

# Unapproved therapies cause significantly more patient injuries than reported

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A team of ophthalmologists went looking for scientific evidence in support of commercially available "cell therapy" for eye diseases. Not only did they find virtually none; they instead discovered a growing number of patients are being irreparably harmed by unapproved cell therapies. Their findings were presented today at AAO 2018, the 122nd Annual Meeting of the American Academy of Ophthalmology.

The researchers' review of published studies found only a few case series, involving a total of 18 [patients](#). All patients were reported to have had positive treatment outcomes or no improvement. However, the researchers were able to identify at least seven patients who experienced devastating harm from an unapproved cell therapy.

The number of clinics that administer stem cell therapies that have not been authorized by the FDA has proliferated in recent years. Nearly 600 clinics have opened in the United States alone. These so-called therapy clinics tout their ability to help patients suffering from a broad range of conditions including the blinding eye disease, age-related [macular degeneration](#), Parkinson's disease, autism and multiple sclerosis.

In May, the FDA began cracking down on clinics marketing unapproved therapies after three women with macular degeneration lost their vision after undergoing an unproven stem-cell treatment at a Florida clinic.

Ophthalmologist Ajay E. Kuriyan, M.D., treated one of those women following treatment at the stem cell clinic. He tried to save her vision,

but the damage was too great.

Determined to learn the extent of the problem, Dr. Kuriyan and Andrew Chen, M.D., and colleagues at the University of Rochester's Flaum Eye Institute and the University of Miami's Bascom Palmer Eye Institute, reviewed evidence supporting cell therapy published in scientific journals and from the clinic's websites and marketing materials.

Though the clinics stopped advertising the treatment that blinded the women, many continue to offer therapies for a variety of blinding eye disease, including serpiginous choroidopathy, Leber Hereditary Optic Neuropathy, and nonarteritic anterior ischemic optic neuropathy.

What the researchers found is that the clinics omit poor outcomes in their reports. The data clinics report suggests that, at worst, no harm was done, and at best, patients experience improvement. But Dr. Kuriyan and his colleagues have found at least seven patients who suffered disastrous outcomes.

"When you look at these company's websites and their publications, you'll see a big under-reporting of profound complications," Dr. Kuriyan said. "This is in stark contrast to what we have seen in our clinics and in our personal experience. There's a fairly significant number of patients who experienced poor, or in some cases devastating results. The cases published to date just scratch the surface of the number of bad outcomes."

Dr. Kuriyan and his colleagues are currently collecting data for a larger study, detailing all the patients who suffered complications from unapproved cell therapy.

## **What Patients can do to Protect Their Health**

he cell therapy clinics are not only endangering patient health, Dr. Kuriyan warns, they are also threatening to undermine both legitimate scientific progress and the public's trust in stem cell research.

To help patients identify legitimate research, Dr. Kuriyan advises against joining studies that require payment. Most large [clinical](#) trials don't require payment. Some smaller clinical trials may have a minimum cost, such as a copay or out-of-pocket deductible payment, and anything beyond that should be viewed more cautiously.

Centers or clinics that only offer cell [therapy](#) is another red-flag, Dr. Kuriyan said. A reputable clinic will offer a variety of treatments for conditions. Most importantly, he recommends patients ask questions and discuss potential treatments with their ophthalmologist.

Provided by American Academy of Ophthalmology

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