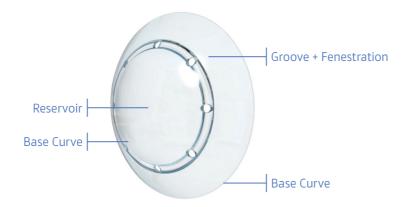
Company Background

EyeYon Medical Ltd. is a pioneer in ophthalmologic medical devices, focusing on developing cornea-focused sight-saving solutions for more than a decade. Our innovative technologies are targeted to preserve the vision of millions of patients worldwide.





Hyper-CL™ Lens Design





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Bacterial Keratitis PMS using Hyper-CLTM

Single-Center in India



MRK-H008 Rev. 1.0 March. 2022

Background

Bacterial Keratitis is a severe bacterial infection of the cornea which can, in severe cases, cause loss of vision. A particular feature of Bacterial Keratitis is its rapid progression; corneal destruction may be complete in 24-48 hours with some of the more virulent bacteria. Early treatment is crucial to minimizing any visual-threatening sequelae.

Topical antibiotic eye drops are the preferred method of treatment in most cases. Antimicrobial ointments lack solubility, and their penetration into the cornea is limited.

Hyper CL[™] is first-of-its-kind Therapeutic Contact Lens that also acts as a reservoir for therapeutics. Our study objective was to compare the efficacy of the Hyper-CL[™] Therapeutic Contact Lens and antibiotic (Hyper-CL[™] group) with a conventional antibiotic alone (Control group) in treating Bacterial Keratitis.

Study Design

A randomized open-label clinical trial using Hyper-CL[™] therapeutic contact lens to treat Bacterial Keratitis study was conducted by Prof. Lional Raj from Dr. Agarwal's Eye Hospital & Research Institute in Tirunelveli, India during 2019-2020.

Thirty-five (35) patients diagnosed with Bacterial Keratitis were randomized into two groups; 17 patients were treated with the Hyper-CL[™] and antibiotics; the control group was composed of 18 patients who received only topical antibiotics. Patients were treated with the Hyper-CL[™] lens for a minimum of 48 hours.

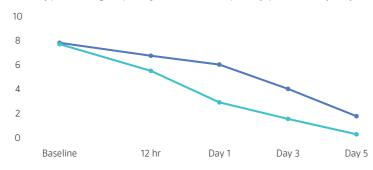
Results **Summary**

In the Hyper CL[™] treated group, we saw significant improvement in both pain level and severity of the infiltrate.

The pain was reduced by 4.77 points in the Hyper-CLTM group, and only by 1.89 points in the control group on Day-1 (p<0.001). By Day-3, the pain was reduced by 6.12 points in the Hyper-CL[™] group and 3.89 points in the control group (p<0.0001).

The Hyper-CL[™] group subjects were completely pain-free by Day-5.

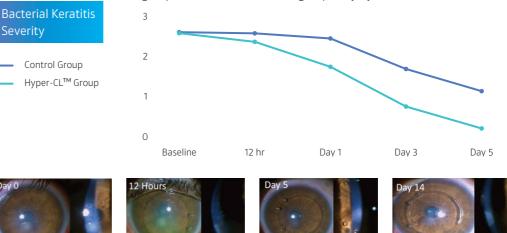




Results Summary

Infiltrates significantly improved in the first 12 hours of treatment at the Hyper-CLTM group. The average resolution of infiltration in the Hyper-CL[™] group was 0.27 mm, and in the control Group (antibiotic only), only 0.04mm (p=0.02).

On Day-5, infiltrate resolved by a mean of 2.45 mm in the Hyper-CLTM group, whereas in the control group, only by 1.50 mm (<0.0001).



Mean BCVA also improved faster in the Hyper-CLTM group than in the control group. No serious adverse events occurred while using the Hyper-CL[™].

Conclusions

The severity of Bacterial Keratitis significantly improved within the first 1-3 days of treatment with Hyper-CL™ and antibiotics, compared with the control group where improvement was slower over time.

Using Hyper-CL[™] Therapeutic Contact Lens extends direct contact time between the drugs and the cornea.

The use of Hyper-CL[™] demonstrated:



Better & Faster healing of the cornea



Significant improvement in pain



Earlier Vision recovery



Reduced treatment burden



No serious adverse events occurred while using the Hyper-CL™