

Jorge L. Alió · Dimitri T. Azar  
*Editors*

# Management of Complications in Refractive Surgery



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With 250 Figures and 44 Tables

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# Foreword

My interest in corneal lamellar surgery began in 1985 when I observed Lee Nordan perform a freeze keratomileusis in Houston with José Ignacio Barraquer's freeze technique. At that time, however, I realized that this type of surgery was subject to too many variables, and that for the most part these were independent of the ability and the competence of the surgeon. A more controllable technique was necessary.

Luck would have it that just a few months later I was invited by Philippe Sourdille to Nantes to perform live cataract surgery. In the adjoining room, Jorg Krumeich performed a no-freeze keratomileusis. My interest for corneal lamellar surgery was stimulated further, where a few weeks later in Germany, I observed this new technique, and started to use it myself just a few months after.

But times were hard, particularly when I look back on them now.

The microkeratomes were precise instruments, but they were rudimentary, they were difficult to use and were also potentially risky. The lamellar cut had to have a thickness of at least 300  $\mu\text{m}$ , the lamella had to be fixed to a workbench, and the refractive cut had to be performed on the stromal face with the microkeratome. The optic zones were extremely small particularly in consideration that the target corrections were in excess of 10 D.

Thinking about all that today makes me cringe...

However, Barraquer's idea was brilliant, and what followed on later proved that it was a winner.

The technique with the surgical correction of refraction, with the variant by Antonio Ruiz and others, stayed alive until the excimer laser appeared on the scene. At that point, everything changed—luckily for surgeons over the world and to the enormous satisfaction of the patients!

When Theo Seiler in Berlin demonstrated the use of this machine and despite the fact that everyone had their attention fixed on its use on the surface tissue, I had an idea...finally, I would be able to perform the refractive step of keratomileusis with a repetitive instrument of micrometric precision. Then in 1989, I performed the first operation (the first case anywhere in the world) of intrastromal ablation, using the excimer laser.

At that time, we were all still tied to the concept of performing the refractive step on the stroma of the cut lamella and that is what I did. However, this was not the road to

the future, and it was Joannis Pallikaris who had the brilliant idea of performing the step on the in situ stroma. The idea was to cut a thinner lamella and ingeniously preserve a hinge to avoid losing continuity with the cornea.

However, the hinge was in a nasal position because the cut progressed from the temporal side to the internal canthus. Unquestionably, it would have been preferable to have the uncut zone at the top to avoid dislocation of the flap during blinking. I decided to perform the operation with a "traditional" microkeratome—again the first ever worldwide in 1989—proceeding with the microkeratome, in an extremely well-exposed eye, from downward up.

Immediately afterwards, we saw the appearance of the first microkeratome with a fixed plate. What a relief! Finally, the anxiety and worry of creating a perforating lamellar cut had disappeared; we had the option of creating a superior hinge. The laser-assisted in situ keratomileusis (LASIK) down-up technique was born.

We then reached the modern era where improvements to the excimer laser appeared every couple of months; there was the transition from the mono-zone to the multi-zone, from a flying-spot treatment to a wave front, with the subsequent addition of the eye tracker and the recognition of the iris, as well as a whole series of minor innovative changes all geared to improving the end result.

We have reached the state of surgical fiction. However, unfortunately, patients do not participate correspondingly. In fact, laser refractive surgery went extremely well for a number of years and then unexpectedly hit a period of calm or stagnation.

Had we possibly created excessively high expectations?

Had we possibly operated on patients who were not suitable?

Had we possibly induced too many complications?

There is no doubt that on reading this book we can find the solution to many of the mistakes that all of us, to a greater or lesser degree, had made in the past, and we can find many useful and positive suggestions. However, more importantly, we find the necessary information for preventing or reducing the complications, both intraoperative and postoperative, even through the more attentive selection of the patients to be subjected to surgery.

In today's world, refractive surgery commands an extremely important place in eye-surgery practice.

Some techniques are still in their infancy, others have been used for more than 10 years, some have almost disappeared totally from the operating rooms, and more will be developed in the future.

The results of any surgical procedure, even those not related to ophthalmology, were evaluated exclusively from a quantitative point of view; in our specific case, the measurement was how many decimals were recovered by the eye after surgery.

Then surgeons realized that the quality of vision is also extremely important and only an evaluation of this could explain some of the often-incomprehensible complaints the patients would make.

Having a clear picture of how a person's quality of life can be changed by the onset of complications becomes of utmost importance, even in consideration of the person's job or leisure activities, as these can be contraindications to certain types of surgery.

The most popular operation is LASIK: The surgical step that, more than any other, causes problems is the cut with the microkeratome.

Are there still problems with the flap?

Yes! Thin flap, non-uniform flap, perforated flap, incomplete flap, etc. This is due to the fact that this step is mechanical, and by definition not precise, and also because it depends on the surgeon skills.

So who makes more mistakes, the surgeon or the machine?

One essential ingredient of refractive surgery is that the treatment is efficacious and achieves the preset objectives. However, even more important is that it is associated with very few complications, and that these will be acceptable to both the patient and the surgeon. This is particularly true if we consider that these operations are not essential but a question of choice; they are not strictly necessary from a medical point of view.

It is therefore important to publish a book that deals specifically with the complications of refractive surgery, their treatment, and how to prevent them.

The first chapter is essential; it presents the refractive results and the complications from surgery. It describes the risk-benefit ratio that allowed refractive surgery to be accepted and listed among the most popular surgical techniques being used at present.

The second of the introductory chapters is original and specific; it takes a separate look at the effect the complications may have on the quality of life.

A number of chapters on the complications of LASIK follow. It makes sense that these form the main bulk of the book, given that this is the most widespread technique on the international scenario.

First, we have an encyclopedic review of the intraoperative problems of the flap, and then the precocious and late-onset postoperative problems.

All the well-known complications are described.

The problems of complications associated with the flap have been greatly reduced since the currently available microkeratomes have been used. These are more reliable and safer; however, possibly a cut that was independent of mechanical instruments would be a better solution. This led to the development and launch of the femtosecond laser that could perform the work of the microkeratome but with greater precision and fewer risks.

In addition to the anatomical complications, specific chapters examine the calculation errors in refractive correction; again, in the past these topics were not dealt with in sufficient detail.

Finally, there are chapters on the complications of the eye, which actually create the subjective problems for the patients and leave them dissatisfied with the results of the operation.

The femtosecond laser can contribute to reducing these and other problems.

What are the advantages associated with this laser? First of all, the lack of blades! In addition, the possibility of no complications in the event of technical problems, and the option of repeating the operation just a short time later.

Potentially, it can also prevent ectasia; subject to the precise preoperative measurement of the corneal thickness, the cut can be performed uniformly over the entire area and that is not all...

Further improvements to the equipment and the software permit greater improvements to the ablation techniques; aberrometers that are more suitable allow the elimination of the optical aberrations; more advanced pupilometers will reduce the patients' functional problems and improve the end result.

However, additional problems persist: scarring, melting, etc., the etiopathogenesis of which must be examined in depth to enable surgeons to identify the key factors for resolving them.

The book also contains descriptions of topics that were previously not treated specifically: nummular keratitis, fluid in the interface, and ptosis. The latter complication is rightly considered, given the complaints it elicits from patients.

Then, ample space is given to the problem of dry eye, which was underestimated when this surgical technique was initially developed.

Rare complications are also examined such as optic neuropathy and the problems of eye motility.

Can any problems related to infection be resolved with the use of disposable instruments, on the understanding that these must have the same validity and competitive

costs as their repeated-use/sterilizable counterparts? Will that be enough? I do not think so. However, if we improve the preoperative diagnosis and the medical preparation of the patient, there is no doubt that we will be able to reduce the frequency of the problems.

The photorefractive keratectomy (PRK) technique, which is still popular, is examined with its main complications, namely haze and regression.

Improvements in laser-assisted sub-epithelial keratectomy (LASEK) are unquestionably linked to finding a way, probably chemical, to attain, precise detachment of the corneal epithelium while respecting the cell vitality.

Will EpiLASIK be able to distance the doctor and patient from the postoperative difficulties similar to those associated with PRK and bring them closer to LASIK?

What will the future hold for the techniques with phakic intraocular lenses (IOLs)?

Surgery that began more than 20 years ago, and then abandoned because of too many complications, has come back into fashion not merely because elevated defects could not be suitably treated with the laser, but mainly due to the improvements in the materials and the design of the phakic IOLs in addition to the better knowledge in the anatomy and physiology of the eye.

Further improvements in the shape, thickness, and dimensions of the IOL and their foldability can avoid complications such as glaucoma, cataract, and corneal decompensation. However, the reduction in problems is also associated by better pre- and postoperative instrumental analysis of the eye; instruments such as Visante and the like must be constantly used and applied in this type of surgery, taking into consideration that, generally speaking, a phakic IOL is not designed to remain in the eye for the rest of the patient's life.

The manufacturers must also aim to develop an IOL that is easy to remove if necessary.

Possibly the most important step will be to produce a precise definition for contraindications for the phakic IOLs and whether the existence of three types of IOLs is justified. The future will tell whether only one of these should be used. By analyzing the complications associated with each one of them, we should be able to provide answers to these questions.

In addition, the more recent surgical techniques for the correction of severe visual defects and presbyopia will be increasingly oriented to the replacement of a human crystalline with a multifocal artificial lens.

However, is this ethically and deontologically correct? And will it be possible to further reduce the residual problems associated with this surgery, namely, capsular opacity and problems with the retina?

The definition of the etiopathogenesis of macular edema and neovascularization present in the eye will allow us to reduce some of these problems.

Dedicated software will avoid the refractive surprises associated with previous corneal refractive surgery.

Four chapters on lesser-used techniques follow: radial keratotomy, conductive keratoplasty, intracorneal segments, and intracorneal inserts.

Specifically for radial keratotomy, a technique that is no longer being used, the chapter describes the problems the surgeon has to face in the event of a repeat refractive operation and/or cataract surgery.

Last but not of least importance in today's scenario, the final three chapters.

Understanding whether the patient will be happy with the result or not is essential for surgery of this type, and associated with this problem is the informed consent.

The final chapter compares the complications presented in the literature over the past 10 years, permitting a comparison of the various techniques and a visualization of how experience and technological progress has led to a reduction in the complications that resulted from the initial inexperience of the surgeons and the learning curve associated with this new technique.

In other words, this book summarizes in a clear, complete, and updated manner all the information associated with this subject. It provides a practical and not an empirical approach to the various problems examined. It is more comprehensive with respect to previous publications, covering every aspect of refractive surgery.

The high quality of the images only serves to augment the validity of the book.

The various chapters were written impartially by experts on the specific subject.

The updated, complete information contained in this book makes it an important publication for all our colleagues who are specialized in this field of ocular surgery.

Another important stimulus from this book is that we must fuel the desire to continue along this road of improvement for these refractive techniques.

However, this subject is constantly evolving and therefore the various chapters will act as a stimulus for additional research and improvements to the techniques: The book contains all we know to date and highlights the areas that still need to be explored.

On behalf of all refractive surgeons, I would like to thank the Aliò Foundation and its staff for its enormous contribution to the improvements and the developments seen in refractive surgery. I would also like to thank them for the effort and commitment to improving the expertise of our colleagues, which in the final analysis is translated into an advantage for the patients.

**Lucio Buratto**

# Preface

The reader will find in this book a modern perspective on complications in refractive surgery. The environment and the perspective of the topic have been changing continuously in the last 10 years, most notably in the last 5 years. Many traditional complications such as flap complications are now in decline, whereas other new complications are appearing. The overall frequency and epidemiology of the different complications of refractive surgery have dramatically changed with the different technological innovations that have been introduced into the practice of corneal refractive surgery. However, not all complications followed this decrease, but rather have increased in their frequency; traditional problems such as endothelial cell loss and cataract induction in some phakic IOL models remain concerns of refractive surgeons, and new forms of inflammatory complications of refractive surgery have emerged. Refractive complications such as aberrations induced by previous procedures, decentrations, and others are now properly treated due to significant technological improvement and knowledge of the performance of eye physiology and optics. This book is aimed at providing current and future refractive surgeons with up-to-date information on the pathogenesis of potential refractive surgical complications and at offering an approach to their prevention and treatment.

In addition to our own experience in refractive surgery, we have relied on the invaluable experience of many friends and colleagues who have authored several chapters within this book. Our author list represents the best of the best in refractive surgery. This unique panel of unparalleled international experts has clearly contributed to the science and the practice of refractive surgery. We would like to thank them for the service and contributions to refractive surgery, to patients, and through their

respective chapters, to advancing the knowledge of refractive surgery.

It is our hope that the reader will find in this book the requisite links between the science and practice of refractive surgery. The acceptance of refractive surgery as a separate subspecialty in ophthalmology is higher than ever, thanks to the attention being paid to surgical complications and their management. The surgical outcomes and quality of life of patients undergoing refractive surgery has steadily improved.

The promise of refractive surgery rests in our singular focus on our patients' quality of life and quality of vision. Continued improvements in our field are dependent on enhanced technologies and superior training. To this end, we offer this book as a complement in order to assist our field in becoming better educated about the complications that we face, by providing better tools to solve them, and by increasing knowledge of how to prevent them, all to benefit our patients.

We would like to thank Springer for its support to this edition and ongoing support for refractive surgery. We also offer our heartfelt thanks to our families for their support, which has allowed us to devote our attention to the edition of this book.

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# Refractive Surgery Outcomes and Frequency of Complications

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## Core Messages

- There is no risk-free surgical procedure.
- There are enough data in literature to determine the risk for the majority of the refractive surgery procedures.
- Refractive surgery risks and benefits should be evaluated individually in order to choose the surgical approach properly.

- Not only incidence, but also morbidity of each possible complication should be considered in this choice.
- Decision making in refractive procedure is an individualized process that should be based on scientific knowledge, patient's characteristics, and surgeon experience.

## 1.1 Common Complications Associated with Refractive Surgery

Some complications are implicit to any surgical procedure, varying only in their incidence and morbidity. Such complications will be evaluated here according to their characteristics in each group of refractive surgical procedures.

### 1.1.1 Refractive Imprecision and Loss of Spectacle-Corrected Visual Acuity

The most frequent complication observed in any refractive procedure is the lack in achieving accurate refraction outcome. As a rule, accuracy decreases with the amount of refractive error. Photoablative procedures tend to be the most accurate ones for low ametropias. Photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) deal with different variables that may affect predictability: corneal wound healing and stromal bed elasticity, respectively [1].

Although results minimally favor LASIK, we may expect that in any photoablative procedure, approximately 60–70% of eyes will achieve 20/20 uncorrected visual acuity and will be within  $\pm 0.50$  D after surgery. If we analyze only low myopias (under 6.00 D), approximately 70–80% will achieve 20/20 uncorrected visual acuity (Table 1.1) [1–9].

A general evaluation of surgical safety should consider spectacle-corrected visual acuity (SCVA). One to 5% of eyes will lose at least two lines of SCVA 6 months after surgery, but 1% or less of all eyes will achieve less than 20/40 of SCVA. One to 2% of eyes that achieved, preoperatively, 20/20 of SCVA will achieve less than 20/25 SCVA after surgery (Table 1.2) [1–9].

Phakic intraocular lenses (IOLs) tend to present less accurate refractive correction; although, since they are nor-

Table 1.1. LASIK versus PRK for correction of myopia

|  | UCVA 20/20 |      |       | +/- 0.50 D |       |      | UCVA 20/20 (low myopia) |      |     |      |
|--|------------|------|-------|------------|-------|------|-------------------------|------|-----|------|
|  | LASIK      | PRK  | %     | LASIK      | PRK   | %    | LASIK                   | PRK  | %   |      |
|  | n          | n    | %     | n          | n     | %    | n                       | n    | %   |      |
| <b>Literature: 6 months postoperative</b>  |            |      |       |            |       |      |                         |      |     |      |
| Wang et al. [4]                            | 109        | 81.7 | 335   | 71.6       |       |      | 109                     | 81.7 | 335 | 71.6 |
| Hersh et al. [5]                           | 61         | 26.2 | 68    | 19.1       |       |      |                         |      |     |      |
| El-Magrabi et al. [7]                      | 28         | 67.9 | 28    | 42.9       | 59    | 27.1 | 68                      | 29.4 |     |      |
| Forseto et al. [6]                         | 8          | 100  | 9     | 88.9       | 8     | 87.5 | 9                       | 88.9 | 8   | 100  |
| Hjortdal et al. [1]                        | 25         | 4    | 20    | 15         | 25    | 20   | 20                      | 25   |     |      |
| <b>Literature: 12 months postoperative</b> |            |      |       |            |       |      |                         |      |     |      |
| Wang et al. [4]                            | 103        | 82.5 | 307   | 72         | 103   | 70.9 | 307                     | 61.2 | 103 | 82.5 |
| El-Magrabi et al. [7]                      | 30         | 66.7 | 30    | 53.3       | 30    | 73.3 | 30                      | 66.7 |     |      |
| el Danasuri et al. [8]                     | 24         | 79.2 | 24    | 62.5       | 24    | 87.5 | 24                      | 83.3 | 24  | 79.2 |
| Forseto et al. [6]                         | 15         | 73.3 | 15    | 53.3       | 15    | 93.3 | 15                      | 86.7 | 15  | 73.3 |
| Hjortdal et al. [1]                        | 25         | 4    | 20    | 15         | 25    | 16   | 20                      | 30   |     |      |
| FDA: 6 months postoperative                | 6,615      | 59.4 | 3,173 | 59.9       | 7,207 | 69.9 | 3,296                   | 62.7 |     |      |
| FDA: 12 months postoperative               | 2,774      | 58.1 | 2,094 | 54.5       | 2,985 | 61   | 2,065                   | 56.3 |     |      |
| 6 months total                             | 6,846      | 59.4 | 3,633 | 59.9       | 7,299 | 69.4 | 3,393                   | 61.9 | 117 | 82.9 |
| 6 months literature total                  | 231        | 57.6 | 460   | 60         | 92    | 30.4 | 97                      | 34   | 117 | 82.9 |
| 6 months FDA total                         | 6,615      | 59.4 | 3,173 | 59.9       | 7,207 | 69.9 | 3,296                   | 62.7 | 0   | NA   |
| 12 months total                            | 2,971      | 58.8 | 2,490 | 56.4       | 3,182 | 61.4 | 2,461                   | 57.3 | 142 | 81   |
| 12 months literature total                 | 197        | 69   | 396   | 66.4       | 197   | 68   | 396                     | 62.4 | 142 | 81   |
| 12 months FDA total                        | 2,774      | 58.1 | 2,094 | 54.5       | 2,985 | 61   | 2,065                   | 56.3 | 0   | NA   |

Data set modified from Shortt et al. [3]

PRK photorefractive keratectomy, UCVA 20/20 eyes that achieved post treatment uncorrected visual acuity (UCVA) of 20/20, +/- 0.50 D eyes within 0.50 D of target refraction, UCVA 20/20 (low myopia) eyes that achieved post treatment UCVA of 20/20 in a subgroup of myopia ≤6 D, FDA US Food and Drug Administration, NA not applicable

**Table 1.2** LASIK versus PRK for spectacle-corrected visual acuity (SCVA)

|   | Loss of $\geq 2$ lines |      |       |     | SCVA < 20/40 |     |       |     | SCVA < 20/25 |     |       |     |
|---|------------------------|------|-------|-----|--------------|-----|-------|-----|--------------|-----|-------|-----|
|   | LASIK                  |      | PRK   |     | LASIK        |     | PRK   |     | LASIK        |     | PRK   |     |
|   | n                      | %    | n     | %   | n            | %   | n     | %   | n            | %   | n     | %   |
| <b>Literature: 6 months postoperative</b> |                        |      |       |     |              |     |       |     |              |     |       |     |
| Wang et al. [4]                           | 307                    | 3.9  | 103   | 1   |              |     |       |     |              |     |       |     |
| Hersh et al. [5]                          | 68                     | 11.8 | 59    | 3.4 | 68           | 1.5 | 61    | 0   | 68           | 1.5 | 59    | 1.7 |
| El-Magrabi et al. [7]                     | 27                     | 7.4  | 27    | 7.4 | 27           | 3.7 | 27    | 0   | 27           | 3.7 | 27    | 3.7 |
| Forseto et al. [6]                        | 24                     | 0    | 24    | 0   | 24           | 0   | 24    | 0   | 24           | 0   | 24    | 0   |
| Hjordtal et al. [1]                       | 20                     | 10   | 25    | 4   | 20           | 0   | 25    | 0   | 20           | 0   | 25    | 0   |
| FDA: 6 months postoperative               | 4,412                  | 3.2  | 7,554 | 1.1 | 4,414        | 0.3 | 7,810 | 0.3 | 4,299        | 2.4 | 7,612 | 1.4 |
| 6 months total                            | 4,858                  | 3.4  | 7,792 | 1.2 | 4,553        | 0.4 | 7,947 | 0.3 | 4,438        | 2.3 | 7,747 | 1.4 |
| 6 months literature total                 | 446                    | 5.4  | 238   | 2.5 | 139          | 1.4 | 137   | 0   | 139          | 1.4 | 135   | 1.5 |
| 6 months FDA total                        | 4,412                  | 3.2  | 7,554 | 1.1 | 4,414        | 0.3 | 7,810 | 0.3 | 4,299        | 2.4 | 7,612 | 1.4 |

Data set modified from Shortt et al. [3]

PRK photorefractive keratectomy, loss of  $\geq 2$  lines eyes that lost of  $\geq 2$  lines of SCVA, SCVA < 20/40 final SCVA worse than 20/40, SCVA < 20/25 final SCVA worse than 20/25 when preoperative best SCVA  $\geq 20/20$ , FDA US Food and Drug Administration, NA not applicable

mally used to correct higher ametropias, an expected result with most of the patients within  $\pm 1.00$ , should be appreciated [10–14]. Image magnification after correcting high-myopic eyes with IOLs generate a confounding factor in evaluating pre- and post-SCVA; therefore, information published on this subject lacks credibility [15].

The only procedure that does not rely on clinical refraction to determine total correction is clear lens extraction. Its predictability depends on how accurately we can determine corneal power, axial length, and the effective position of the implanted IOL. Approximately 95% of normal eyes should present less than 1.00 D of refractive error [16]. Predictability reduces greatly when operating eyes that underwent corneal refractive surgery, but new approaches for calculating IOL power have improved the results [17, 18].

### 1.1.2 Infection

Determining the risk of infection on photoablative procedures is a difficult task due to misdiagnoses and lack in laboratorial information. We may expect an incidence between 0.1:10,000 and 1:10,000, favoring LASIK over PRK [19–21]. Infection has been reported after LASIK with femtosecond laser [22]. Bilateral simultaneous keratorefractive procedures are considered standard of care [23, 24], but the risk of bilateral infection may add extra damage to this po-

tentially devastating complication. Risk of infection in intraocular surgeries should follow the incidence of infection in cataract surgery that is approximately 1:1,000 [25–27]. Intracorneal implants are theoretically more susceptible to infection due the difficulty of the immune system to act in an intrastromal fashion [28–30].

### 1.1.3 Infection and Contact Lenses

Risk of infection in contact lenses wearers should be considered when evaluating incidence of infection in refractive surgery. The risk of keratitis in contact lenses wearers depends on the modality of use (daily wear or extended wear) and the lens type. Literature has shown that, per year, the risk of presenting a severe keratitis will vary from 3:10,000 to almost 100:10,000 [31], and the risk of presenting loss of visual acuity is 3.6:10,000 among silicone hydrogel extended wearers [32].

### 1.1.4 Subjective Complaints

Subjective complaints such as halos, glare, starburst, and low-contrast sensitivity maybe correlated to low- and high-order optical aberrations [33, 34] as well as to optical characteristics of the implanted IOL [35–38] and the diameter of

the pupil [39]. All refractive procedures present the risk of subjective complaints, but special attention should be paid in keratorefractive surgeries in eyes with larger pupil diameter, since this procedure is performed further from the pupil plane, when compared with phakic intraocular implants or clear lens extraction.

### 1.1.5 Retinal Detachment

Retinal detachment has been associated with LASIK [40–44]; but, so far, it is not possible to detect a cause–effect relationship nor to determine a higher incidence of vitreoretinal pathological conditions post-LASIK.

Cataract extraction increases the cumulative risk of retinal detachment an average of fourfold. There is no difference between patients who underwent extracapsular cataract extraction and phacoemulsification. The risk increases in myopic [45], younger men (less than 50 years old) [46, 47]. It has been suggested that phakic IOLs implantation may be related to a higher risk of retinal detachment [48, 49].

## 1.2 Keratorefractive Procedures

### 1.2.1 Photorefractive Keratectomy

#### 1.2.1.1 Haze

Incidence of haze and treatment regression is associated to the attempted correction and may be expected to be up to 2% in the first year post-PRK [50]. Although it is commonly suggested that haze may be less incident with newer lasers, there is no scientific evidence that it is true [51].

#### 1.2.1.2 Mitomycin C

The use of intraoperative mitomycin C has raised the expectation for treating higher ametropias with PRK [52–57]. Potential risks associated to its use are the consequences of keratocyte depletion [58] as well as endothelium and anterior chamber toxicity [59, 60].

#### 1.2.1.3 Keratectasia

Although there are reports of keratectasia that occurred in normal eyes after PRK [61], most the few cases reported so far are of forme fruste keratoconus that progressed after PRK [62–64] or phototherapeutic keratectomy (PTK) [65, 66]. It is still to be proven if the procedure influences the progression of the disease.

### 1.2.2 LASIK

#### 1.2.2.1 Microkeratome-Related Complications

Irregular flaps related to the microkeratome cut maybe presented as incomplete flaps, free caps, buttonholed flaps [67], thin flaps, thick flaps, and partially cut flaps. Irregular flaps

are expected in less than 1% of the procedures performed with new microkeratomes [23, 68–72]. Microkeratome-related complications depend on the learning curve and may be two or three times more frequent in the first 1,000 surgeries [69]. Initial microkeratomes had a complication rate of up to 6%; their evolution, with new safety concerns, decreased the incidence [70, 72]. Outcomes after an irregular flap are improved if photoablation is not carried out at the time of the complication [73, 74].

#### 1.2.2.2 Femtosecond Laser

Most of the literature shows that reliability in flap creation has increased with the use of femtosecond laser [75–77], but some articles do not differentiate the outcomes between microkeratome and femtosecond laser [78, 79]. A new entity, transient light-sensitivity syndrome (TLSS), was reported in approximately 1% of the eyes with femtosecond laser-created flaps [80, 81].

#### 1.2.2.3 Dislocated Flap

Flap dislocation is a complication encountered in approximately 2% of the procedures [71, 82] and has been reported up to 30 months after the surgery [83–85].

#### 1.2.2.4 Diffuse Lamellar Keratitis

Diffuse lamellar keratitis (DLK) is a disease of unknown pathophysiology [86–88] that was first described in 1998 [89]. It occurs in an average of 0.7% of the procedures, and it is most frequently present in outbreaks [90]. A hyperopic shift and increased optical aberrations are expected in patients that presented DLK [91, 92].

#### 1.2.2.5 Keratectasia

Although there are reports of ectasia that occurred in eyes without known risk factors [93], approximately 90% of the eyes that develop ectasia have preoperative signs of forme fruste keratoconus [94]. Besides the diagnosis of forme fruste keratoconus and residual stromal bed of less than 250  $\mu\text{m}$  [94], known topographical risk factors for corneal ectasia post-LASIK are corneal curvature, pachymetry, oblique astigmatism, posterior corneal surface elevation, difference between inferior and superior corneal dioptric power, and correlation between anterior and posterior best-fit sphere [95]. Treatments for corneal ectasia include rigid contact lenses, intrastromal corneal rings [96], keratoplasty, and collagen cross-linking [97, 98].

## 1.3 Phakic Intraocular Lenses

### 1.3.1 Endothelial Cell Loss

Anterior chamber angle-supported phakic IOLs present an initial decrease in endothelium cell density of 5–10% in 2

years, with a slightly higher than normal decrease after that [99–102]. Iris-supported lenses appear to present continuous decrease in cell density at longer follow-up, achieving between 10 and 15% at 2 years [99, 103, 104]. Although posterior-chamber IOLs have a lower risk of endothelial cell loss, a decrease of 5 to 10% may be expected 2 years after surgery [105]. Careful follow-up of patients who have undergone phakic implants should allow lenses to be removed before any clinical symptoms present, if damage of the endothelium persists.

### 1.3.2 Pupillary Block Glaucoma

Pupillary block glaucoma has been reported in anterior chamber iris-supported [106], angle-supported [107, 108], and posterior chamber phakic IOLs [109–111]. Preoperative iridectomy is mandatory, but pupillary block has been reported even in the presence of effective iridectomy [111].

### 1.3.3 Iris Atrophy and Pupil Ovalization

Eyes with anterior chamber angle-supported phakic IOLs have a tendency to present sectorial iris atrophy and consequent pupil ovalization [100–102, 107]. Its frequency depends on the limits accepted, but up to 40% ovalization (difference of 0.5 mm in orthogonal diameters) may be expected [101].

### 1.3.4 Chronic Inflammation

Chronic inflammation is present in all phakic IOL models. It has been reported to be higher than are controls in anterior chamber iris-supported and anterior chamber angle-supported at 12, 18, and 24 months after surgery [101, 112]. Aqueous flare was slightly better for the angle-supported group.

In posterior chamber IOLs, aqueous flare increased by 49.19% in the first postoperative month in relation to preoperative values, decreasing afterward, but remaining above preoperative values up to 2 years postoperatively [105].

### 1.3.5 Intraocular Lens Dislocation

Traumatic and spontaneous IOL dislocations have been described in anterior chamber iris-supported phakic IOLs [113, 114].

### 1.3.6 Cataract

Anterior subcapsular cataracts are related to posterior chamber phakic IOLs implants and are present in 8.2% of the eyes [115–118]. Most of the eyes that presented cataract were operated on in the beginning of the surgeon's learning curve [117]. Nuclear cataract has been reported in ante-

rior chamber angle-supported IOLs [118, 119], but it has not possible to determine a cause–effect relationship.

### 1.3.7 Pigment Dispersion

Pigment dispersion has been observed in approximately 3% of eyes that underwent posterior chamber phakic IOL implants [110, 120, 121]. There are no reports of glaucoma in eyes that presented pigment dispersion.

### 1.3.8 Posterior Luxation (in Phakic Refractive Lens™)

Spontaneous luxation to the vitreous of one specific model of silicone posterior chamber phakic IOL (Phakic Refractive Lens, PRL™) is a severe complication related to the weakening of the zonule [122, 123].

#### Take-Home Pearls

- Refractive surgery provides a variety of elective procedures to be performed in otherwise healthy eyes. The knowledge of their possible complications is mandatory to inform our patients of their options.

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# Influence of Refractive Surgery Complications on Quality of Life

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## Core Messages

- A number of questionnaires exist for the measurement of quality of life (QOL) in the refractive surgery patient, but not all questionnaires are equal in validity.
- Rasch analysis is important in the development of questionnaires to optimize question inclusion, unidimensionality, and to provide valid linear scoring.
- A quality of life instrument should include a breadth of content areas, e.g., well-being, convenience, and concerns, not just functioning or satisfaction.
- QOL instruments readily demonstrate the benefits of refractive surgery.
- A sound QOL instrument is also sensitive to the negative impacts of surgical complications, providing an insight into the real impact of the intervention on the person.

## 2.1 Introduction

It has been customary to evaluate the success of refractive surgery using objective clinical measures such as postoperative uncorrected visual acuity (UCVA) and residual refractive error [19]. However, these measures do not necessarily correlate well with patients' postoperative subjective impressions [13]. Ultimately, the patient's perspective is an important outcome of refractive surgery and a number of instruments have been developed to assess quality of life (QOL), including the Quality of Life Impact of Refractive Correction (QIRC) questionnaire [15], the Refractive Status Vision Profile (RSVP) [17], and the National Eye Institute Refractive Quality of Life (NEI-RQL) [12]. While these instruments and others have chiefly been used to show the improvement in QOL that occurs with laser refractive surgery [2, 5, 7, 12, 13, 18], a sound QOL instrument should also be sensitive to the effect of complications from refractive surgery.

The purpose of this chapter is to outline the key issues in QOL measurement, discuss the instruments available for use, and to summarize specifically what is known about the impact of the complications of refractive surgery on QOL.

## 2.2 Measurement Concepts

Perhaps the most important issue in questionnaire selection is the validity of the scoring system. Without this, the information gathered is meaningless. The RSVP and NEI-RQL instruments use traditional summary scoring, in which an overall score is derived through summative scoring of responses [9]. Summary scoring is based on the hypotheses that all questions have equal importance, and response categories are accordingly scaled to have equal value with uniform increments from category to category. For example, in a summary-scaled visual disability questionnaire, the Activities of Daily Vision Scale (ADVS) [10], "a little difficulty" scores 4, while "extreme difficulty" is twice as bad and scores 2, and "unable to perform the activity due to vision" is similarly two times worse, with a score of 1. The same scale is applied across all questions. This rationale of "one size fits all" is flawed, and Rasch analysis has been used to confirm that differently weighted response categories are necessary to provide a valid and contextual scale that truly represents QOL. For instance, the ADVS ques-

tionnaire ascribes the same value to “a little difficulty” regarding visual ability “driving at night” as “a little difficulty” with “driving during the day,” though the former is by far the more difficult and complex task, and it defies logic to equate the two.

Rasch analysis is a new approach to questionnaire development that utilizes modern statistical methods to measure health outcomes in a meaningful way by incorporating an appropriate weighting factor for each QOL measure to provide true linear scoring, and through improved validity in terms of question inclusion and demonstration of unidimensionality [11, 20].

## 2.3 Instruments

### 2.3.1 Quality of Life Impact of Refractive Correction Questionnaire

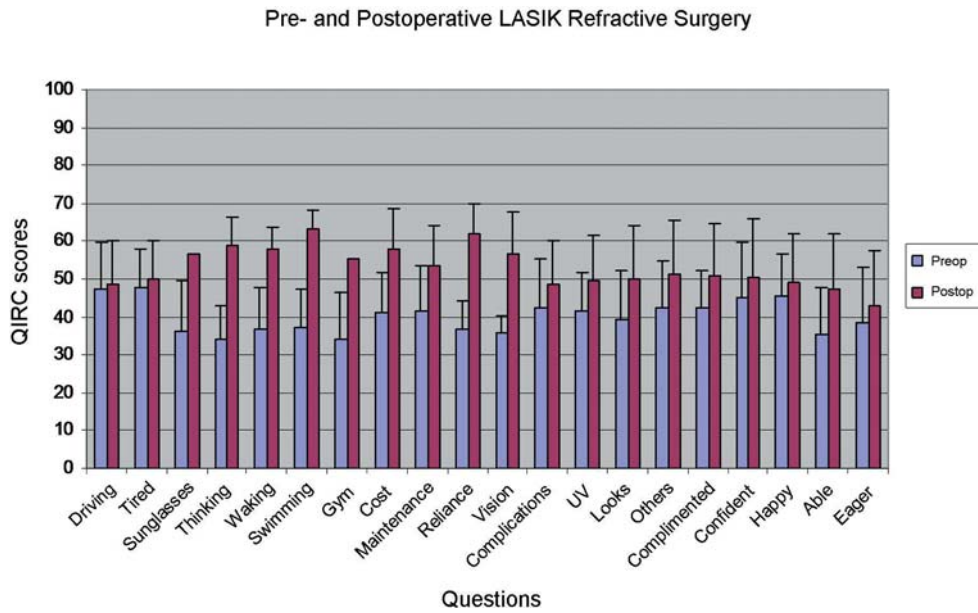
Pesudovs et al. developed and validated the QIRC questionnaire [15] to measure the impact of refractive correction on QOL. Visual function, symptoms, convenience, cost, health concerns, and well-being are included in the content of this instrument, which was rigorously developed using literature review, expert opinion, and focus groups. Content was determined using a pilot questionnaire with Rasch analysis for item reduction [20]; this resulted in the final 20-item questionnaire (Table 2.1, available in full at <http://konrad.pesudovs.com/konrad/questionnaire.html>). QIRC is ratified as a valid and reliable measure of refractive correction-related QOL by both Rasch analysis and standard psychometric techniques [15]. QIRC scores are reported on a 0–100 scale, which is free of floor and ceiling effects, with a higher score representing better QOL, and the average score being close to 50 units. QIRC has been used for measuring outcomes of refractive surgery [5] and for comparing the QOL of patients wearing spectacles, contact lenses, or post-refractive surgery [16].

The QIRC questionnaire effectively differentiates between spectacle wearers, contact lens wearers, and post-refractive surgery patients, with the refractive surgery group having a better QIRC score ( $50.23 \pm 6.31$ ) than did contact lens wearers ( $46.70 \pm 5.49$ ,  $p < 0.01$ ) and spectacle wearers ( $44.13 \pm 5.86$ ,  $p < 0.001$ ) [16]. There were significant differences between scores on 16 of the 20 questions; of the remaining 4 questions, 2 health concerns and 2 well-being questions did not detect differences between groups. QIRC scores have also been shown to improve after laser assisted in situ keratomileusis (LASIK) refractive surgery from a mean  $\pm$ SD of  $40.07 \pm 4.3$  to  $53.09 \pm 5.25$  [5].

Individual item analysis showed 15 of the 20 items demonstrated statistically significant improvement. Patients reported improved QOL on all 5 convenience items, both economic items, all 4 health concern items, and on 4 of the 7 items in the well-being domain (Fig. 2.1).

**Table 2.1.** The 20 items included in the QIRC questionnaire

| Item description |  |
|------------------|--|
| 1.               | How much difficulty do you have driving in glare conditions?   |
| 2.               | During the past month, how often have you experienced your eyes feeling tired or strained?   |
| 3.               | How much trouble is not being able to use off-the-shelf (non-prescription) sunglasses?   |
| 4.               | How much trouble is having to think about your spectacles or contact lenses or your eyes after refractive surgery before doing things, e.g., traveling, sport, going swimming?     |
| 5.               | How much trouble is not being able to see when you wake up, e.g., to go to the bathroom, look after a baby, see alarm clock?   |
| 6.               | How much trouble is not being able to see when you are on the beach or swimming in the sea or pool, because you do these activities without spectacles or contact lenses?          |
| 7.               | How much trouble are your spectacles or contact lenses when you wear them when using a gym/doing keep-fit classes/circuit training etc?  |
| 8.               | How concerned are you about the initial and ongoing cost to buy your current spectacles/contact lenses/refractive surgery?   |
| 9.               | How concerned are you about the cost of unscheduled maintenance of your spectacles/contact lenses/refractive surgery, e.g., breakage, loss, new eye problems?                      |
| 10.              | How concerned are you about having to increasingly rely on your spectacles or contact lenses since you started to wear them?   |
| 11.              | How concerned are you about your vision not being as good as it could be?  |
| 12.              | How concerned are you about medical complications from your choice of optical correction (spectacles, contact lenses, and/or refractive surgery)?                                  |
| 13.              | How concerned are you about eye protection from ultraviolet (UV) radiation?  |
| 14.              | During the past month, how much of the time have you felt that you have looked your best?  |
| 15.              | During the past month, how much of the time have you felt that you think others see you the way you would like them to (e.g., intelligent, sophisticated, successful, cool, etc.)? |
| 16.              | During the past month, how much of the time have you felt complimented/flattered?  |
| 17.              | During the past month, how much of the time have you felt confident?   |
| 18.              | During the past month, how much of the time have you felt happy?   |
| 19.              | During the past month, how much of the time have you felt able to do the things you want to do?  |
| 20.              | During the past month, how much of the time have you felt eager to try new things?   |



**Fig. 2.1.** Pre- and post-LASIK mean (error bars  $\pm 1$  SD) responses on each QIRC question

### 2.3.2 Refractive Status Vision Profile

The RSVP was developed almost exclusively on a refractive surgery population (92% of subjects), so it is really only valid for refractive surgery [17]. Its 42 items fall into the domains of concern (6 items), expectations (2), physical/social functioning (11), driving (3), symptoms (5), glare (3), optical problems (5), and problems with corrective lenses (7 items) [18]. The RSVP has been shown to be sensitive to QOL changes related to visual functioning and refractive error, and is responsive to refractive surgery [18]. Improvements after refractive surgery occurred in the subscales: expectations, physical and social functioning and problems with corrective lenses.

The RSVP was developed using traditional techniques, but its psychometric properties were re-evaluated by Garamendi et al., using Rasch analysis. The original 42-item questionnaire showed poor targeting of item impact to patient QOL, items with a ceiling effect, underutilized response categories, and a high level of redundancy. Rasch analysis guided response-scale restructuring and item reduction to a 20-item instrument, with improved internal consistency and precision for discriminating between groups. Fourteen items relating to functioning and driving were reduced to five items and eight related to symptoms and glare were reduced to three. This is consistent with the content of the QIRC questionnaire, in which Rasch analysis identified that patients with corrected refractive error experienced few problems with visual function, and issues of convenience, cost, health concerns, and well-being were more influential on QOL [15]. Perhaps the reason why the original RSVP was so heavily weighted with functioning and symptoms questions was because the items were principally determined by clinicians [17], who tend to deal with patients' presenting complaints of symptoms or functional

difficulties instead of using more objective methodology to discover the less acute but still important QOL issues.

### 2.3.3 National Eye Institute Refractive Quality of Life Instrument

The NEI-RQL instrument is a conventionally developed 42-item questionnaire that includes subscales related to clarity of vision, expectations, near and far vision, diurnal fluctuations, activity limitations, glare, symptoms, dependence on correction, worry, suboptimal correction, appearance, and satisfaction. The development and validation of the NEI-RQL was spread across three papers and despite rigorous work with focus groups, there is no report on how the final 42 items were selected [3, 6, 12]. However, the NEI-RQL can discriminate between modes of refractive correction and is sensitive to QOL changes related to visual functioning and refractive error. Two studies have used the NEI-RQL to demonstrate improved QOL after refractive surgery [12, 14]. The NEI-RQL has not been tested or scaled using Rasch analysis.

### 2.3.4 Others

The Myopia Specific Quality of Life and the Canadian Refractive Surgery Research Group Questionnaires have been conventionally validated and shown to be responsive to refractive surgery [4, 8]. Other studies that report QOL issues before and after refractive surgery have used informal, non-validated questionnaires, [1, 2, 7, 13] so really only provide limited evidence.

## 2.4 Complications and QOL

### 2.4.1 QIRC

Two studies using the QIRC questionnaire have highlighted QOL problems after LASIK. In a cross-sectional comparison of spectacle, contact lens, and refractive surgery patients, the post-refractive surgery group was also asked to report any visual disturbances that arose after surgery, and a small number optionally reported postoperative complications. Nine (8.6%) LASIK patients volunteered written comments regarding their postoperative status (including poor vision in low light, dry eyes, regression, and halos at night); five of these nine were very negative about their refractive surgery. Seven patients (6.7%) had a very low QIRC score ( $37.86 \pm 2.13$ ), which included the five who volunteered negative comments and two who did not comment. Three of these patients were still wearing spectacles all day every day, and two suffered from significant dry eye [16]. In another study, looking at the outcome of LASIK, large improvements in QOL were found in the majority of subjects [5]. Three (4.5%) subjects had decreased QIRC scores, and these were associated with complications. All reported decreased quality of vision including driving at night, and one reported light sensitivity. Low scores were manifested in visual function, symptoms, concerns, and well-being items. None of the patients with improved QIRC scores experienced any serious complications after LASIK.

### 2.4.2 RSVP

Schein et al. investigated laser refractive surgery outcomes using the RSVP and found a worsening of overall score in 4.5% of patients [18]. With regard to individual subscales, poorer postoperative scores occurred for 29.5% of subjects on the driving subscale, 19.9% for optical problems, 16.3% for glare, 12.7% for symptoms, 7.4% for concern, 5.9% for functioning, and 2.3% had trouble with corrective lenses. A worsening of at least one subscale score was found in 26% of patients, and 15% reported dissatisfaction with vision postoperatively. Increased age at surgery was the strongest predictor of poorer RSVP scores or dissatisfaction with vision.

### 2.4.3 NEI-RQL

McDonnell et al. found QOL, as measured with the NEI-RQL, improved overall after LASIK, but symptoms of glare were significantly worse, and clarity of vision showed no significant change [12]. Nichols et al. also looked at the NEI-RQL and did not report any adverse outcomes [14]. These results raise the possibility that the NEI-RQL is not very sensitive to the negative QOL impacts of complications of refractive surgery.

### 2.4.4 Outcomes Reported with Other Instruments

In early PRK outcomes research, 77.5% of 173 patients reported improvement in their general QOL, but 16.8% were debilitated by subjective visual symptoms [2]. The only significant preoperative predictor was refractive error—higher preoperative refraction leads to lower satisfaction rates. In another large PRK study, 31.7% of 690 patients reported worsening night vision after surgery, and 30% reported dissatisfaction with night vision [4]. The frequency of each of the reported symptoms was 34.3% for starbursts, 52.4% for halos, and 61.5% for glare from oncoming headlights. For the patients who experienced glare, 55.6% reported that it was more debilitating post-PRK. These findings are in contrast to those reported after LASIK.

McGhee et al. reported only 3 of 50 LASIK patients experienced night vision symptoms, and only 1 reported dissatisfaction or that their QOL was not improved [13]. They also reported that patients who aimed for a residual myopic refraction expressed disappointment with UCVA, and that presbyopia experienced suboptimal near vision. However, limitations of this study are that the only content area tested was functioning, and no patients had any serious complications. Hill found that only 3 in 200 subjects would not have LASIK again despite 24% reporting worsening night vision and 27% reporting light sensitivity [7]. The 3 individuals cited worsening night vision, presbyopia, and psychological distress as reasons for opting against the intervention. Bailey et al., in a patient satisfaction survey, found 16 of 604 patients were dissatisfied after LASIK, and a high percentage of these reported symptoms of glare, halos, or starbursts (81.3%) [1]. Those who had surgical enhancement were found to be more likely to experience these symptoms, and along with those with increased age, greater corneal toricity, or smaller pupil size were less likely to be satisfied with the intervention.

Lee et al. developed the Myopia Specific Quality of Life Questionnaire, which contains four domains: visual function, symptoms, social role function, and psychological well-being [8]. They identified eight adverse symptoms that were most frequently reported after LASIK: eye dryness, blurred vision, lowered indoor or night vision, halos, regression, glare, temporary reduction in near vision, and infection. Multivariate analysis showed that patients having symptoms that are more adverse experienced significantly less improvement in QOL, so they concluded that freedom from adverse effects is one of the most important requirements for achieving excellent outcomes.

## 2.5 Implications

The caveat with the usually high QOL afforded by refractive surgery is the associated risk. Common complications of laser refractive surgery such as loss of contrast vision, loss of best-corrected vision, regression, and dry eye problems are effectively identified by QOL instruments, with patients

requiring spectacle or contact lens correction or experiencing severe dry eye faring the worst. Night vision symptoms are common, but these do not necessarily negatively affect QOL. While QOL research has identified some risk factors for poorer outcome, e.g., older age and multiple treatments, this information does not translate into an altered patient selection strategy. While these results suggest that night vision symptoms are less prevalent with LASIK than PRK, there is no evidence that newer laser treatment paradigms provide any QOL benefit compared to older systems. Ongoing evaluation of refractive surgery outcomes using QOL measurement is required to demonstrate the benefits of technological increments.

### Take-Home Pearls

- Questionnaires can effectively demonstrate improved QOL from laser refractive surgery.
- Serious complications of refractive surgery lead to markedly reduced QOL, but minor complications, like night vision disturbances, may not negatively affect QOL.
- Routine evaluation of refractive surgery outcomes should include QOL measurement.
- The ideal QOL outcome measure for refractive surgery would contain broad content, be developed and validated with Rasch analysis and have valid linear scoring, e.g., QIRC.

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## Core Messages

- A thin, irregular, or buttonhole flap is a significant complication of lamellar surgery that typically calls for aborting the case.
- Thin, irregular or buttonhole flaps can occur with all keratomes, including the new femtosecond devices.
- The cause of a thin, irregular, or buttonhole flap is often unclear and can be multifactorial.
- Causes of a thin, irregular, or buttonhole flap may include low pressure, poor corneal lubrication, poor blade quality, preexisting corneal pathology, or a keratome malfunction.
- Most thin, irregular, or buttonhole flap cases can be redone with either LASIK or PRK and do have a good prognosis.
- Remember, the key when faced with a poor flap typically is not to ablate.

**3.1 Thin, Irregular, Buttonhole Flaps***Stephen G. Slade*

Many of the serious complications of laser assisted in situ keratomileusis (LASIK) are related to the use of the keratome. In this chapter, we will at the causes, prevention, diagnosis, and treatment of thin, irregular, or buttonhole flaps of poor quality or “poor-quality flaps.” These poor-quality flaps are a significant concern with lamellar surgery, for example, the incidence of buttonhole flaps using a mechanical microkeratome ranges between 0.3 and 2.6% of general LASIK procedures [1]. The incidence with the femtosecond laser seems lower. No buttonhole flaps were reported during the clinical evaluation of the IntraLase® FS laser. To date, IntraLase has received one confirmed buttonhole flap report out of 873,777 procedures performed. This represents an incidence of 0.0001%. This is still serious, as various sources state that of all of the flap complications, the occurrence of a buttonhole flap is the most likely to result in a poor refractive outcome, if not managed properly (Fig. 3.1.1).