STARflo™: A Suprachoroidal Drainage Implant Made from STAR® Biomaterial

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Introduction

Aqueous humor is produced in the posterior chamber of the eye by the ciliary body epithelium at a relatively constant rate of about 2.5 µl/min and flows into the anterior chamber, passing around the lens and through the pupillary opening in the iris. It is a complex mixture of electrolytes, organic solutes, growth factors, and other proteins that supply nutrients to the nonvascularized tissues of the anterior chamber (i.e., trabecular meshwork, lens, and corneal endothelium). Egress of aqueous humor from the anterior chamber occurs via two distinct pathways: conventional and uveoscleral. In the primary (conventional) outflow pathway, accounting for the majority of the aqueous outflow in normal individuals, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm's canal), and drains into collector channels and then into the aqueous veins. The uveoscleral outflow pathway, which may account for 10–60 % of total flow in the human eye [1–4], comprises the interstitium of the ciliary body, the suprachoroidal space, and, ultimately, the choroidal and scleral vasculature. Elevated intraocular pressure (IOP) typically results from increased resistance or compromise in either or both outflow pathway.

While research is investigating ways to protect the optic nerve and the vision from an elevated pressure, the only therapeutic approach currently available in glaucoma is to reduce the intraocular pressure. Glaucoma surgery is intended to reduce the IOP when the target IOP cannot be reached with maximal medical therapy or laser treatment. Due to complications with established surgical approaches such as trabeculectomy (early hypotony, blebitis, endophthalmitis, shallow anterior chamber, etc.) and closure by the body's natural healing process, a variety of seton devices, including aqueous shunts, are in use or being evaluated as alternative surgical treatments for patients with glaucoma. Glaucoma drainage devices (GDDs) aim at creating an alternate aqueous pathway from the anterior chamber by channeling aqueous humor out of the eye, hence reducing IOP. Traditionally, GDDs have been developed to provide an artificial conduit (small tube) for aqueous humor to travel from the anterior chamber and spread across a subconjunctivally located plate to form a filtering bleb [5, 6]. Although this filtration is nonphysiologic, the traditional tube shunts can effectively reduce IOP. However, they share similar postoperative challenges with trabeculectomy including bleb leakage, overfiltration, bleb dysesthesia, bleb encapsulation, and fibrosis. They also have their own unique set of postoperative risks, such as corneal endothelial cell death, ptosis, diplopia, tube migration, tube or plate exposure, and tube lumen occlusions. As a result,

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Electronic supplementary material Supplementary material is available in the online version of this chapter at http://dx.doi.org/10.1007/978-1-4614-8348-9_22. Videos can also be accessed at http://www.springerimages.com/videos/978-1-4614-8347-2

J.R. Samples, I.I.K. Ahmed (eds.), *Surgical Innovations in Glaucoma*,
DOI 10.1007/978-1-4614-8348-9_22, © Springer Science+Business Media New York 2014

many recent efforts have been directed towards new "blebless" procedures that do not rely on conjunctival placement and are less prone to these complications.

STARflo™ is a new glaucoma drainage device designed to provide a pathway for aqueous humor to travel from the anterior chamber into the suprachoroidal space, enhancing the natural uveoscleral outflow and eliminating the need for a filtering bleb. It is comprised entirely of Healionics' proprietary silicone STAR® Biomaterial, a precision-pore structure that creates a permanent multi-porous wicking system and that enhances biointegration and reduces fibrosis [7–9].

Background

The shape of the STARflo Glaucoma Implant is based on designs developed by Dr. Robert Nordquist in the 1990s [10, 11]. Originally based on cellulosic membrane, the material composition of the seton has evolved towards the use of a more advanced biomimetic structure and a more robust biocompatible material – the silicone STAR® Biomaterial manufactured by Healionics Corporation.

Cellplant Device

The use of setons to permanently lower IOP has been attempted for many decades. The first seton made of horsehair was implanted in 1906 to drain fluid out of the anterior chamber [12]. Since then, devices made from numerous other materials including silk thread, nylon, hydrogels, collagen, gold, platinum, silicones, and polythene have been described in the literature [13, 14]. Over time, these devices have varied widely in size, material composition, and design. In the 1990s, a novel approach was created by Drs. Robert Nordquist and Bing Li to overcome shortcomings that limit conventional aqueous tube shunts, such as foreign body reactions, inflammation, tube obstruction, and infection. Nordquist and Li described the material, the design, and the surgical protocol for a novel method of lowering the IOP [10, 11, 15, 16]. The material should exhibit certain characteristics for seton use:

- Biocompatible to avoid foreign body reaction, inflammation, and capsule formation
- Highly resistant to cellular attachment and invasion
- Nonabsorbable and stable at body temperature
- Pliable so as to fit the contours of the eye
- Soft enough to avoid scleral erosion, corneal irritation, inducement of undesirable changes in eye curvature, or damage to adjacent vasculature and tissue, but resilient enough to maintain shape and thickness
- Strong enough to keep the surgical fistula open permanently
- Porous so as to naturally regulates the flow of aqueous humor through the seton by mimicking the trabecular meshwork

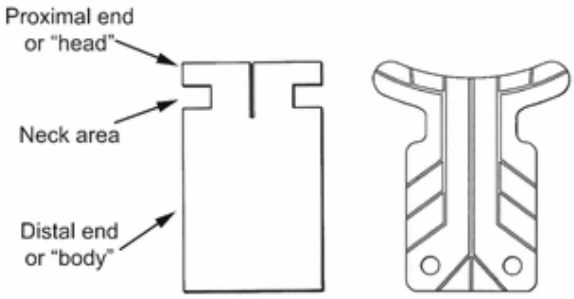

Fig. 22.1 Norquist's designs for seton use [11, 15]. Seton is comprised of a head, a neck, and a body portions. Further versions of the seton included grooved drainage channels, curved edges and proximal end, and suture holes

The multi-porous structure should also exhibit an inherent controlled resistance to flow first to prevent postoperative hypotony and second to regulate the rate of aqueous humor outflow proportional to the intraocular pressure. The material should also inhibit closure at the surgical site without producing inflammation, obstruction, or infection.

In the initial iteration, the seton devices were formed as thin flexible sheets with bottle-shaped profiles (Fig. 22.1). The proximal end ("head") extended into the anterior chamber and reduced to a narrow neck area passed through a limbal opening at the iridocorneal angle. The neck shape regulated the flow and securely held the seton in position. The distal end ("body") was rectangular shaped and entirely placed under a conventional 50 % thickness scleral flap. Typically, these setons were designed approximately 8–10 mm long with a width of 4–6 mm and a thickness of 50 μm. Some versions further included grooved drainage channels to facilitate increased ocular fluid flow from the anterior chamber, curved proximal ends to conform with the curvature of the anterior chamber, and suture holes in the body to secure the implant to the sclera.

The resultant "CELLplant" device (Fig. 22.2) was a filtering implant of similar shape to the first model shown on the left in Fig. 22.1 and made from the cellulosic membrane material widely used for hemodialysis filtering [10, 11]. This material exhibited many of the needed characteristics.

Toxicity, safety, and efficacy of the CELLplant device were successfully demonstrated in rabbits [10, 11]. In a first short study, the average IOP dropped from 22.0 to 14.3 mmHg in the eyes treated with the CELLplant device, whereas the control eyes treated with a normal filtering surgery had an average IOP of 20.2 mmHg after 70 days (p-value of 0.001). A 1-year study showed similar results with an average IOP reduction more than 30 % at the end of the experiment (Fig. 22.3). None of the rabbits developed corneal decompensation, conjunctival erosion, or uveitis as a result of the