

A new treatment modality for corneal oedema

Initial results suggest this could be an alternative to more drastic options

By Professor Claes Feinbaum, MSc, PhD

The endothelial cells of the cornea pump out fluid to keep vision clear. When these cells stop working, it creates water retention, which leads to swelling in the cornea. This condition is also known as corneal oedema.

The endothelial cells of the cornea are arranged in a single layer. These cells rarely divide, therefore, when they are damaged they are not replaced. To mend the gap left by the damaged cells, the surviving cells change in size and shape to fill their places. In addition, fluids leak into the gaps left by the damaged cells.

The combination of the irregularly shaped endothelial cells and accumulated fluids interferes with the ability of the cornea to effectively focus light in the eyes. If left untreated, these factors can lead to blindness.

This excessive hydration interferes with normal spacing of the proteins (Type I collagen fibrils) of the corneal stroma.

Optical performance is diminished because:

- The surviving epithelial cells change size and shape to close the gap created by the destroyed cells. These changes affect the light-bending properties of the endothelial cells.
- The excess fluid reaching the stroma scatters incoming light and reduces the ability of the cornea to focus the light properly.

Symptoms

Distorted or blurred vision is the most notable early symptom of corneal oedema. It may often become worse when the person wakes up after a night's sleep and then improves throughout the day.

Other notable symptoms of corneal oedema are: eye discomfort, halos around light, sensitivity to foreign particles and photophobia (increased sensitivity to light).

As corneal oedema progresses, it may become more painful and include blisters that form on the surface of the eye. The disorder may cause corneal nerves to rupture, resulting in severe pain.

Causes

This medical condition is caused by problems

associated with dehydration, endothelial disorder, ocular surgery, viral infections, traumatic injury, increased ocular pressure and toxins.

Endothelial Fuch's dystrophy is the most common cause of this problem. It is a genetic disorder, which is characterized by the gradual loss of the endothelial cells. Women are usually at a higher risk of endothelial dystrophy than men.

An infection by the herpes virus may also result in an inflammatory response in the cornea, leading to corneal oedema. This condition may also occur right away or after a few years of undergoing any kind of ocular surgery.

Corneal oedema can develop as a postoperative condition after eye surgery. Cataract surgeries are the most likely procedures to present with corneal oedema complications. When it develops after a surgery to remove cataracts, it can be described as pseudophakic corneal oedema, pseudophakic bullous keratopathy or aphakic bullous keratopathy.

Corneal oedema is more commonly found in people who are 50 years and older.

Treatment

There is no treatment to promote the healing of the endothelial cells. However, the extent of the corneal oedema can be controlled.

Patients who are suffering from a mild form of the disease can get relief from using hypertonic solutions and ointments such as 2% and 5% solutions and ointments of sodium chloride.

However, evaporation is limited at night because

In short...

Corneal oedema occurs when the endothelial cells stop working and the cornea swells as a result of water retention. Currently, there is no treatment to promote the healing of endothelial cells, however, the extent of the corneal oedema can be controlled. In this article, Prof. Feinbaum discusses a new treatment option aimed at alleviating complications of visual loss and pain secondary to corneal oedema.

the eyes are closed during sleep. Therefore, the effects of corneal oedema are worse in the morning. To reduce this discomfort, 5% sodium chloride ointment can be applied at night and/or a hypertonic solution early in the morning to remove the fluid build up during the night.

To help the epithelium affix to the cornea, a bandage lens will be placed on the cornea for some time. Usually, the kinds of lenses used are thin, permeable and with high-water content so that they can allow the passage of oxygen.

The Hyper-CL

EyeYon Medical (Jerusalem, Israel) has developed an innovative, patent-protected solution to the complications of visual loss and pain secondary to corneal oedema.

The Hyper-CL is a hyperosmotic contact lens. The unique structure of the lens enables extraction of fluid from the corneal stroma, combined with increased evaporation over the lens surface. The dual base curve combined with the groove and the holes inside the lens creates a micro-environment above the cornea centre that holds fluid with high ionic concentration and thereby absorbs fluids from the cornea. (See Sidebar for the benefits, indications and contra-indications of these lenses.)

Treatment modality in first trial

1. No treatment 7 days before starting with Hyper-CL.
2. 7 days with Hyper-CL only
3. 7 days with Hyper-CL + saline solution 5%
4. 7 days with saline solution 5% only

There was a one week break without any treatment between treatments. Clinical evaluation was performed at 7, 14, 21 and 28 days post baseline.

Results of 12 eyes

The eyes included in this trial were recruited from Vision4You, Lund, Sweden. No adverse event occurred

Sidebar: Benefits, indications and contra-indications of the Hyper-CL.

The benefits of this lens are many:

- Unique lens design enables extraction of fluids by osmosis from the corneal oedema.
- Acts as a pump.
- No preparation required.
- Disposable, reusable within two weeks.
- Can include refractive correction.
- CE approved, ISO 13485 certified.
- Given by prescription.
- Patent protected.

Indications

The Hyper-CL (Hioxifilcon D) contact lenses are indicated for therapeutic use to protect the corneal surface and to relieve corneal pain, in the treatment of acute or chronic ocular pathologies, such as bullous keratopathy, corneal erosions, entropion, corneal oedema and corneal dystrophies. They are also indicated for post-surgical conditions resulting from cataract extraction and corneal surgery.

The lenses may be prescribed for daily use with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. In addition, these contact lenses can also provide optical correction during healing, if required. To increase the effect of alleviation of corneal oedema, it is recommended to use hypertonic solution in combination with the Hyper-CL.

Contra-Indications

- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as Mercury or Thimerosal, contained in a solution that is to be used to care for the contact lenses.
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

during the periods when patients were wearing the Hyper-CL lens. None of the lens designs caused any side effects other than normal irritation due to the presence of a contact lens on the cornea.

Pachymetry:

- Average baseline pachymetry before treatment was 800 µm.
- After washout with 5% NaCl it was 722 µm.

- After Hyper-CL with 5% NaCl it was 688 µm.
- After wash out 666 µm.
- An average decrease of corneal thickness of 134 µm was seen.

Discomfort and vision:

Discomfort was noted in 2 eyes and in 1 eye there was a tendency for the lens to drop out. A slight improvement of vision was noted.

Conclusions

Based on the results of this initial trial, the safety and efficacy of the Hyper-CL have been established. However, a larger multicentre study is required to make sure this method is effective for corneal oedema and corneal dystrophies (which is currently underway). This method could offer an alternative option for patients to other more drastic treatments of corneal disease.

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