An Innovative Surgical Technique for Subretinal Transplantation of Human Embryonic Stem Cell-Derived Retinal Pigmented Epithelium in Yucatan Mini Pigs: Preliminary Results.

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**Funding Grants:** Stem cell based treatment strategy for Age-related Macular Degeneration (AMD). Phase 1 Safety Assessment of CPCB-RPE1, hESC-derived RPE Cell Coated Parylene Membrane Implants, in Patients with Advanced Dry Age Related Macular Degeneration

**Public Summary:** Subretinal Transplantation of Human Embryonic Stem Cell-Derived Retinal Pigmented Epithelium (CPCB-RPE1) were carried ou in Yucatan Mini Pigs to develop a safe and efficient surgical procedure. The hESC-RPE cells survived for 3 months in this animal model. The surgical procedure for subretinal implantation of CPCB-RPE1 is feasible and safe, without cell migration off the scaffold or development of ocular or systemic tumors.

**Scientific Abstract:**

**BACKGROUND AND OBJECTIVE:** To develop a safe and efficient surgical procedure for subretinal implantation into porcine eyes of a human embryonic stem cell-derived retinal pigmented epithelium (hESC-RPE) monolayer seeded onto a Parylene-C scaffold. This implant is referred to as CPCB-RPE1. MATERIALS AND METHODS: Ultrathin Parylene-C scaffolds were seeded with hESC-RPE and surgically implanted into the subretinal space of Yucatan mini pigs (n = 8). The surgery consisted of pars plana vitrectomy, induction of a limited retinal detachment, and peripheral retinotomy for insertion of the monolayer using a novel tissue injector, followed by silicone oil tamponade injection, laser photocoagulation around the retinotomy site, and inferior iridectomy. Oral cyclosporine was administered from day 1 and during the entire follow-up period. Three months later, the animals were euthanized and the eyes and major organs were submitted for histological analysis. Adjacent sections underwent immunohistochemical analysis to detect human cells using anti-TRA-1-85 (human blood group antigen) antibody and DAPI antibodies. RESULTS: The cell monolayer was immunopositive for TRA-1-85 3 months after implantation and migration from the Parylene-C scaffold was not detected. One eye had a mild inflammatory reaction around the implant that was negative for human biomarkers. No intraocular or systemic tumors were detected. CONCLUSION: The hESC-RPE cells survived for 3 months in this animal model. The surgical procedure for subretinal implantation of CPCB-RPE1 is feasible and safe, without cell migration off the scaffold or development of ocular or systemic tumors. [Ophthalmic Surg Lasers Imaging Retina. 2016;47:342-351.]

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