1 Biological Considerations for an Intraocular Retinal Prosthesis

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Introduction

The idea of replacing a dysfunctional or missing body part with a prosthesis is perhaps as old as the history of humankind; yet, it still continues to be a fascinating theme. While early prostheses were limited to external organs (e.g. wooden legs), the twentieth century witnessed the implantation of numerous devices inside the human body, some of which have since become routine surgical procedures. For external prostheses, both proper fitting and functionality are needed to make a device acceptable for use; however, internally implanted prostheses have additional challenges, and the implantation of intelligent devices which interact with surrounding tissues is even more difficult.

Despite being one of the most delicate organs of the body, the eye has proven to be a hospitable environment for a variety of materials. Whereas some metals such as iron and copper are highly toxic to the eye, other substances such as silicone, polymethyl-metacrylate (PMMA), and acrylic are well tolerated. Intraocular lenses made of these substances are routinely used to replace the natural lens during cataract surgery, the most commonly performed intraocular surgical procedure. Prior to surgical procedures that could be performed within the back of the eye (vitrectomy), retinal detachment had almost exclusively been treated with scleral buckling, a procedure whereby silicone rubber is placed around the eyeball. Even now, a significant number of retinal detachments are treated this way. Ocular implants are also used in some procedures relating to orbital, keratorefractive, and glaucoma surgeries. Thus, the use of prosthetic devices in an ocular environment is well established and a number of materials are proven to be suitable in the fabrication and use of these devices.

Retinal prostheses are being developed to apply electrical stimulation to the retina in order to restore vision. Several different configurations have been proposed and these will be reviewed in detail later in the chapter. However, common qualities of almost all of the implants are: (1) a light-sensitive device for
capturing image data, (2) implanted microelectronic for converting image data into a stimulus pattern, and (3) a microelectrode array interface for delivering the stimulus current to the retina. The implementation of these functions is system dependent; however, the potential for harmful interaction between the device and the eye is considerable in all cases. The following issues must be considered for any of these implants.

- **Toxicity**: The device should either be made of (or hermetically coated with) materials that are not toxic to the retina or any other ocular tissue.
- **Degradation**: Even if the outer coating is not toxic, over time, the degradation of the device coating can expose the retina to toxic materials which are part of the implant electronics.
- **Mechanical damage**: The electrode array should also properly fit over the area of the retina that is being implanted. The retina is a delicate neural tissue, and rigid electrodes and microelectronic chips can easily cut the retina, without careful mechanical design. Additionally, limited space in the eye and orbit will constrain the device size and shape.
- **Electrical damage**: An electrical stimulus beyond safe limits may damage the retina.
- **Thermal damage**: The retinal prosthesis electronics produce heat which can be damaging to the retina and other ocular structures, if beyond a given threshold.
- **Reversibility**: Extreme measures in fabricating a robust prosthesis and preoperative testing of the device reduce the chance of its becoming dysfunctional; however, despite best efforts, some prostheses may break down, and it is important to be able to remove the faulty device.

**Background**

*Anatomy and Physiology of the Eye*

The eyeball is classically divided into two segments: the anterior segment, composed of the cornea, iris, lens, and ciliary body; and the posterior segment, composed of the sclera, choroid, retina, vitreous, and optic nerve (Figure 1.1).

The eyeball is located within a bony socket called the orbit (Figure 1.2). In addition to housing the eyeball, the orbital cavity contains extraocular muscles, vessels, nerves, connective tissue, and orbital fat.

Although it may be possible to insert a prosthetic device around the eyeball, the device size and shape are important limiting factors. For instance, a poorly shaped, rigid object inside the orbital cavity may damage vessels and nerves, interfere with eye movement, and directly damage the eyeball. On the other hand, a bulky device may displace the eyeball, jeopardize the blood supply to the eye, or raise the intraocular pressure (IOP), thereby resulting in nerve fiber layer damage. These constraints will obviously limit the capability of an electronic device because of necessary size restrictions.