Asymmetric Perfluorocarbon liquids (aPFCLs) and combination aPFCLs/silicone oil (PDMS): Pilot *in-vivo* Biocompatibility Study

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PURPOSE

To assess the stability and biocompatibility of aPFCLs, combination aPFCLs with PDMS, and control polymers as a vitreous substitute.

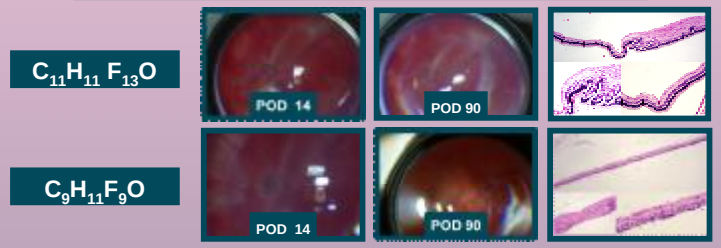
BACKGROUND

Perfluorocarbon liquids (PFCLs) are heavier than water and are used in vitreoretinal surgery for the management of retinal detachments (RD). PFCLs can only be used as an intraoperative tamponade to flatten the retina until laser is applied to secure the retina. Currently, for RD long-term management, PFCLs are exchanged intraoperatively with either gas (air, SF6, C3F8) or silicone oil (PDMS) that can remain in the eye for several days to weeks without exhibiting toxicity. As PDMS is lighter than water it only applies a tamponade to the superior retina. However, aPFCL can be injected into the PDMS bubble at anytime postoperatively changing the bubble's specific gravity and making it sink on the inferior retina. The potential for this new approach is being investigated.

METHODS

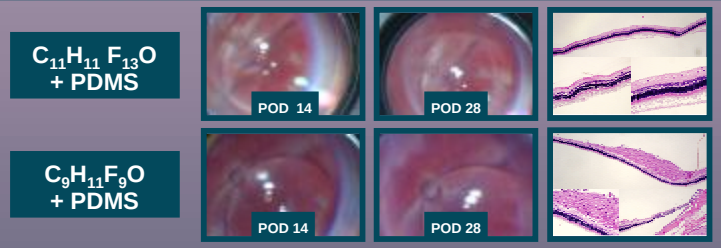
14 NZW rabbits were used for this blind study. 4 different polymers consisting of either an aPFCLs, or varying concentrations of PDMS combined with an aPFCLs (Al.Chi.Mi.A, SRL, Italy) and 4 control polymers: 1000 cts, 5000 cts PDMS (Al.Chi.Mi.A, SRL, Italy), F6H8 (semi-fluorinated alkane with $C_{14}H_{17}F_{13}$ - Fluoron GmbH) and DENSIRON 68 (mixture of F6H8 and PDMS 5000 cts) were randomly implanted. Lens phacoemulsification (PE) and total vitrectomy was performed under deep IM anesthesia: Corneal wounds were closed and peritomies made at 10 and 2 o'clock and 2 scleral mattress 7-0 Vicryl sutures (VS) were preplaced; fluorescein was injected into the vitreous cavity, a total vitrectomy performed with a 20G vitrectome (Storz, B&L, USA), injection of polymer ~1.8-1.0cc above the retina, VS were tightened and the conjunctiva was closed. The rabbits were examined at POD 1 and 3 by slit-lamp and at POD 7, 14, 21, and 28 and then monthly under the operation microscope. Half the animals were euthanized at POD 28 and the other half at POD 90. Histological analysis were performed on all implanted eyes.

TEST POLYMERS - aPFCLs (LONG-TERM STUDY)

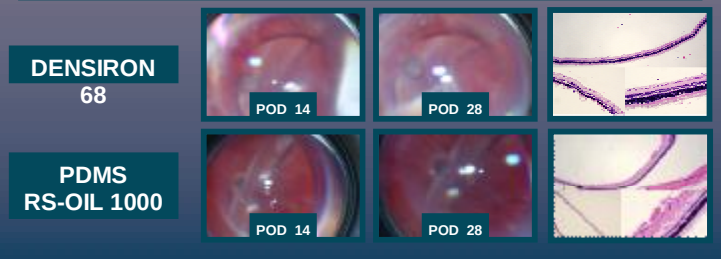


CONTROL POLYMERS (LONG-TERM STUDY)

TEST POLYMERS - aPFCLs + SILICONE OILS (SHORT-TERM STUDY)



CONTROL POLYMERS (SHORT-TERM STUDY)



RESULTS

There were no clinical signs of infection in any rabbits. At POD 28 all animals had a normal cornea and conjunctiva, except for those that received F6H8 or DENSIRON 68 which had chronic diffuse corneal edema. Lens regrowth was seen throughout the periphery in all operated animals. PDMS controls: the retina remained normal in appearance even at POD 60. F6H8 control: the medullary ray (MR) appeared white at POD 14. DENSIRON 68 control: vessels of the MR appeared thin at POD 21. Both aPFCLs ($C_{11}H_{11}F_{13}O$) and ($C_9H_{11}F_9O$): the retina remained normal until POD 7, aPFCL (C9H11F9O)/PDMS: retinal vessels appeared slightly tortuous at POD 14, aPFCL ($C_{11}H_{11}F_{13}O$)/PDMS: retinal vessels appeared normal at POD 28. Histology shows retinal damage in all eyes except in the animal implanted with aPFCL ($C_{11}H_{11}F_{13}O$)/PDMS.

CONCLUSION

This pilot study indicated the aPFCL ($C_{11}H_{11}F_{13}O$)/PDMS was best tolerated in the rabbit model and could potentially be effectively used in vitreoretinal surgery as a short term vitreous substitute. All PFCLs and PFCLs were found toxic to the retina. A formal study in a larger number of animals is needed to confirm these findings.

ACKNOWLEDGEMENTS

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