Autologous Serum ocular inserts for treatment of Dry Eye Disease

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Background

Dry eye disease (DED)

Costs US economy approximately $3.8 billion

Prevalence rate is 5–50%, 75% in adults >40 years old

Loss of tear film homeostasis

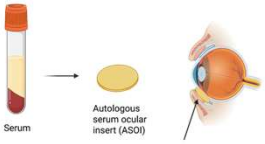
Current treatment

- DED treatment requires multiple eye drop instillation daily
- Poor bioavailability
- Ocular toxicity with prolonged use

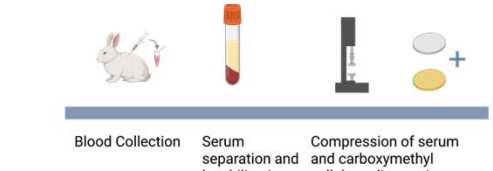
Proposed treatment

Preparation of ocular insert containing serum as an active ingredient.

- Growth factors that help maintain eye health
- Once daily treatment
- Improved shelf life
- Reduced side effects



Methods

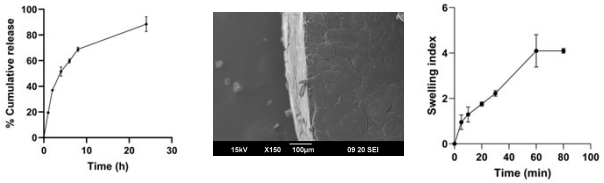


Dry eye disease model, n=4
-Topical Benzalkonium Cl twice daily to left eye, 7 days to generate DED. ASOI treatment, once daily. Right eye is control.

Healthy Rabbit model, n=10
-ASOI applied once daily to left eye, 5 days
-Autologous serum eye drops (ASED) applied 8 times daily to right eye, 5 days

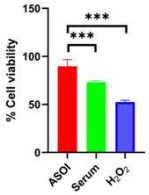
Results

Characterization of ASOI

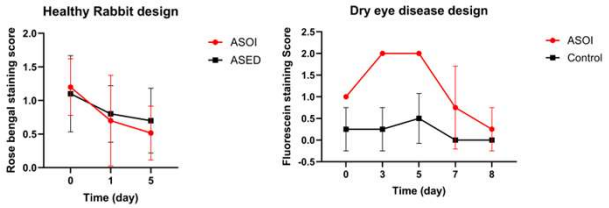


In vitro activity in dry eye corneal cells model

- 200 µM of H_2O_2 was selected to generate ROS in corneal cells.
- ASOI demonstrated superior ability to protect the cells from excessive oxidative stress.
- One way ANOVA, p<0.001



In vivo activity in Healthy and dry eye rabbit models

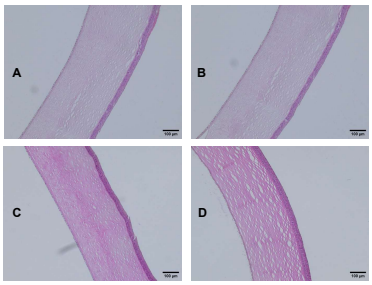


ASOI was able to deliver the same amount of serum as ASED without showing signs of inflammation and to reverse the symptoms of DED triggered by Benzalkonium Cl

H&E corneal sections

Healthy rabbit design

Dry eye disease design



ASOI (A), ASED (B), Benzalkonium Cl treated eye and ASOI (C), Control (D)

Conclusion

- This insert allowed for the release of serum in a simulated physiological environment over 24h.
- High therapeutic efficacy in cellular and rabbit dry eye models.
- Lack of signs for corneal infection or inflammation.
- It could enhance patient compliance by decreasing the frequency of administration and promoting therapeutic efficiency.

References

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