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Service (sector) Retina and Vitreous N° CEP

SELECTIVE SUBRETINAL DELIVERY OF BETA-RADIATION

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Purpose: To quantify the acute effects of beta-radiation on retinal and subretinal tissue over a prescribed dose range and evaluate the feasibility and initial safety of retina-sparing subretinal delivery of beta-radiation using a novel NeoVista Brachytherapy System (NBS). Methods: Eighty rabbits and 4 dogs underwent pars plana vitrectomy (VVPP) for selective subretinal delivery of beta-radiation. Rabbits received localized doses of radiation in the retinal and subretinal tissue ranging from 0 to 246 Gy. Feasibility study in dogs included VVPP, creation of a subretinal bleb and introduction of the NeoVista brachytherapy probe in the subretinal space for retina-sparing delivery of 26 Gy. Subjects were followed for 1 and 2 months. Main outcome measures included changes in fundus appearance, FA, ERG and histology. **Results**: Controlled intraocular delivery of subretinal radiation was achieved in all subjects. Clinical changes were seen only at 123 Gy and above. In dose areas up to 77 Gy, histological evaluation demonstrated no significant changes in the retina, and subretinal tissues at both follow-up time points. All 4 dogs underwent the surgical procedure proposed. At this dosage, no clinically significant acute changes were seen in the retina and subretinal tissues at one month. Conclusion: Toxicity data demonstrates that the minimum threshold for acute damage of healthy retinal and subretinal tissue is at least 3 times our target dosage of 26Gy. Submacular surgery for selective (retina-sparing) subretinal delivery of beta radiation is feasible and appears to be safe. We are currently evaluating the NBS in eyes with exsudative AMD.