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General Comment

Comment

I am an ophthalmologist but I do not perform refractive surgery. I have no financial relationships with corporations in the refractive surgery industry. I do not believe that excimer laser surgery should be "banned". I refer patients to my conservative, ethical associate if they express an interest in surgical reduction of refractive error.

The statement that "one percent" or "less than one percent" of patients undergoing refractive surgery experiences complications is widely quoted in the lay press and is often stated by refractive surgeons, who also report their anecdotal experience with many satisfied patients. My purpose in writing today is to debunk this number.

Effect of the Euphoria Period

When first liberated from glasses and/or contact lenses, patients are understandably astonished and euphoric over their ability to navigate through life without optical correction. Many of the superlatives applied by patients are garnered during this early post-operative period. Poor contrast sensitivity, night vision difficulties, and pain from dry eye symptoms are dismissed as expected, short term issues which do not (yet) detract from satisfaction with the final

outcome.

Refractive surgeons who perform their final patient examination less than 6 months after surgery have no experience with long-term patient satisfaction or the frequency of permanent vision difficulties which interfere with daily function. Sporadic reports from co-managing optometrists are not sufficient to create a detailed professional understanding of these issues.

Therefore, the personal anecdotal experience of typical high volume refractive surgeons is suspect, since most do not follow their patients long-term.

Inadequate Measurement of Induced Visual Aberrations

The original phase III FDA trials of excimer laser refractive surgery contained a fatal conceptual flaw as regards assessment of vision. Vision, broadly defined, encompasses many psychovisual phenomenon, of which high-contrast visual acuity is not the most functionally important in many situations. Yet, the FDA allowed high-contrast visual acuity, residual refractive error and 6-month refractive stability to be the major determinants of the "safety and efficacy" of excimer laser devices(1-3). No formal testing of point-light-source scatter (the origin of halos and starbursts around car headlights at night) was performed, despite the fact that it could be accomplished with relatively simple computer software(4-7). Contrast sensitivity testing was not routinely incorporated into study designs(8). Even accurate measurement of pupil diameter was neglected during the trials of fixed-zone treatments(2), despite the fact that principles of physiologic optics clearly predicted the hazards of creating an optical zone smaller than the low-light pupil (9).

Instead, these early trials depended exclusively on "patient satisfaction surveys" and "better or worse" symptom questionnaires(1, 2) as indirect measures of overall vision function. The original surveys were not published and there is no evidence that they were validated prior to use(10). One person's "highly satisfied" may be another patient's functional disaster, especially as regards vision performance in low light environments (for an illustrative patient/study subject story, see the comments of Mr. Rick Kwiecinski at the July 23, 1999 meeting of the Ophthalmic Devices Panel; http://www.fda.gov/ohrms/dockets/AC/99/transcpt/3528t2.pdf).

In published clinical trial reports, the use of statistical averages prevented neutral readers from identifying worrisome groups of outlier patients. Vague wording and favorable opinion were applied frequently. How are we to interpret the statement (2) that "Overall, at least 82.8% of spherical subjects and 81.5% of astigmatic subjects were satisfied or extremely satisfied with the results of their surgery"? Perhaps the answer is that nearly 20% of subjects in this trial were not satisfied with the overall effect of refractive surgery on their visual function. It is amusing to find "at least" juxtaposed with statistical precision to one-tenth of a patient.

The FDA has no idea of the true rate of permanent, functionally important induced vision aberrations or reduction in overall vision performance.

As a separate but related issue, the FDA has no idea of the scope of the public health issue which may arise as millions of post-refractive surgery patients grow older, develop inter-current eye disease, and drive with halos/starbursts and degraded contrast sensitivity. A level of reduced low-light driving performance which is "satisfactory" to one individual may, in the aggregate(11, 12), present a significant risk to the populace at large.

Failure of Post-Market Surveillance

Manufacturers have a regulatory obligation [21 CFR 803] to participate in post-market surveillance and to report adverse events. This process is easily circumvented. Several market forces combine to make it particularly ineffective in refractive surgery.

First, refractive surgeons dismiss or ignore patient complaints which should be reported as adverse events. For evidence of this, see the public comments of the Ophthalmic Devices Panel meeting held on April 25, 2008. In particular, the true incidence of permanently symptomatic dry eye syndrome after LASIK is probably higher than 1%, especially in middle-aged female patients.

Second, excimer laser manufacturers "hold all the cards" when a surgeon reports a poor outcome to the company. Surgeons are usually told "the laser is fine". Since we are entertaining anecdotal commentary, I, personally and anecdotally, have never heard of a single incident in which the surgeon was told by the field technician "the laser malfunctioned". The excimer laser in refractive surgery is an open-loop engineering system and no surgeon can ever be positive that the device achieved the desired ablation profile. Surgeons must face multiple patients with poor results (vis the recall of the Alcon LADARvision 6000) or compare notes at national meetings to detect patterns of poor outcome that cannot be explained by

similarly incorrect surgical technique on the part of many practitioners.

Third, laser manufacturers may use internal complaint review processes to "determine" that no device fault occurred, and then fail to create a manufacturer device report (MDR) as required by regulation. At least one manufacturer (Alcon Laboratories Inc.) has been caught by the FDA suppressing surgeon complaints regarding retreatment by declaring that retreatment is "not a complication" and "not a reportable adverse event" [see the letter dated July 16, 2005 from Timothy Couzins, Compliance Officer, Florida District, FDA to Rebecca G. Walker, Vice President, Regulatory Compliance, Alcon Laboratories Inc.; see the letter dated December 30, 2005 from Sharon Kapsch, Branch Chief, Reporting Systems Monitoring Branch, FDA to Rebecca G. Walker].

Summary

The true incidence of permanent vision loss and/or symptomatic ocular surface disease following laser refractive surgery is unknown for the following reasons:

1) The original clinical trials were poorly designed and failed to incorporate relevant visual performance metrics beyond high-contrast visual acuity and refractive error.

2) The original clinical trials were poorly designed and failed to capture data on the effects on vision function beyond self-reported, subjective patient surveys.

3) The original clinical trials were poorly designed and failed to capture sufficient data regarding the induction and/or exacerbation of permanently symptomatic ocular surface disease ("dry eye syndrome") and to identify sub-populations at greater risk.

4) Refractive surgeons tend to dismiss patient complaints in the early post-operative period, and many do not provide long-term follow-up.

5) When surgeons do complain to manufacturers, they are dismissed as being "at fault" for a poor outcome and are subjected to financial penalty if they persist (see Brian Will MD vs Alcon Laboratories Inc.)

5) Laser manufacturers can (and have) violated FDA adverse event reporting requirements, nullifying efforts at post-market surveillance.

Implications

Many commentators have asserted that laser refractive surgery is an elective procedure and that the consent process – which has become increasingly elaborate – fully informs the patient of the risks it entails. In fact, the true frequency of various adverse events is not known therefore patients cannot be accurately and fully informed. Further, patients are provided with flawed "satisfaction" data as a proxy for the effects of refractive surgery on ordinary activities of daily living, which does not create the context for a truly individual decision to accept the risks inherent in these procedures: one patient's "highly satisfied" result may encapsulate poor contrast and night vision disturbances that another patient finds nearly intolerable. What is needed is a consent process which states (for example): 12 months after surgery, 25% of formerly myopic patients see car headlights which look like this standard clinical trial photograph. Do you feel you could drive safely at night with similar vision? If no, do not proceed.

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