

46-Prospective randomized comparison of simultaneous and sequential bilateral laser in-situ keratomileusis (LASIK) for the correction of myopia

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Is it safe and ethical for refractive surgeons to perform bilateral simultaneous LASIK on their patients? This question regarding the appropriateness of bilateral simultaneous refractive surgery was first raised regarding RK and later PRK. If not reality, at least the perception of many ophthalmologists is that the incidence of serious, visually-disabling complications may be greater by the more technically-challenging LASIK technique. All the more reason to raise this question again.

George O. Waring, III, of Emory University in Atlanta, GA was the first author in this study comparing simultaneous vs. sequential bilateral LASIK for the correction of myopia. Co-authors in this study included Jonathan D. Carr, M.D., R. Doyle Stulting, M.D., Ph.D., and Keith P. Thompson, M.D., all also of Emory University.

According to Dr. Waring, "One of the most challenging questions that refractive surgeons today face is whether or not to perform bilateral, simultaneous LASIK versus sequential surgery."

Dr. Waring's group therefore obtained data on 251 consecutive patients who were randomized to receive either simultaneous, or sequential LASIK. Mean follow-up was 10 months.

Dr. Waring gave the caveat that enrollment in his study was limited by the FDA's IDE protocol. The numbers of patients in the study, therefore, were too low to generate sufficient power to definitively analyze certain parameters, and to answer certain questions one might wish to address.

For example, Dr. Waring stated, in order to prove a difference (or the lack of a difference) in the incidence of postoperative refraction within +/- .50 D between the simultaneous and sequential groups, 22,000 eyes would need to be included in the study group. Clearly, this is a practical impossibility.

Too often, authors incorrectly state, "there were no statistically significant differences between the groups," when the more correct statement would be, "no statistically significant differences were found, given the power of the study." The current paper by Dr. Waring and his colleagues at Emory University is notable for the attention to statistical detail and frank discussion of statistical limitations. We all would do well to follow this lead.

Despite such limitations, however, Dr. Waring and colleagues were able to make several interesting comparisons between the simultaneous and sequential groups.

No significant difference in best corrected visual acuity (BCVA), refractive outcome, or loss of 2 or more lines of BCVA was found between the simultaneous and sequential groups.

There was also no statistically significant difference in intra-operative complication rate between the two groups. Moreover, looking at each intra-operative complication, no pattern of complications between the first and second eyes could be found. The second eyes of both the simultaneous and the sequential groups had the same outcome.

There *was* a higher incidence of postoperative complications in the simultaneous compared to the sequential group. Indeed, postoperative complication rate was the one parameter with an incidence high enough to be easily within the power of the current study. The incidence of epithelial ingrowth under the LASIK flap, for example, was significantly higher in the simultaneous group compared to the sequential group.

Perhaps the most feared postoperative complication, and the one preventing some refractive surgeons from offering bilateral simultaneous LASIK to their patients, is bilateral bacterial keratitis. Of note in the current study, there were two patients with bilateral postoperative keratitis. Fortunately, both of these cases were considered “sterile,” both resolved with appropriate treatment, and in neither case did the patient suffer a permanent loss of BCVA.

These encouraging results may lead us to ask ourselves what we really mean by “simultaneous” surgery. As Dr. Waring points out, “bilateral simultaneous” surgery is not really simultaneous. Rather, it is really “immediately sequential.” A refractive surgeon can utilize the time between the two surgeries to examine the flap under the microscope, and make a decision whether to proceed with the second surgery. This is really just a compression of the steps and the thought process that we make when performing “sequential” surgery.

Dr. Waring concludes by stating, “It is reasonable for *experienced* surgeons to offer patients bilateral simultaneous surgery with proper informed consent.” Discussion of this paper was by Stephen G. Slade, M.D., of Houston, Texas. Dr. Slade commended the authors for the prospective, randomized design of the study. Although follow-up was less than 1 year, this may be adequate, in Dr. Slade’s opinion, given the rapid stabilization of refractive outcome following LASIK.

Dr. Slade commented that one of the drawbacks of the current study, namely the recruitment limitation under the FDA protocol, may also be a relative strength, since studies performed under the FDA also tend to be more rigorous.

Dr. Slade pointed out the relatively high re-treatment rate in both groups. He also offered one possible explanation for why there might be more postoperative epithelial ingrowth in the simultaneous group--because the same blade was reused for the second eye.

Examining the first eye before operating on the second eye, Dr. Slade noted, can help reduce the complication rate of the second eye only if surgeon uses good judgment. It is all too easy for the involved surgeon to decide to "press ahead" with the second eye despite a sub-optimal result in the first eye--especially with the patient already lying down under the laser, prepped and draped, expecting the second eye to be done.

Dr. Slade concludes, and I agree, that this study by Dr. Waring, et al, will have a strong impact on both patients and surgeons alike. The current study may be the one that provides sufficient support to allow more surgeons to begin to offer their patients bilateral simultaneous LASIK. One final caveat should not be ignored: it behooves patient and surgeon alike to sign a separate informed consent for simultaneous versus sequential refractive surgery.