Non Invasive pterygium excision and peeling (Tel Hashomer)
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Non Invasive pterygium excision and peeling

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Abstract

A pterygium is fleshy tissue that grows in a triangular shape over the cornea. These growths are believed to be caused by dry eye, exposure to wind and dust, and UV exposure. Pterygium is more often seen in men than in women. This is attributed to the fact that males are exposed to dust and environmental irritants more than women. It is usually seen within the intrapalpebral fissure and most often from the nasal side. Patients often have foreign body sensation, discomfort, congestion (redness), irritation, grittiness, blurring of vision either because of induced astigmatism or obscuring visual axis. Indications for surgery include visual impairment, cosmetic disfigurement, motility restriction, recurrent inflammation, interference with contact lens wear and rarely, changes suggestive of neoplasia.

The goal of pterygium excision is to decrease irritation/ inflammation, achieve a normal, smooth ocular surface, improve the decreased vision caused by the pterygium, and prevent regrowth, if possible. Pterygium surgery can be challenging due to the extent of corneal involvement. In addition, postoperative recurrences can often be more difficult to manage than primary pterygium. Hence, there is a large menu of surgical techniques to choose from to optimize outcomes , and none of these techniques is universally accepted because of variable recurrence rates. Regardless of the technique used, excision of the pterygium is the first step for repair.

The Need

Although pterygium is classified as a corneal degenerative disorder, it may be considered more of a proliferative condition that has several possible inciting factors . UV light , abnormal conjunctival expression of tumor suppressor gene p53 , presence of angiogenesis-related factors , human papillomavirus infection , and abnormal HLA antigen expression , have all been proposed as pathogenic factors. In particular, UV radiation may trigger events that produce damage to cellular DNA, RNA, and extracellular matrix composition. Hereditary factors may also contribute to pathogenesis and therefore to varying prevalence rates among populations .

Patients with pterygium that does not affect vision or eye movement may be treated symptomatically with topical lubricants including drops, ointments, and gels. Treatment with topical

decongestants, non-steroidal anti-inflammatory drugs (NSAIDs), and glucocorticoids may also be effective for symptomatic relief of pterygium.

Surgery generally involves excision of pterygium, often with adjuvant medical and surgical treatments to help lower rates of recurrence. Limited data are available on surgical outcomes for pterygium, as there are few randomized trials with large numbers of patients and long-term follow-up. Excision usually corrects pterygium-induced astigmatism and visual impairment from a visual axis opacity . However, recurrence of pterygium is common.

Repeated excisions tend to lead to corneal scarring, irregular astigmatism, fibrotic restriction of extraocular movements leading to diplopia, and formation of symblepharon (adhesions of eyelid to ocular surface of globe). All of these can contribute to an abnormal appearance of the globe and can interfere with visual function.

Knife free removal of membrane is a critical unmet need to minimize post-operative complications that include ocular perforation, as well as possible retinal detachment or endophthalmitis that might occur as a result of inadvertent perforation of the globe.

The Technology

The novel system will enable to separate and cleave membranes and tissues using three different modalities forces in the cleavage location

1. Repeated desiccation

2. Pushing and partial cutting

3. Pulling

Our novel device, enables the excision of the membrane using a smart system for delivery surgical sponge (triangular, similar to Weck-cel) . Applying the sponges induces push forces and dryness of the corneal under the pterygium evolving in peeling of the pterygium from the cornea without the need of cleavage.

The sponges absorb local bleeding and the device can be used for other surgeries and indications: suction of absorption of liquids with or without suction, separating membranes, such as: Epiretinal membrane, corneal opacities any other fibrovascular membrane such as proliferative diabetic retinopathy PVR or any other tumor removal in the body needed to be removed by include delamination, and en-bloc dissection

This system can include additional hook up push and pull forces instruments such as suction tube and forceps which will work together and simultaneously using only one hand -instrument. The excision of the membrane will be performed by surgical sharp sponge (triangular) which will induce push forces and dryness of the corneal under the pterygium evolving in peeling of the pterygium from the cornea without the need of cleavage

The Market

Pterygium has a worldwide distribution though it is considered more common in warm, dry climates with a reported prevalence as high as 22% in equatorial areas and less than 2% in latitudes above 40 degrees.

It is speculated to be associated with corneal and conjunctival microtrauma from exposure to

sunlight and/or dust . The exposure to UV light is thought to cause repeated rapid evaporation and destruction of the tear film with subsequent elastoid degeneration of the sub epithelial connective tissue.

A number of risk factors have been identified for the development of pterygium. In a large case control study in Australia , a 4.1 fold greater relative risk of pterygium development was found for persons living in the tropics (less than 30 latitude), 11 fold for those working in a sandy, outdoor environment, 9-fold for subjects without a history of wearing spectacles or sunglasses and 2-fold for those who never wear a hat.

The cost to remove pterygium(s) depends on many factors including:

The size and thickness of the pterygium

The location of the pterygium

The number of pterygiums in each eye

Whether there is enough natural tissue to perform a graft or whether an amniotic membrane graft needs to be used

Whether there was previous surgery to remove your pterygium

The Cost of pterygium removal is between 3.5 K USD to 15K USD. The market for Pterygium removal may reach over 1.8 Billion USD by 2018.

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