



Pharmacodynamic Evaluation of Recombinant Human Lysozyme Eye Drops

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DESCRIPTION

Dry Eye Disease (DED) is among the most common ocular surface disorders affecting the visual comfort and function of individuals worldwide. DED, caused by various factors, is a complex, multifactorial disease and difficult to be characterized by a simple process, sign or symptom, thus, long term treatment of DED is required. Artificial tears are regarded as the main therapy for all severity grades of dry eye. Different artificial tears comprise a wide variety of products, which typically target one or more layers of the tear film, merely with relief of symptoms. The reason may be that the component of existing agents is simple, not targeting underlying pathophysiology of DED. Among the mechanism of pathophysiology of DED involving tear film instability, tear hyper osmolarity and inflammation at the ocular surface, ocular surface inflammation is critical. The inflammatory cascades lead to severe ocular surface damage, and develop a self-perpetuating inflammatory cycle. It is detected that the expression of inflammation related cytokines IL2, IL6, TNF α , and TGF β are increased in tears or ocular surface of DED patients comparing with the normal ones. Anti-inflammatory therapy, rather than other treatment, is considered as the effective treatment due to its target of the underlying pathology. It was documented that corticosteroids and cyclosporine are performed as the anti-inflammatory therapies to moderate severe dry eye symptoms, while, side effects and restricted efficacy limit the treatment. In addition, multi dose artificial lubricants, another treatment of DED, typically require a preservative, whereas, preservatives is well recognized to induce toxicity and adverse changes to the ocular surface, companying with dry eye symptoms progression. Generally, natural tear protect the ocular surface and prevent DED development physiologically, thus, the artificial tears, homologous with nature tears, with fewer side effect were targeted. Meanwhile, lysozyme in natural tears with the high concentration of up to 2.07 mg/mL, is well known for

the muramidase activity, also possesses immune stimulating, anti-inflammatory, regenerative, and analgesic activity. Recent decades of researches have implicated that accompanying with aqueous deficient, lysozyme level of natural tear is reduced in DED patients. Therefore, it is critical for OTC and clinical therapy to develop the novel artificial tears, analogue with nature tears, with antibacterial and anti-inflammatory function as well as no preservative to prevent and cure the DED in long term, accompanying with low side effects. For the above reasons, industrialized recombinant human lysozyme (rhLYZ), which is highly homologous to natural human lysozyme, was fermented and purified using genetic biotechnology. In addition, a new artificial tears containing prepared rhLYZ, called rhLYZ eye drops, has been designed and developed. The composition and physicochemical properties of rhLYZ eye drops were essentially similar to natural tears. By establishing a stable and reliable model of dry eye in New Zealand rabbits, we systematically evaluated the physiological and pathological effects of various concentrations of rhLYZ eye drops on DED symptoms. This study of new types of eye drops may be patho physiologically important and beneficial in the treatment of dry eye.

DED is a complex disease with multiple different symptoms. Further advances in understanding dry eye have been discovered, but important knowledge gaps remain. The limitation is due to the lack of a typical and meaningful animal model. Various dry eye models have been created, but it is difficult to obtain a stable animal model of dry eye. Some models suffering from simple surgery, such as atropine eye drops and administration of a low vitamin-A diet, showed no symptoms of dry eye and showed significant individual differences. In addition, a new dry eye model was obtained by fixing the upper and lower eyelids to reduce blinking time with obvious dry eye symptoms, but it only stayed for a few hours, satisfying long-term studies.

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