

Implications of Stem Cell Clinics for Retina Patients and Clinical Trials

Recent practices at clinics providing unproven, unregulated treatments raise high concern for patients.

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The blinding complications of 3 patients who underwent bilateral intravitreal injections of adipose-derived stem cell injections for dry AMD at a “stem cell clinic” were recently published in the *New England Journal of Medicine*.¹ The patients’ vision in their better-seeing eye deteriorated from 20/30 to 20/50 prior to the injections to 20/200 to no light perception. The vision loss was attributed to a combination of intraretinal and vitreous hemorrhage, retinal detachments with severe proliferative vitreoretinopathy, and zonular weakness.

THE “STEM CELL CLINIC” PROBLEM

The issue of complications after treatments at foreign stem cell clinics has received attention in the past.¹ However, a study found that the United States has the largest number of stem cell clinic websites in the world: 187 unique websites offering interventions at 215 clinics.² These stem cell clinics offer costly, unproven, and unregulated “stem cell treatments” for a variety of disorders, charging up to \$50,000 for the procedures.^{3,4}

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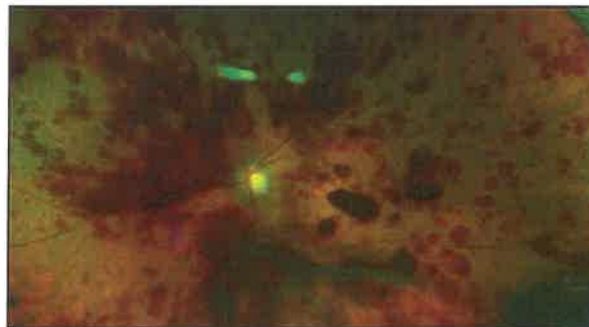


Figure 1. Fundus photo of the left eye of a patient showing diffuse preretinal and intraretinal hemorrhage 13 days after intravitreal stem cell injection. Collections of cells can be seen in the vitreous cavity below the optic nerve and in the lower right-hand corner. This retina detached 3 weeks later.

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GOOD STEM CELL SCIENCE

There has been positive progress in research of therapeutic use of stem cells in retinal disease. A study by Schwartz et al in which researchers transplanted subretinal human embryonic stem cell-derived retinal pigment epithelium (RPE) cells demonstrated favorable safety and efficacy data in a phase 1/2 study.⁵ Another study by Mandai et al demonstrated the safety of subretinal transplantation of an induced pluripotent stem cell-derived RPE cell sheet.⁶

These promising studies were run with a focus on patient safety and provide a stark contrast between some of the practices at the stem cell clinic that administered the intravitreal injections. Most importantly, only one eye was treated with the experimental intervention, which is a standard in ophthalmic research. In addition to harming patients, the actions of stem cell clinics have the potential to slow progress in stem cell research, if the public and funding agencies were to lose hope for safe and effective stem cell treatments.

CLINICALTRIALS.GOV

The stem cell clinic that administered the bilateral intravitreal injections had a study examining intravitreal stem cell injections for dry AMD listed on [Clinicaltrials.gov](https://clinicaltrials.gov). However, the patients were not enrolled in the study. By having studies listed on [Clinicaltrials.gov](https://clinicaltrials.gov), stem cell clinics seemingly bolster their legitimacy to patients. However, the [Clinicaltrials.gov](https://clinicaltrials.gov) site is simply a repository of clinical studies and does not judge the merits of the listed studies. The website has recently added a statement on its homepage reinforcing its purpose and encouraging patients to speak with a “trusted health care professional” prior to enrolling in a study.

PATIENT EDUCATION AND REGULATION

The American Academy of Ophthalmology issued a clinical statement in 2016 that highlighted the stem cell clinic issue and emphasized that the risks of treatments at these stem cell clinics is not known. Disseminating that information to patients is extremely important; explaining the difference between the positive stem cell research and the activities carried out at stem cell clinics is essential to preventing such catastrophic outcomes. Further regulation of these stem cell clinics is also necessary to help prevent similar outcomes in the future. **RP**

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