

## **LASIK Surgery: Do the Advertising and Risk Disclosures Reflect the True Risk of Complication?**

Megan Yu\*

Keywords: LASIK, Misleading Advertising, Marketing Ethics, Risk Disclosure, Informed Consent

### INTRODUCTION

LASIK surgery, one of the most common elective procedures worldwide, aims to decrease or eliminate the need to wear glasses or contact lenses by reshaping the cornea's curvature to restore the eye's refractive power.<sup>1</sup> There is a popular belief among the public that the procedure is "virtually foolproof",<sup>2</sup> which is largely shaped by LASIK advertising and marketing techniques.<sup>3</sup> However, recent studies and news reports suggest that complications after LASIK surgery are not uncommon and that many eye centers and LASIK advertisements continue to promise "20/20 vision or your money back" or fail to disclose possible LASIK complications.<sup>4</sup> In fact, a recent study conducted by the U.S. Food and Drug Administration (FDA) found that 1 to 4 percent of participants were dissatisfied with the visual complications after LASIK surgery.<sup>5</sup> Misleading information provided to the public about the procedure contributes to the popularity of LASIK. This paper discusses the ethical issues currently associated with both advertising and physicians' disclosures of risks surrounding the procedure and provides recommendations to address these LASIK complications.

LASIK is the most popular procedure used to correct the refractive error, which includes myopia and hyperopia.<sup>6</sup> Using this procedure, the ophthalmologist reshapes the cornea by removing eye tissue in different areas depending on the patient's condition.<sup>7</sup> A flap approximately the size of a contact lens is formed using a femtosecond laser. This flap folds back in place and adheres to the corneal surface.<sup>8</sup>

\* MD Candidate, UQ-Ochsner

## ANALYSIS

### *Misleading LASIK Advertising & Failure to Disclose Business Relationships*

Misleading advertisements that portray LASIK surgery as a complication-free procedure are unethical. Many eye centers continue to display misleading advertisements by using phrases such as “20/20 vision or your money back” or “package deals.”<sup>9</sup> Direct to consumer advertisements created by ophthalmology groups, laser vision centers, and other LASIK providers make inflated claims regarding the efficacy or safety of LASIK surgery. For instance, some feature images that imply patients who had undergone LASIK surgery would be permanently free from glasses or claim LASIK surgery is a “safe and painless” alternative to glasses and omit any relevant complications of LASIK surgery.<sup>10</sup> Complex bioethical issues arise from false and misleading advertising.

Any partnership ophthalmologists have with the companies that manufacture LASIK surgery equipment undermines physician integrity and may create pressure on ophthalmologists not to disclose LASIK surgery’s risks and limitations. Deceptive marketing tactics and business profits may also interfere with the physician’s professional obligation to patients and entice a patient to undergo risky surgery. These issues violate the principle of non-maleficence because they expose patients to unnecessary risks violating physicians’ obligations not to harm patients. Patients also suffer financially, as they may have to pay thousands of dollars for a procedure that may be ineffective or harmful. Ophthalmologists also violate the principles of virtue ethics and beneficence because physicians should display virtuous qualities, such as integrity and honesty in their practice and should promote good to their patients.

The American Academy of Ophthalmology (Academy) and the FDA should oversee the behavior of ophthalmologists to ensure any financial or professional ties they have with the manufacturers that make the lasers for LASIK surgery do not override the professional obligation to disclose the risks and limitations of LASIK surgery. Government and professional associations should also discourage scientific journals from publishing studies where the authors have financial or professional ties with manufacturers that make the lasers used in LASIK surgery unless full disclosure is made clear. Financial ties and perverse incentives to overtreat are ethical issues that undermine trust.

### *Failure to Disclose Possible Complications of LASIK Surgery by Ophthalmologists*

The FDA and the Academy have issued statements that compel ophthalmologists to properly inform patients of the indications, limitations, and complications of LASIK surgery and the lasers used during this procedure in 2008, 2009, and 2011.<sup>11</sup> Yet some ophthalmologists neglect to disclose possible LASIK surgery complications to patients or fail to take the time to answer patients’ questions regarding LASIK surgery,<sup>12</sup> which could cause long-term medical harm to the patient. In 2019, two Canadians filed a lawsuit against LASIK MD Clinics for neglecting to warn them that they could potentially develop corneal neuralgia after LASIK surgery,<sup>13</sup> which is a rare complication of LASIK surgery that is often misdiagnosed as dry eye.<sup>14</sup> Some patients have reported years of suffering from debilitating eye pain and visual symptoms such as glares and halos,<sup>15</sup> and some patients who had undergone LASIK surgery testified at an FDA meeting that they experienced impaired vision after LASIK surgery that resulted in job loss and social isolation. Suicides have also been reported.<sup>16</sup> Based on patient reporting of adverse events, ophthalmologists must disclose serious consequences.

A failure to disclose complications of any medical procedure is a severe ethical breach. In the US, *Canterbury v. Spence* set forth a strong stance on failure to disclose rare severe side effects.<sup>17</sup> Informed consent is a cornerstone of bioethics—patients must know the risks before they agree to undergo any procedure. The moral foundation of informed consent is the protection of bodily integrity and respect for autonomy.<sup>18</sup> Patients have a fundamental liberty interest in being free of non-consensual bodily intrusion. Without accurate information, informed consent has not transpired; the agreement to undergo the procedure is based on misinformation. Doctors must disclose risks to educate the patient. It is the doctor's duty to ensure that the patient is informed.

Failing to disclose LASIK surgery's possible complications violates the principles of virtue ethics and non-maleficence as it withholds knowledge from patients that is essential to the sound management of their health. It also tarnishes the doctor-patient relationship's fiduciary nature as patients may place less trust in their physicians after discovering they withheld essential knowledge from them.

*There is moral value in the life-changing benefits of LASIK Surgery*

Restoring one's vision can be life-changing for many patients. Those who previously had to rely on glasses or contact lenses to see clearly could feel empowered and gain more autonomy after having LASIK surgery. LASIK helps patients avoid having contact lens intolerance. A successful LASIK surgery also allows patients to pursue certain professions or sports that they previously could not, such as becoming a chef or swimming.

The ethics of advertising to enable potential LASIK patients to learn more about LASIK are compelling. More patients with poor vision will learn about an important solution. Advertising brings patients to doctors who must discuss the procedure realistically. Advertising LASIK would be ethically prohibited if it drew in patients with unrealistic expectations, and the doctor did not clearly state the efficacy, risks, and side effects. Continuing to allow advertising is the better moral choice as it allows many in need of help to seek it. However, it is a moral choice that is dependent on truth-telling and full disclosure by doctors.

Despite the life-altering benefits of LASIK surgery, ophthalmologists have a professional obligation to patients and the public to provide truthful, informative advertising of LASIK surgery and ensure patients fully understand the purpose, benefits, limitations, and complications of LASIK surgery before having the procedure. Beneficence should compel ophthalmologists to act in the best interests of patients, as the intended purpose of LASIK surgery is to help patients improve their vision. LASIK can be a life-changing improvement ethically compelling its availability to patients for whom it is the right fit. Appropriate advertising and risk disclosure empower the patient in making an informed decision to undergo LASIK surgery.

*Actions to ensure an ethical process for patients deciding to undergo LASIK surgery*

To ensure full transparency, ophthalmologists should confirm patients understand the nature, purpose, and risks of the procedure by encouraging them to ask questions during consultations and taking the time to answer their questions. They should ensure patients read and understand the fine print of informed consent forms and screen for patients who may not be suitable for LASIK surgery. Physicians also should substantiate any claim they made with the latest evidence from scientifically robust clinical studies. If an advertisement claims "90% of LASIK patients achieve 20/40 vision or better,"<sup>19</sup> the ophthalmologist should corroborate the claim with a reliable clinical study and ensure his outcomes do not differ significantly from the study's outcomes. Ophthalmologists should verify they did not omit any relevant information regarding the

effectiveness or nature of LASIK surgery as the omission might influence the patient's decision to undergo surgery.<sup>20</sup>

Any claim made in advertisements and marketing materials, whether implicitly or explicitly, must provide an accurate impression of LASIK surgery.<sup>21</sup> For instance, a LASIK advertisement that features a man throwing away his glasses might cause patients to believe they would be permanently free from glasses or contact lenses after LASIK surgery.

Federal and global organizations, such as the Academy and the FDA should promote public awareness about LASIK's risks and benefits and continue to regulate any promotional material that ophthalmologists use to promote LASIK surgery. The FDA should take action if an eye center in violation of the policies chooses not to comply. The Academy and the FDA should also prohibit ophthalmologists from classifying LASIK surgeries "successful" based on achieving "20/20 or 20/40 or better vision" after surgery if a complication was reported.<sup>22</sup>

## CONCLUSION

Physicians must bar misleading advertisements and fully disclose the complications of LASIK surgery to patients. Through these measures, patients would make more informed choices about whether they should undergo LASIK surgery. Rather than marketing LASIK to those with minor vision impairment or with higher risk profiles, ophthalmologists must behave according to the ethical foundation of their profession. Even with relatively few risks, doctors must be certain to minimize risk by evaluating patient eligibility for LASIK, cautioning all patients about the risks, and ensuring proper advertising and marketing practices. LASIK can give people enhanced vision expanding career and athletic opportunities and make life simpler with less need for contacts, and glasses for the right candidates.

---

<sup>1</sup> Tran, Khai et al., "Laser refractive surgery for vision correction: A review of clinical effectiveness and cost-effectiveness," *CADTH Rapid Response Report: Summary with Critical Appraisal*, June 22, 2018. <https://www.ncbi.nlm.nih.gov/books/NBK532537>.

<sup>2</sup> Rabin, Roni, "Blurred Vision, Burning Eyes: This Is A Lasik Success?" June 11, 2018. <https://www.nytimes.com/2018/06/11/well/lasik-complications-vision.html>.

<sup>3</sup> LasikComplications.com, "THE LASIK REPORT: A Call for the Discontinuation of a Harmful Procedure," April, 2008. <https://www.lasikcomplications.com/The-LASIK-Report.pdf>.

<sup>4</sup> Rabin, Roni, 2018; The Associated Press, "Witnesses Tell of Suffering after Lasik," April 25, 2008. <https://www.nytimes.com/2008/04/25/business/aplasik-web.html>; Eydelman, Malvina et al., "Symptoms and satisfaction of patients in the patient-reported outcomes with laser in situ keratomileusis (PROWL) studies," *JAMA Ophthalmology* 135, no. 1 (2018): 13-22; U.S. Food and Drug Administration, "What are the risks and how can I find the right doctor for me?" August 8, 2018. <https://www.fda.gov/medical-devices/lasik/what-are-risks-and-how-can-i-find-right-doctor-me>; American Academy of Ophthalmology, "Guidelines for refractive surgery advertising," October 2008. <https://www.aao.org/about/policies/guidelines-refractive-surgery-advertising>

<sup>5</sup> Eydelman, Malvina et al, p. 13

<sup>6</sup> Wilkinson, John et al., "Refractive eye surgery: Helping patients make informed decisions about LASIK," *American Family Physician* 95, no. 10 (2017): 637-644

<sup>7</sup> Wilkinson, John, et al., p. 638

<sup>8</sup> Wilkinson, John, et al., p. 639 Other procedures, such as laser-assisted subepithelial keratomileusis, epithelial LASIK, femtosecond laser extraction, and small incision lenticular extraction, have been developed that have similar effectiveness as LASIK but their long-term outcomes are unknown. Some contraindications to LASIK surgery include corneal abnormalities, pregnancy, uncontrolled diabetes, uncontrolled glaucoma, and significant cataracts, and patients with abnormal wound healing, controlled diabetes, glaucoma, a history of herpetic keratitis, or systemic autoimmune disease should be cautioned before

undergoing LASIK surgery. Some complications of LASIK surgery include dry eye, visual symptoms (including glare, halos, and starbursts), diffuse lamellar keratitis, and infections, with dry eye and visual symptoms accounting for 20-40 percent and 20 percent of the complications, respectively. (Wilkinson 639, 640 & 641)

<sup>9</sup> U.S. Food and Drug Administration, 2018; American Academy of Ophthalmology, 2008

<sup>10</sup> American Academy of Ophthalmology, 2008

<sup>11</sup> U.S. Food and Drug Administration, "FDA Letter to Eye Care Professionals (May 22, 2009)" May 22, 2009.

<https://www.fda.gov/medical-devices/lasik/fda-letter-eye-care-professionals-may-22-2009>; U.S. Food and Drug Administration, "FDA Letter to Eye Care Professionals (September 23, 2011)" September 23, 2011. <https://www.fda.gov/medical-devices/lasik/fda-letter-eye-care-professionals-september-23-2011>; American Academy of Ophthalmology, 2008

<sup>12</sup> Aubry, Allison, "Some patients say life after lasik not perfect," May 1, 2008.

<https://www.npr.org/templates/story/story.php?storyId=90070220>

<sup>13</sup> Favaro, Avis et al., "Lasik MD patients allege nerve damage, file class action lawsuit," November 21, 2019.

<https://www.ctvnews.ca/health/lasik-md-patients-allege-nerve-damage-file-class-action-lawsuit-1.4697069>

<sup>14</sup> Theophanous Christos et al., "Corneal Neuralgia after LASIK," *Optometry and Vision Science* 92, no. 9 (2015): e233-e240

<sup>15</sup> Robin, Roni, 2018

<sup>16</sup> The Associated Press, 2008

<sup>17</sup> *Canterbury v. Spence*, 464 F. 2d 772 (1972)

<sup>18</sup> *Schoendorff v. Society of New York Hospital*, 106 N.E.93 (N.Y. 1914)(every patient has the right to decide what is done with "his own body.")

<sup>19</sup> American Academy of Ophthalmology, 2008

<sup>20</sup> American Academy of Ophthalmology, 2008

<sup>21</sup> American Academy of Ophthalmology, 2008

<sup>22</sup> [LasikComplications.com](http://LasikComplications.com), 2008