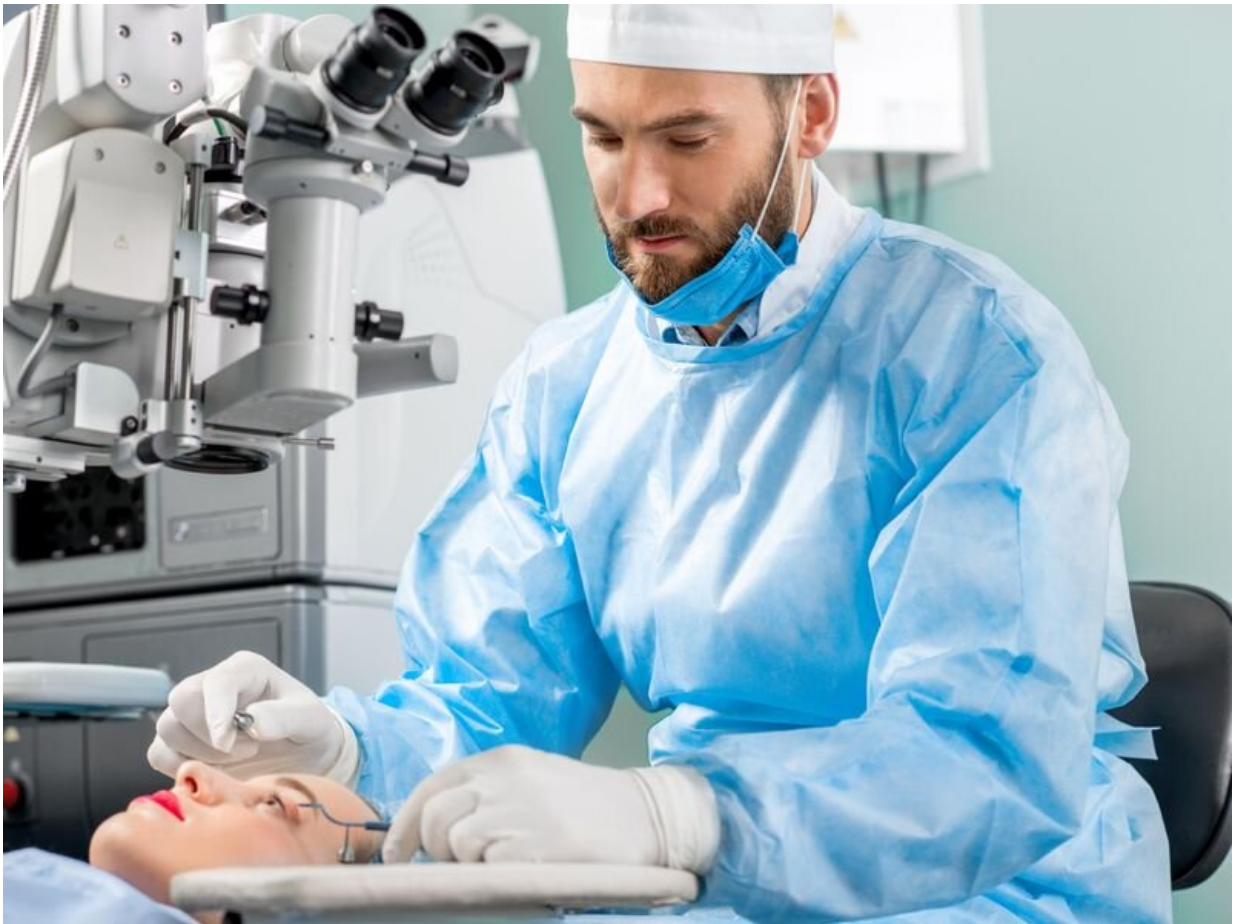


Lasik surgery should carry warnings of possible complications, FDA says

December 8 2022, by Cara Murez HealthDay Reporter



Lasik eye surgery is a common vision-correcting procedure that many

Americans view as safe and effective, but the U.S. Food and Drug Administration has now drafted guidance that warns of potential complications.

Although many [patients](#) are happy with the results after [surgery](#), the recommended [new guidance](#) says complications can include dry eyes, [double vision](#), difficulty with night driving and, in rare cases, chronic eye pain. Even after surgery, some patients will still need eyeglasses.

The draft also notes that certain types of patients may be at higher risk of problems, including people with [chronic conditions](#) such as diabetes and those who take certain medications, the *New York Times* reported.

Since the recommendations were first released this summer, more than 600 people and professional organizations have weighed in on the issue.

"All we're asking for is balance," said [Dr. Vance Thompson](#), incoming vice president of the American Society of Cataract and Refractive Surgery, told the *Times*. "This document mainly emphasizes the dangers and complications of Lasik, with no mention of the advantages, and the tone is negative enough that it will scare patients."

Thompson noted that more than 90% of patients in the FDA's studies were satisfied because they were "achieving good vision without spectacles, which is the goal of most patients."

Surgeons and device manufacturers have sought to have the draft recommendations withdrawn.

But a professional organization representing optometrists recommended adding even more precautions to the draft, to include [pregnant women](#) and those with irregular astigmatism, the *Times* reported.

Paula Cofer, a Florida woman who testified before the FDA in 2008 and again in 2018 that Lasik surgery ruined her eyesight and left her with chronic pain, told the *Times* that, "I've been waiting 14 years for this to happen."

"Right now, even if patients do research on the internet and see warnings, they think it's just one or two unhappy people. Now they see it's the FDA saying this," Cofer added.

Lasik is typically a procedure completed in just 15 minutes per eye, where the surgeon reshapes the cornea with cuts and a laser to correct poor vision. Often the procedure is not covered by insurance and can cost patients thousands of dollars out of pocket, the *Times* reported.

Still, more than 500,000 adults opt for the surgery each year and many ophthalmologists declare it safe, with complications happening very rarely.

To arrive at the draft recommendations, the FDA both collaborated on and analyzed studies on Lasik outcomes published in the past decade.

One of those [studies](#) found that three months after Lasik nearly half of patients who had previously not had visual symptoms did after the procedure. This included seeing halos around lights. About one-third of the patients had dry eyes.

"Patients undergoing Lasik surgery should be adequately counseled about the possibility of developing new visual symptoms after surgery before undergoing this elective procedure," the study authors wrote.

The FDA has not said when the guidance will be finalized. The agency did respond to the *Times* with a statement dismissing some criticism and noting that it routinely issues labeling guidance for [medical devices](#), the

newspaper said.

More information: The National Library of Medicine has more on [Lasik eye surgery](#).

Copyright © 2022 [HealthDay](#). All rights reserved.

Citation: Lasik surgery should carry warnings of possible complications, FDA says (2022, December 8) retrieved 11 May 2024 from <https://medicalxpress.com/news/2022-12-lasik-surgery-complications-fda.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.