Laser in situ keratomileusis (LASIK) for high myopia

EXCIMER laser vision correction in the form of LASIK and PRK/LASEK has been proved to be highly effective and safe in the treatment of low to moderate myopia (less than –6 diopters [D]) and astigmatism. It is the most common refractive-surgery procedure done worldwide. However, the outcome of laser vision correction among those with high myopia (greater than –6D) may not be the same as in those with low to moderate myopia.

CLINICAL SCENARIO
A 26-year-old, female, myopic patient unhappy with spectacle correction and contact lenses heard about LASIK and sought opinion regarding the probability of her achieving 20/20 vision. Her last refraction was –7.00 sphere –1.00 cylinder x 100 in the right eye (OD) and –9.00 sphere –0.50 cylinder x 90 in the left eye (OS). Best-corrected visual acuity (BCVA) was 20/20 OD and 20/20 OS. Her refraction has been stable for 5 years.

CLINICAL QUESTION
The patient has high myopia and is concerned about her chances of seeing 20/20 after undergoing laser vision correction. Among patients with high myopia, how effective is LASIK in achieving 20/20 vision?

SEARCH METHOD
An electronic literature search was performed using MEDLINE (PubMed). The following search terms were used: “Myopia,” “LASIK,” “laser in situ keratomileusis,” “technology assessment.” The search was further limited to the English language and human studies published from 1968 to April 2005. The search yielded 5 articles but only one was relevant to the clinical question.

CITATION

Keywords: Laser in situ keratomileusis, LASIK, Myopia, Refractive surgery, Astigmatism
**STUDY CHARACTERISTICS**

The article is a systematic review on the safety and efficacy of LASIK for myopia. The authors performed an electronic search using Medline and Cochrane. The literatures were limited to the English language and to peer reviewed journals published from 1968 to May 2001. Search term used was LASIK or Laser in situ keratomileusis. The search yielded 729 articles; 160 were chosen for evaluation and 47 were finally included in the review. The articles were submitted to a panel of methodologists for review and were classified as follows:

- Level 1 (RCT): 7 articles
- Level 2 (Cohort and Case Control): 10 articles
- Level 3 (Case Series): 30 articles

**DISCUSSION**

**Validity criteria**

The article was valid based on the 4 validity criteria for systematic reviews (Table 1).

A focused clinical question is essential in a systematic review, and should apply across a range of patients where an intervention will have similar impact. The focused question also serves as the inclusion criteria to avoid bias in the selection of studies. It also limits the scope of the search and helps readers decide if they share the same interest as the authors. As stated in the article, the focus of the authors’ assessment was to address the following questions: What is the efficacy (predictability, stability) of LASIK for myopia and astigmatism? What are the complications of LASIK?

The clinical question is sensible because it fulfills the components of a good clinical question, namely: population (patients with myopia and astigmatism), intervention (LASIK), outcome (efficacy and complications).

The search included all published articles in the peer-reviewed literature but was limited to those in the English language. Although some relevant studies could have been missed, it is unlikely that major studies were not included since these studies are usually published in English language publications.

All the selected studies were reviewed and assessed by a Panel of Methodologists and each paper was rated. Level I rating was assigned to properly conducted, well-designed randomized clinical trials; Level II to well-designed cohort and case-control studies; and Level III to case series. In this systematic review, only 7 papers merited a rating of Level I.

**Results**

The systematic review was done for the purpose of an ophthalmic technology assessment of LASIK for myopia and astigmatism. As such, it covered the entire range from low to moderate to high myopia. Table 2 is a summary of results from different studies relevant to the clinical question and included in the systematic review.

The studies by Hersh and Steinert were randomized controlled trials with at least 6 months of follow-up comparing LASIK with PRK in the treatment of moderate to high myopia and astigmatism. Visual acuity of 20/20 was achieved after LASIK in 26% and 36% of eyes, respectively. The studies by Casebe and Perez-Santonja, both level II studies, did not provide any data on the percentage of patients who achieved 20/20 vision. The case series by McDonald has the most number of patients with 20/20 post-LASIK vision; however, the range of myopia was from –1 to –11 diopters. The articles by Kawesch and Reviglio concentrated on very high myopia, which are beyond the range of the myopia described in the case scenario.

**Table 1. Validity criteria.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the review explicitly address a sensible clinical question?</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the search for relevant studies detailed and exhaustive?</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Were the primary studies of high methodologic quality?</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Were assessments of studies reproducible?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Table 2. Visual acuity after LASIK for moderate to high myopia.**

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of Eyes</th>
<th>Level of Evidence</th>
<th>Range of Preop Myopia (D)</th>
<th>Mean Preop Refraction (D)</th>
<th>Postop UCVA ≥ 20/20 (% of eyes)</th>
<th>Postop UCVA ≥ 20/40 (% of eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hersh, et al. 1998</td>
<td>115</td>
<td>I</td>
<td>–6 to –15</td>
<td>–9.3</td>
<td>26.2</td>
<td>55.7</td>
</tr>
<tr>
<td>Steinert, et al. 1998</td>
<td>76</td>
<td>I</td>
<td>–9 to –12</td>
<td>–9.2</td>
<td>36.0</td>
<td>85.0</td>
</tr>
<tr>
<td>Casebe, et al. 1997</td>
<td>911</td>
<td>II</td>
<td>–7 to –10</td>
<td>NR</td>
<td>NR</td>
<td>68.0</td>
</tr>
<tr>
<td>Perez-Santonja, et al. 1995</td>
<td>143</td>
<td>II</td>
<td>–8 to –20</td>
<td>–13.2</td>
<td>NR</td>
<td>46.4</td>
</tr>
<tr>
<td>McDonald, et al. 1999</td>
<td>347</td>
<td>III</td>
<td>–1 to –11</td>
<td>NR</td>
<td>57.0</td>
<td>95.0</td>
</tr>
<tr>
<td>Kawesch, et al. 1998</td>
<td>290</td>
<td>III</td>
<td>–9 to –22</td>
<td>NR</td>
<td>NR</td>
<td>85.1</td>
</tr>
<tr>
<td>Reviglio, et al. 1999</td>
<td>126</td>
<td>III</td>
<td>–10 to –25</td>
<td>–12.7</td>
<td>9.8</td>
<td>78.4</td>
</tr>
</tbody>
</table>

1 Diopter

2 Uncorrected visual acuity
Applicability

All these studies involved the use of LASIK for the correction of moderate to high myopia with UCVA as 1 of the outcome measures. However, only the studies by Hersh and Steinert are applicable to the clinical scenario because the range of myopia in their studies is similar to the case. Other outcome measures considered were postoperative refraction within \( \pm 0.50 \) D and \( \pm 1.0 \) D, loss of \( \geq 2 \) lines of best-corrected visual acuity, and frequency of operative (button holes, flap striae, etc.) and postoperative (diffuse lamellar keratitis, infections, dry eye, glare and haloes, reduced contrast sensitivity, etc.) complications. When evaluating the safety and efficacy of refractive-surgery results, it is important to consider not only visual acuity, but also other relevant clinical outcomes like quality of vision and patient satisfaction.

Refractive surgery, specifically laser vision correction, is a rapidly evolving field and is intimately related to the development of new technology. Although the basic principles of LASIK have remained essentially the same since it was first introduced by Pallikaris in 1990,2, 3 many new developments have occurred since then. Excimer laser machines have evolved from broad-beam lasers to high-frequency, small-diameter, flying-spot lasers with active eye trackers. Better understanding of corneal biomechanics and high-order optical aberrations led to the development of new nomograms and wavefront-guided customized LASIK. Microkeratomes have become safer with smoother stromal beds and more consistent flap thickness. It is, therefore, essential that any published results of studies on LASIK should be interpreted in the light of the existing technology when the study was done. Results may no longer be applicable to a particular case if the technology and techniques used were not similar.

STUDY AUTHORS’ CONCLUSIONS

For low to moderate myopia, results from studies in the literature have shown that LASIK is effective and predictable in terms of obtaining very good to excellent uncorrected visual acuity and that it is safe in terms of minimal loss of visual acuity. For moderate to high myopia (>6.0 D), the results are more variable, given the wide range of preoperative myopia. The results are similar for treated eyes with mild to moderate degrees of astigmatism (<2.0 D). Serious adverse complications leading to significant permanent visual loss such as infections and corneal ectasia probably occur rarely in LASIK procedures; however, side effects such as dry eyes, night-time starbursts, and reduced contrast sensitivity occur relatively frequently. There were insufficient data in prospective, comparative trials to describe the relative advantages and disadvantages of different lasers or nomograms.

REVIEWERS’ CONCLUSIONS

The appraised article on the safety and efficacy of LASIK for myopia and astigmatism is a valid systematic review. The results of the different studies included in the review are applicable only to the period and setting when the studies were performed. Constant updates should be made to reevaluate the procedure. Uniform methodology guidelines must be agreed upon and followed when these studies are done to allow for metaanalysis. Clinically relevant outcome measures like quality of vision and patient satisfaction must be emphasized.

RESOLUTION OF THE CLINICAL SCENARIO

The refraction of the patient in the scenario falls within the range of the cited studies for high myopia. She can be advised that the probability of her achieving 20/20 visual acuity after LASIK is 26% to 36%, assuming that the same excimer laser machine, microkeratome, operative technique, surgeon’s expertise, and postoperative medications will be used as those mentioned in the cited studies.

References