Implantable Medical Devices in the Eyes [HW9]

Human Eye

Briefly, human eye is able to sense light and pressure. To achieve the first one, light crosses the cornea, enters the pupil and is finally diffracted by one natural lens present in the eye. Then, light is detected in retina by 2 different structures called rods and cones. The most sensitives, rods, can detect one single photon. This property empowers them with an important role of enabling vision in very dark environments. Additionally, they are not able to distinguish any colors (only provide white and black vision). On the other hand, there are 3 different types of cones in the human body. Each one has its own absorption peak in 3 different spectral regions (red, green, blue). Depending on the stimulation of each type, people are able to perceive different colors. One, in average, is not able to see light with a wavelength lower than 380 nm because all this radiation is completely absorbed in the lens and cornea.

Many pathologies arise from deficiencies in diffracting the light due to abnormal morphologies of cornea; lens opacity (due to aging, most of the times) …

Two practical cases are now studied deeply in a patient and biocompatibility scope.

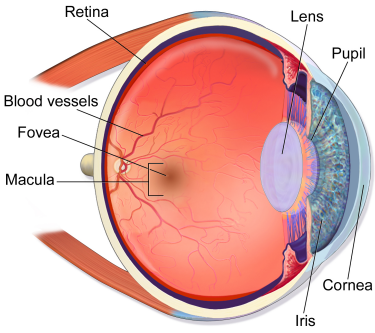

Fig. 1 – Eye Anatomy. [4]

Phakic Lens [5]

Lenses made of plastic or silicone that are implanted into the eye permanently to reduce a person's need for glasses or contact lenses (approved by FDA to treat myopia). Phakic refers to the fact that the lens is implanted into the eye without removing the eye's natural lens. During phakic lens implantation surgery, a small incision is made in the front of the eye. The phakic lens is inserted through the incision and placed just in front of or just behind the iris. These lenses are able to correct the point where the light beam is being focused (in front of retina, instead on its surface).

Apart from the usual risks related to any surgery (infection, inflammation/immune responses…), one specific may be found:

The endothelial cells of our cornea are a thin layer of cells responsible for pumping fluid out of the cornea to keep it clear. If the endothelial cells become too few in number, the endothelial cell pump will fail and the cornea will become cloudy, resulting in loss of vision. We start with a certain number of cells at birth, and this number continuously decreases as you age, since these cells are not replenished. Some lens designs have shown that their implantation causes endothelial cells to be lost at a faster rate than normal. If the number of endothelial cells drops too low and your cornea becomes cloudy, a corneal transplant is needed to see more clearly.

Subconjunctival Implant [6]

Among diabetic people, glaucoma (second leading cause of irreversible blindness in the world) is one of the biggest concerns due to its disabling factor (and the incidence of the disease). It is known that diabetes mellitus can cause restrict blood flow to the eye, this way, it may lead to severe diabetic retinopathy. Other risk factors for glaucoma apart from diabetes are family history of the condition, migraines, high blood pressure and obesity. The main consequences linked to this pathology lead to nerve optic damage and, unavoidably, to vision loss.

Although intraocular pressure is only one of the major risk factors for glaucoma, lowering it via various pharmaceuticals (initial stage) and/or surgical techniques (advanced stage) is currently the mainstay of glaucoma treatment. The biggest challenges using eye drops (pharmaceutical method) is due to its efficient protective barriers (typically <5% of the topically applied drug penetrates the cornea and reaches intraocular tissues) and patients' compliance (need for frequent instillation). Consequently, it is very resistant to penetration by drugs. The recognition of this limitation in efficient ocular drug delivery has led to a range of systems that vary in mode of administration, implantation site, composition and vehicles. One possible solution is related to the use of biodegradable polymers to create implants that may be capable of sustained ocular drug delivery, to overcome the disadvantages.

Polyhydroxyesters are easily fabricated with predictable biodegradation kinetics and biocompatible degradation. These polymers, such as PLGA or PLC, degrade through hydrolysis of their ester bonds into lactic acids, glycolic acids and caproic acid – and eventually into water and carbon dioxide. Since the body effectively deals with these degradation monomers, there is very minimal systemic toxicity associated with its use in surrounding tissues.

After polymers' insertion, appearance and examination of the implanted microfilms revealed minimal localized inflammation and vascularity. All rabbit eyes (18) had mild conjunctival hyperemia and chemosis, which resolved at one week post-operatively. The cornea, anterior chamber and lens remained clear with no evidence of inflammation or scarring. There was no evidence of scleral erosion of the subconjunctival implants in any of the eyes. There was no significant fibrosis or collagen capsule formation seen around the implant site. Histological examination did not show an obvious foreign body encapsulation of the implanted films. This is important as excessive scarring and encapsulation often affects ocular function or lead to surgical failure in different surgeries. A minimal infiltration of T cells was also detected by immunohistochemistry surrounding the implant site.

PLGA and PLC microfilms were proved biocompatible and safe to be inserted subconjunctivally in the rabbit eye. This result can be somehow extrapolated due to similarities between rabbit and humans' eyes.

References

[1] Wikipedia, “Glaucoma”. Available at: https://en.wikipedia.org/wiki/Glaucoma#Treatment (Consult. 06/05/2017);

[2] Wikipedia, “Cone cell”. Available at: https://en.wikipedia.org/wiki/Cone_cell (Consult. 06/05/2017);

[3] Wikipedia, “Conjunctiva”. Available at: https://en.wikipedia.org/wiki/Conjunctiva (Consult. 06/05/2017);

[4] Wikipedia, “Human eye”. Available at: https://en.wikipedia.org/wiki/Human_eye (Consult. 06/05/2017);

[5] FDA, “Phakic Intraocular Lenses”. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/PhakicIntraocularLenses/default.htm (Consult. 06/05/2017);

[6] PLOS, “Biocompatibility and Biodegradation Studies of Subconjunctival Implants in Rabbit Eyes”. Available at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0022507 (Consult. 06/05/2017);

Quiz

1.

2.

3.

4.

5.