

Commentaries

Predictability

The English weather is notoriously unpredictable. Tourists travelling in the summer months are more likely to have periods of sunshine with warmer temperatures than they would have in the winter months, but no honest touring company would offer a guarantee of freedom from rain. Snow in the warmer months is not exactly unknown, though it is certainly rare. For a predictable climate, one might choose Singapore where the weather is relentlessly hot and invariably humid. There are well known rainy months. The weather in the Sahara desert is similarly predictable. Predictability in the mind of the public, therefore, tends to be something that you either have or that you do not. A matter is predictable or unpredictable.

In medical terms, a young healthy patient who develops acute appendicitis and submits himself to surgery has a fairly highly predictable chance of surviving and continuing to lead a healthy life. Nearer to home in ophthalmological terms, a patient undergoing modern small incision cataract surgery also can enjoy a highly predictable outcome of success. Patients being counselled before such operations can, therefore, be assured that they have little cause for alarm, despite the fact that there are no guarantees in the surgical world.

Predictability has become a commonly used term in connection with refractive surgery,^{1,2} both in the assessment of results and for the counselling of patients who present themselves for possible treatment. What, however, does the term now mean?

The only refractive procedure with comparable predictability to the above examples likely to have a successful outcome and a predictable optical result would be clear lens surgery for the alleviation of an underlying refractive error. Radial keratotomy could be said to enjoy an excellent record for good vision after surgery providing the patient has no more than 1 or 2 dioptres of myopia. For more than this, the predictability progressively falls away sharply as the preoperative myopia increases.^{3,4} What is worse, however, is that the stated predictability fails to include the high likelihood of progressive overcorrection with relentlessly increasing hypermetropia which, in some cases, can be a continuous process going on for years.

The refractive service at Moorfields Eye Hospital has maintained an investigative, experimental programme for nearly 20 years, initially offering radial keratotomy in addition to a variety of techniques to deal with post-surgical astigmatism. From 1990 onwards, the service has been overwhelmingly concerned with the complex question of laser photorefractive keratectomy (PRK). As our experience expanded, we were able to use our results to produce a 'predictability table' for other patients intending to proceed. Although, for example, patients with 4 or 5 dioptres of uncomplicated myopia would be told that their chances of achieving emmetropia following PRK were not better than 60% at the best, only a minority of patients so advised elected to be deferred. This is very worrying. A predictability of 60% is not much better than 50%. In other words, total unpredictability. The use of the expression predictability in the minds of those who are not necessarily geared up to assessing chances may very well be misleading. Predictability of 50% sounds more encouraging than 'highly unpredictable'.

If failing to achieve emmetropia were the worst thing that could befall such patients one would not mind so much. The fact is, however, that corneal refractive surgery can damage vision. Reports of surgical outcomes continue to list the proportions of patients who have lost two or more lines of best corrected visual acuity (BCVA). The loss of only one line of BCVA is regarded as being so frequent as to be scarcely worth reporting. Other patients who are reported as achieving acceptable levels of uncorrected vision following refractive surgery may complain that the quality of their vision is seriously impaired and is incomparably inferior to that which they previously enjoyed before surgery, either with their glasses or contact lenses. These patients are not reported at all as, from a surgical point of view, they are deemed to be successes. Their problems with perception do not fall within the commonly recognised spectrum of complications.

If a patient diagnosed as having carcinoma of the stomach is offered a 50% chance of surviving surgery for a period of 5 years, then the chance may well be worth taking. Why would patients who are not faced with a life and death situation and are merely inconvenienced by the presence of a refractive error submit themselves to surgical procedures involving the welfare of one of their most important sensory functions?

The difficulties for the surgeon in explaining to a potential refractive surgical patient the problems of regression, loss of best corrected acuity, donation of surgically induced corneal scarring, astigmatism,⁵ and loss of contrast sensitivity⁶ are immense and most won't even attempt it, relying instead on the provision of written lists upon which they may well be prepared to answer questions at a later date. The result is that very, very few patients are truly well informed before submitting themselves to a procedure which, in many instances, has to be a gambling exercise. In my experience, most medicolegal problems arising after refractive surgery are related to patients claiming that they were not warned sufficiently about what might occur following their surgical procedures. Estimates of predictability where they have been provided were frequently misunderstood.

The problem is that we are dealing with techniques that are still in their relative infancy. Technology is advancing rapidly, and predictable outcomes based on information even as little as a year old may no longer be relevant. Refractive surgery is going to continue to be available. How can patients be protected from their own often misguided enthusiasm? Our own answer to this involves multimedia teaching, including a video lecture, a question and answer session, and the provision of detailed reading matter in addition to a personal interview with a surgeon . . . all very expensive and time consuming, but for an investigative programme, however, all absolutely essential.

The fact of the matter remains that corneal refractive procedures, unlike clear lens surgery, are followed by variable biological responses, difficult to control or eliminate, which can continue to affect the refractive outcome of a procedure for years. Progressive hypermetropia after an earlier RK procedure has no definable limit. 'Corneal haze' with scarring after PRK is said to disappear with time, and may, in fact, well do so. No one yet can say how long the

most persistent cases will take. Corneal refractive procedures looked at in this light can never be truly predictable in the same sense as the term would be used in more straightforward surgical circumstances.

Light is showing at the end of this tunnel. As our experience with PRK progresses and the software and hardware available are progressively refined, so we are starting to see increasing numbers of patients and proportions of patient populations falling into the category of both surgical success and good patient satisfaction.^{7,8} In our own refractive service, the quality of results between our phase III and phase IV has been dramatic. The 1 year results for patients with up to 8 dioptres of preoperative myopia are now as good as anything that can be achieved by laser intrastromal keratomileusis (LASIK), and, of course, with a very much simpler technique. Corneal opacity as a worrying iatrogenic factor is steadily subsiding and, hopefully, with it will disappear the problems of irregular astigmatism, central islands, and lines of lost BCVA. When such pleasing improvements can be reported following procedures for hypermetropia and high myopia, we will be able to feel more comfortable about the risks to vision. Meanwhile, it is my contention that the expression

of predictability should not be aired in a clinical context where patients are likely to misunderstand the expression as being positively encouraging, irrespective of whatever figures are put up beside it.

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A British ophthalmological surveillance unit

There are a number of rare ophthalmological conditions that individual clinicians may only see every 1 to 2 years. By themselves, these conditions contribute very little to national visual morbidity but are often of great inherent interest to the ophthalmological community as a whole for a number of reasons.

Firstly, it is evident that certain rare diseases provide fundamental models that would help in the understanding of the pathogenesis of other commoner disorders. In the field of uveitis, for instance, comprehension of the mechanisms that underlie sympathetic ophthalmia would not only improve the management of this disease in those rare patients that contract it, but also might throw light on the pathogenesis of many disorders that result in intraocular inflammation from whatever cause. Similarly, the rapid identification of patient pedigrees in uncommon genetic disorders and the application of modern molecular genetic techniques to these rare cases could have a major impact in the field of prenatal screening and, ultimately, in their possible cure. Secondly, the ability to identify rare complications of common diseases or procedures may be of direct relevance to the ophthalmological community as a whole: the changing incidence of life threatening reactions to different techniques of ocular anaesthesia or the prevalence of systemic complications to the injection of fluorescein dye are cases in point. The size of the problem needs to be known in order to advise on optimum clinical practice—for example, the necessity for full time anaesthetic support, etc. Thirdly, the collection of rare cases for cohort studies either for the characterisation of the natural history of the disorder (such as the outcome in patients with treated retinopathy of prematurity) or for the accumulation of sufficient cases for meaningful prospective therapeutic trials (for example, in fungal keratitis) would be a major benefit.

Finally, and most importantly, the collection of epidemiological data on the incidence and prevalence of rare diseases (or changes in these factors) would have

important implications for public health. This aspect is possible since ophthalmologists are the only members of the medical profession involved in the management of eye disease. The impact on public health is exemplified by the two infectious diseases, toxoplasmosis and toxocariasis. These diseases have emerged as public health problems, not because their epidemiology is changing, but because of increased public awareness of their impact on the health of both children and adults, in particular their potential to cause blindness. In the case of toxoplasmosis this has revolved around campaigns to promote a nationwide screening programme of pregnant women for congenital toxoplasmosis and, in the case of toxocariasis, campaigns to promote responsible dog ownership and the exclusion of dogs from public parks. In both instances, statements about the size of the problem are not based on fact and have often been embellished in order to stimulate public and political interest. The figures quoted tend to be alarming and consequently emotive, and are usually derived from old ad hoc studies whose results have been unreasonably extrapolated. Further recent examples to illustrate these public health issues might be the change in incidence of acanthamoeba keratitis with disposable contact lens wear, or the possible association of anophthalmia with insecticide usage.

Against this background there is clearly a need for a specialised ophthalmological surveillance unit. At present, investigators interested in identifying these rare diseases nationally must rely on passive, retrospective reporting resulting from expensive and extensive mailshots often with poorly validated, cumbersome questionnaires. Since remembering individual cases is rarely good the result is usually a poor response. A suitable model for acquiring the necessary information would be by active case ascertainment of the disease of interest. In this system individual ophthalmologists would receive a reporting card every month on which they would tick whether they had had a



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