night vision problems persisting after three months, although only 23% of those reporting night vision problems would not have the surgery again. Even if this number is exaggerated, consumers need to be aware that there is not full agreement in the field and the

[57] A paper being prepared concurrently with this one by the Public Interest Advocacy Centre in Ottawa and the Consumers' Association of Canada addresses this issue in some detail. There is no current consensus across the country or within the health sector as to how to demonstrate that consent is informed. See *Privacy and Personal Health Information*, April 2002

issue is not yet resolved, a fact they can take into consideration based on the potential impact having poorer night vision would have on their lives. For many, the impact may be negligible, as seemed to be the case for many of the satisfied clients surveyed. On the other hand, for the taxi driver who earns his/her living at night, it may be chance he/she is not willing to take.

Also in the context of consumer awareness is the need for a greater understanding of the quality of information being provided. This is an issue endemic to the information age in which we live, particularly as more and more individuals turn to the Internet for the bulk of their information. Specifically with regard to laser eye surgery, there is very good information to be had, some of which has been cited here, such as FDA guidelines and background information on the surgery, peer-reviewed journal articles and well moderated sites which present factual information about good and bad experiences with the surgery. There is also a wealth of information from other sources, from specific clinics (some of which can be misleadingly positive) to angry rants from dissatisfied customers that are not particularly helpful and imply all in the sector are crooks. The advantage of so much information is that it is very easy to check from site to site to see if information is consistent. The disadvantage is in sorting out impartial information from market-driven 'spins' and deciding when information is contradictory, which is right. At the very least consumers may be better informed when they speak to their surgeons about potential problems if they take the time to do their research.

Issue 4: Follow up and Redress

Data from the qualitative interviews with service providers and more quantitative survey responses do not provide great insight into this issue other than to confirm that, indeed, some individuals who go through this procedure will have a poor outcome which can drastically change their lives. Of the approximately 100 respondents, ten of whom were unsatisfied, only one stands out as belonging to this category, the individual quoted in section 4.3 whose activities are now severely limited by chronic pain and the side effects of the surgery. The fact that these individuals exist, and certainly their stories are not hard to find, does reinforce as valid the issue raised in section 1.4 regarding who is to be responsible for these individuals. In a profit-driven venture, it seems only fair that those profiting from successful outcomes must shoulder at least some of the cost associated with the relatively few poor outcomes. Clinics say they do, offering many post-operative touch ups and major corrective surgery, in some cases, but, as far as this research was able to ascertain, they are only held responsible for the major loss of income, well-being and quality of life when held accountable by the judicial system.

Given the relative infrequency of such extreme cases, a solution presents itself that should not be very onerous on any single party and is in keeping with the spirit of socialized medical care. Clinics should be required to maintain insurance that can be used to compensate individuals for surgeries gone wrong and provide some protection to the individual who may not have adequate disability insurance. Some sort of precedent for such cases is particularly important if there is to be more privatization of medical services, as discussed below in section 6.2

The issue of responsibility in the face of bankruptcy is one that is in clear need of regulation. Even those more premium service clinics that were interviewed did not have much in the way of contingency plans to address potential bankruptcy. Consumers are concerned about this issue. We asked them to rate on a scale of 1 (not at all) to five (a great deal) how concerned they were while going through the process that the clinic they were with might close or go bankrupt. Of the five items in the question, this was the item that engendered the most concern, although not significantly moreso than the other major worry: where do I turn if anything goes wrong? (see below). Clinics must be held responsible to ensure both adequate follow up care and patient access to their medical records in the event of financial failure. This might be accomplished through a formal agreement between surgeon and clinic, so that if the clinic should fail, the surgeon automatically assumes responsibility of any patients treated. If clinics cannot regulate themselves, this will need to be addressed as part of improved regulation of the sector.

Also relevant to the issue of follow up and redress is where clients can turn for help when they are not satisfied with the outcome of their surgery. This is not specifically in the cases where something drastic has gone wrong, but if they are unhappy with service, with the outcome (even if not devastating), with the financial terms, or the way their contract has been honoured. It was clear from data collected in the interviews and surveys that most people have no idea where to turn. Most were satisfied and did not need to turn anywhere, but for those who are not, there needs to be a clear path of redress set out that is consistent and felt to be impartial. In the US this redress procedure is, for more serious cases, through the judicial system. Canadians are less litigious and many of the problems that arise are probably not so serious as to warrant litigation, but some clearly defined body who can hear complaints is needed. It is not at all clear if the colleges of physicians and surgeons of each province are serving this role. It may be a question of simply making clearer to clients where they should go, but few in this sample even mentioned their local College of Physicians and Surgeons.

Issue 5: Regulation of Laser Eye Surgery

There seemed to be widespread agreement among service providers and consumers alike that more regulation is required for this sector and both clinics and clients mentioned specifically increased federal regulation. There would be major advantages to federal regulation; however, realistically, it seems unlikely given provincial responsibility for health care. Perhaps what is needed are nationally agreed standards and regulations that reflect provincial consensus. Whatever form the increased regulation takes, it would go along way to reassuring clients that their interests are well protected in privatized health care as they are in socialized care and would help clinics ensure they were meeting a nationally recognized standard for care.

One area where greater transparency appears to be required is in the area of federal regulation of laser technology and the nature of client participation in ongoing testing of new laser technology. It seems that laser eye techniques, like so many other medical technologies, are evolving so rapidly that traditional, long-term clinical trials are no longer practicable. Critics of the sector would argue that they must remain the norm, although it could be countered that

improved technologies with lower risks to patients may need to get to the market as soon as possible if their use is going to minimize the chance of negative outcomes. At the very least, consumers need to be made aware in very clear terms that there are no long-term studies available, so that even an initially positive outcome may not necessarily mean that as an elderly individual new and different side-effects may not emerge.

Since most of these issues involve at least to some extent improved consumer awareness and knowledge about the sector, efforts on the part of clinics, consumer associations, consumers themselves and governments are needed to ensure the buyer knows as much as possible before committing. To the adage we have adopted as our title: buyer beware, we might add the caution buyer be aware!

6.2 Lessons in the context of privatization of medical services

If Canadian health care moves towards greater and greater privatization two lessons seem clear from the case of laser eye surgery advertising. First regulation of advertising, such as that set out in the 1994 Canadian Ophthalmologic Society guidelines, must be mandatory and comprehensive in its application. The fact that in Alberta, clinics are held to the same standard as the surgeons working in the clinic, but in Ontario they are not, is cause for considerable concern. Moreover there is a need for will and a mandate on the part of the regulatory body to enforce regulations or standards strictly. Regulations "without teeth" will do consumers little good.

The second lesson is that consumers will have to become much better informed about their medical options, be smarter 'shoppers' and do their research. With professional values colliding with business values, the consumer can no longer rely on the physician-come-businessman for full impartial advice. With that requirement comes many problems for Canadians, including understanding often conflicting reports about safety and advisability of procedures, weighing different sources of information cautiously and appropriately given the nature of that information, and spending time, that most precious of consumer commodities, on gathering the information necessary to make decisions. This is a major shift for Canadians, who have for generations learned to trust their doctor, the expert in the field. Doctors will, of course, remain the experts and, based on their professional guidelines, put consumer well-being first, but the framework within which they work will certainly preclude confidence in impartiality.

In the context of pricing, greater regulation appears to be in order, if lessons from the laser eye sector are taken to heart. Price cutting of the sort seen in the late 1990s, as the sector became more and more competitive, must be regulated both for the benefit of the consumer, who can be sure that he or she is getting the necessary treatment and *follow up*, and for the sector itself, which runs the risk of pricing itself into bankruptcy. As one respondent noted, garages are better regulated. It might be argued that a capitalist approach to the delivery of discretionary medical services appears to be regulating the system with 'discount' clinics going out of business

and premium chains hanging on. However, the toll in terms of clients who now have no follow up, given bankruptcies, not to mention those who may be visually impaired as a result of corners cut, even if few in absolute terms, is still far more than a caring society should be able to tolerate. Any systematic delivery of privatized medical services must be accompanied by a well articulated and well regulated system of (sector) self insurance that will ensure current patients get the follow up they require and any former patients with poor surgical outcomes are looked after.

Unless stricter regulations are imposed, Canadian consumers will have to learn to use their shopping skills in a totally foreign market: health care. Recent media reports of US consumers bargaining with their physicians for 'deals' on procedures they need but cannot afford are an extreme case, but highlight what privatization of medical services may entail. This puts enormous strain on the consumer, who may be sidetracked from thinking seriously about risks and consequences when forced into thinking about financial considerations. " Can I afford this?" vs. "Do I really need this?" This issue is not just one of price, but what is included in the price, which can vary greatly as we have seen in the laser eye sector. The need for clarity in terms of what is to be done and for how much needs to be clearly reflected in a contract between service provider and client.

Among the terms of the contract is a need for follow-up guarantees that transcend the life of the business and ensure consumers can receive the follow up treatment they need without having to fall back on the public medical system. As suggested in section 6.1 some sort of regulation is required that ensures that firms delivering the service have adequate funds set aside (or in trust with the government) to cover follow up treatment in the event of bankruptcy or sale of the firm. The extent of those funds will likely depend on several factors, including the incidence of follow-up problems, the cost of treating such problems and the associated ancillary costs. For laser eye surgery, while the number of incidents is fairly low and the cost of "touch ups" and follow up care, if successful, is not that great, if unsuccessful, ancillary costs (retraining, psychological counselling, etc.) can be a lifelong commitment.

The fact that both service providers interviewed and consumers surveyed were calling for greater government regulation in laser eye surgery, suggests that if more medical services are privatized, there will be a need for much more comprehensive regulation. In the case of laser eye surgery we have seen in Canada the rapid introduction of many new techniques, with only short term clinical studies to support their use, along with new technologies that are being moved out onto the market, albeit on an "investigational" basis, at what can only be described by traditional scientific standards as breakneck speed. In the US where private medical care is the norm, the FDA has taken a much more cautious and measured approach; for example, in approving the excimer laser only five years after it was being used for commercial purposes in Canada. Approval processes will need to be reviewed and likely verification procedures strengthened. That this is a potential problem is made evident by the lawsuit in the US against LaserVision, which was found guilty of distributing altered software cards which allowed laser

surgery for myopia to be performed beyond the approved range (in diopters)[58]. This case also shows, though, that the US is ready and capable of taking action when regulations are breached. Canadian regulatory bodies must be equally prepared to police health care and target offenders in a transparent fashion so that consumers can have confidence that they are well protected.

In summary, the implications for consumers and for government in adjusting to greater privatization of medical services are considerable. We have raised only a few issues that have been highlighted by the laser eye experience, but it is clear that privatization of health care services to any extent involves a major shift in the way in which consumers will have to go about procuring such service. Such a shift cannot happen overnight and, if it were to happen, would involve a massive commitment of resources and effort by government, the health care sector, consumer advocate and consumers themselves. Without such a massive commitment the potential for harm to the Canadian consumer of health care services is great.

[58] Henderson, C.W. (2001). LaserVision settles FDA lawsuit. *Medical Letter on the CDC and FDA*, p. 10 - 14.

7 Recommendations

7.1 Recommendations for action

Issue 1: Advertising

- Given the potential for abuse, closer regulation of how laser eye surgery is being advertised is warranted at both the federal and provincial levels.
- The provincial Colleges of Physicians and Surgeons should ensure their marketing regulations apply to both the surgeon AND the clinic where the surgery is performed.

Issue 2: Cost

- Consumers should be encouraged to consider a variety of issues in deciding to proceed with laser eye surgery and not to focus exclusively on price. Consumers need to be more aware of the risks of poor surgical outcome, if they choose to save several hundred dollars and receive a lower quality service and coverage.
- Provincial governments who shoulder the additional costs for poor surgical outcomes should explore the possibility of regulation or legislation that forces clinics to bear at least some of the financial burden.
- Service providers should not charge consumers for pre-operative assessment to ascertain their suitability for the procedure. This practice may need to be regulated by either the provincial Colleges or the federal government.
- In those cases where the head surgeon is also the owner and primary business advisor for the clinic, there may be a clear and direct conflict of interest between both roles. Therefore, consumers should be made aware of the "business" relationship between the surgeon and the clinic and not be afraid to ask for clarification where needed. Once again, developing guidelines or standards that regulate conduct in such a situation would also be invaluable to consumer safety.

Issue 3: Risk awareness

- There need to be more long-term studies that examine the long-range effectiveness and outcomes of laser eye surgery. Although there have been several recent clinical studies published using Canadian data, two of the three reviewed were published by individuals affiliated with a laser eye clinic. Although this does not necessarily undermine the integrity of the findings as these articles were peer-reviewed, there exists the potential for perceived conflict of interest and thus long-term studies conducted by independent evaluators are of crucial importance.

- Clinics need to ensure that as much consumer education as possible is undertaken so that the latter fully understand the risks involved. Although the service providers interviewed for this study provided a wealth of both written and oral information to the client in this area, this may not be the case in the entire sector. Thus, closer regulation or clearer guidelines in terms of how clients are made aware of the risks involved by the clinics need to be addressed at either a provincial or federal level.

- Consumers need to educate themselves more regarding the issues surrounding laser eye surgery. More specifically, as this procedure does have the potential to have some very damaging permanent impacts, it is a primary responsibility of the consumer to ensure he/she is aware of the risks associated with surgery and is prepared to handle the consequences. Therefore, consumers should seek out information other than marketing material or information provided by the clinic, whether positive, negative, or neutral, to ensure a more balanced view of the field.

- Consumers must also be certain to ascertain the nature of their own disability insurance and its applicability to poor surgical outcomes in the case of discretionary medical procedures.

Issue 4: Follow up and Redress

- Consumers need to ensure they are aware of the extent of follow-up services offered by the clinics. More specifically, consumers need to know what is in fact covered in their contract for services and, equally as important, who will be performing these services. Clinics should ensure that clients are well-informed of the follow-up procedures that are in place in the clinic and, most importantly, what additional costs may be incurred by the consumer.

- Regulations must be developed to ensure clients are protected should a particular clinic go bankrupt.

- A clearly defined and transparent path of redress which will be viewed as consistent and impartial by consumers must be set out either provincially or federally to allow consumers to seek remedies for perceived poor service or surgical outcomes.

Issue 5: Regulation of Laser Eye Surgery

- Clearly, there is widespread agreement that more regulation is required, particularly at the federal level. Given the complications of the current provincial/federal jurisdictions regarding health care delivery, a more formal recommendation goes beyond the parameters of this research as it would require more intensive study in terms of how best regulatory oversight is achieved. However, there are several areas mentioned throughout this report where tighter regulation is required, including pre-operative assessments to

determine client suitability, marketing of services, payment for services, follow-up procedures, and redress.

- At the very least the Provincial Colleges of Physicians and Surgeons should develop guidelines and standards that are specific to the laser eye surgery industry and other discretionary medical services marketed privately. There is considerable variability across provinces now (ranging from no guidelines whatsoever to detailed guidelines and monitoring for each aspect of the sector).

7.2 Recommendations for further study

- There is a need for a more in depth analysis of the service provider clinics in Canada. As noted in this report, only eight clinics were interviewed and the responses received raises suspicion that these clinics are at the highest end of service delivery. More partnerships need to be forged with service providers so there is more transparency of business practices and so that clinics see the inherent value of participating in such research.

- Future studies of the sector should include surveying a larger sample, allowing a more fine-grained analysis of consumer perspectives in terms of demographics (e.g., region, year of surgery, etc).

- Future studies should separate more clearly the key players in the industry and categorize clinics according to certain criteria. For example, analyses could focus on clinics where the surgeon is also the manager of the business. In addition, interviews with service providers could be conducted with the surgeon, the clinic director as well as support staff. Attempts could also be made to identify discount firms and compare them with premium service clinics.

- International perspectives on the issue should be studied and the lessons learned in other countries used to help develop various options for improved sector regulation and a more consumer-oriented approach to the delivery of private medical services.