What literature review says about modern LASIK

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By Michelle Dalton

New Orleans—A systemic review of the peer-review literature has shown modern LASIK surgery is more effective and produces better outcomes than has been reported historically, said Kerry Solomon, MD.

Speaking at ASCRS 2016, Dr. Solomon said this updated analysis retrieved 4,474 references related to LASIK published between 2008 and 2015. Articles that included human clinical studies, primary procedures, visual and refractive outcomes in eyes without previous surgeries, and no presbyopia treatments were selected for further review.

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Of those, the study authors identified 213 manuscripts deemed pertinent. These were further qualified: 47/97 were rated highly relevant, 42/97 deems moderately relevant, and 8/97 were deemed to be of low relevance.

Ensuring bias was not present

Dr. Solomon noted the group also compared the results of their analyses to those of the FDA’s PROWL study. (The PROWL-1 study was a multiyear undertaking that examined patient-reported outcomes following LASIK. PROWL-1 evaluated responses from 262 military personnel, and the recently completed PROWL-2 evaluated responses from 312 non-military patients).

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“We wanted to know if modern LASIK is better than our historical reviews,” Dr. Solomon explained. “Have we gotten better? Have our outcomes gotten better? How did our results compare to the PROWL study?”

The 97 articles included for the updated analysis comprised 67,893 eyes.

“We also looked to see what influence industry had,” Dr. Solomon said. “We found 33 articles that reported a financial interest aligned with industry, but industry did not have an affiliation with the studies, and no industry bias was found based on our meta-analysis.”

What the analysis said

This analysis also separated the findings by microkeratome or femtosecond laser, and by wavefront-optimized or wavefront-guided to determine if patient satisfaction or visual outcomes were affected by either.
The meta-analysis showed uncorrected visual acuity of 20/20 or better was achieved in 90.8% of the 56,000 eyes that reported that data.

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“Plus, 99.5% of patients were 20/40 or better,” Dr. Solomon said. “These results are significantly better than what had been reported in the FDA studies, and are pretty close to what was reported in PROWL-1.”

When evaluating the outcomes of more modern LASIK surgery to the original FDA trials, “it’s clear we are having much better outcomes,” Dr. Solomon said. “I want to specifically bring your attention to the fact that these results are substantially better and well above the nominal level for FDA approval.”

Overall, 90.9% of patients were within 0.5 D of target, and 98% were within 1 D.

“That’s just way better than the FDA studies,” he said.

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Safety has improved as well, with 1.45% of patients gaining 2 or more lines, and only 0.61% losing 2 lines.

“In this case, there was a difference between the treatment groups with the more modern groups performing much better,” Dr. Solomon said. “The PROWL study reported 0.44% of patients lost 2 or more lines, so again, the worldwide data is comparable.”

Of interest, he said, was that of the lasers used, the one that resulted in the most lost lines was the Summit, a laser that is no longer manufactured and no longer used by the overwhelming majority of refractive surgeons.

Other contributory factors

In this updated analysis, there were “very few” studies that compared other factors, Dr. Solomon said. There was one study, however, that reviewed dry eye in 32,569 patients.

“Postoperative dry eye rates of 0.8% also match what we found in PROWL,” he said. “Night vision and halo complaints are also very low.”

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In short, the worldwide literature supports the contention that modern LASIK is a more effective and a better technology than its predecessors.

“The advanced ablation profiles have yielded very good outcomes,” Dr. Solomon said. “The FDA PROWL-1 study results are consistent with what this evaluation show as well.”
During a question-and-answer period, Eric Donnenfeld, MD, said LASIK started more than 20 years ago, so to compare modern LASIK with the original outcomes data “is to do a disservice to the procedure overall.”

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Many refractive surgeons—Dr. Donnenfeld included—continue to believe that glare and halo are exclusionary symptoms for LASIK because of the mistaken assumption LASIK would increase those phenomenon.

“PROWL has shown that to be incorrect,” he said.

[Previous analyses](http://ophthalmologytimes.modernmedicine.com/ophthalmologytim...)

Dr. Solomon first reported on the worldwide satisfaction rates of LASIK in 2009, having analyzed data from studies published between 1994 and 2008. At that time, he identified more than 100 relevant studies based in the United States, 100 from Europe, and 65 from Asia; 19 of these evaluated both patient satisfaction rates and overall visual outcomes.

From [ASCRS 2016: Predicting, treating keratoconus in 2016](http://ophthalmologytimes.modernmedicine.com/ophthalmologytim...)

Overall, more than 95% of patients were satisfied with the procedure and their vision. A further analysis of myopes (n = 1,929) found a 95.3% satisfaction rate and a satisfaction rate of 96.3% for hyperopes (n = 297). In the United States, there was an overall 95.2% satisfaction rate (n = 1,262).

At the time, Dr. Solomon noted more than 16.3 million procedures had been performed worldwide.

“LASIK surgery should be considered among the most successful elective procedures,” he said. “LASIK surgery compares more favorably with other elective surgical procedures in terms of generally higher satisfaction rates.”

Dr. Solomon has no financial disclosures.