Surgical Innovations in Glaucoma
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Trabeculectomy has been a gold standard for almost 100 years. We believe that many of the emerging technologies can offer significant improvements for our patients. In this volume, we seek to present the most significant new technologies offering promise for glaucoma surgery; some are still investigational, and some are already on the market. These alternatives raise a host of issues which we seek to address throughout the book. We are confident that many of the technologies in this volume will prevail and go on to become mainstream over time. In many instances, these are the first reviews of new devices. Authors have been asked to provide videos, and we provide links to those videos. We will include videos which will really work at the “how to” level for those interested in doing these procedures.

The new approaches described herein use laser, ultrasound, and incisional surgery. In many instances, the new technologies use fibers, stents, or tubes in Schlemm’s canal, the suprachoroidal space, or the subconjunctival space. At the outset, we have provided a discussion of anatomy of these spaces, as well as a discussion of the intellectual property issues and regulatory issues pertinent to glaucoma. Regulatory issues for approval of the devices are rapidly changing, and we realize, as we hope the reader will, the limitations of discussing them in a book, which de facto, in this rapidly changing environment, means some elements are subject to going out-of-date.

In the middle of the book, we include a cross section of the therapeutic targets which include the subconjunctival space with improved forms of filtration, Schlemm’s canal and its collector channels, the suprachoroidal space, and the ciliary body. These areas are treated with a variety of modalities, each with its own potential pitfalls. A uniform goal for all the procedures is for them to be routine and efficiently performed. Glaucoma is a worldwide problem, and the best and most successful procedures will be those which can succeed with a variety of skill levels in a variety of environments, including third-world settings.

All procedures need to be evaluated while thinking about the risk/reward/effort balance. Risk must always be balanced against the natural history of the disease in glaucoma, as well as the type of glaucoma. Even open-angle glaucoma is really a group of diseases as proven by the genes which have been discovered. Often, glaucoma surgeons get trapped in a rut of doing the most familiar procedure; we need to customize procedures to the life of the patient taking into account expectations, progression, and the surgical risks.

A lot of the things in this book are going to be used outside of their approved use(s) in the USA. Cost and regulatory issues remain concerns with these new procedures. Data needs to constantly be reevaluated keeping in mind our responsibility to do the best that we can for the patient. In some instances, the best available data may suggest “off-label” use which is permitted in the USA when it is clearly in the best interest of the patient. However, going off-label with any drug or device must always be well documented so that the patient and the patient’s family have a clear understanding of the reasons for going off-label. As of our December 2013 publication date, off-label use can be discussed in the context of continuing medical education lectures but not in promotional discussions of products. The legal landscape of off-label discussions may be changing with the current finding (subject to reversal) in a federal court that off-label discussions may be constitutionally protected free speech in the USA. Transparency
through candid and accurate discussions with patients of potential surgical procedures is an important part of the implementation of these new devices.

These new techniques throw into question long-standing assumptions which – in light of new technologies – need to be challenged. We have both often taught our children to question authority (often, but not always, with good results). Phacoemulsification and the development of the posterior chamber lens are good examples. These hallmark developments in ophthalmology were not well received at inception. It was only with time that they were accepted, particularly by the ophthalmic academic community. Don’t forget that phacoemulsification was initially perceived to be almost impossibly difficult to do. Yet, today, it is practically the standard of care and complications are rare. So it will be with some of the procedures outlined in this book.

We thank Rebekah Amos and Daniel Dominguez for their help in assembling this book. We thank all of the chapter authors, some of whom had to put up with all sorts of questions and harassment; they were very kind to put up with us. We thank our families for putting up with us (for JRS that means Griff, Wes, Laura, Andrew, and Lily, and for IKA that means Ruby, Yusuf, Aadam, and Issa).

This book is not comprehensive. At the time we are writing this, we are aware of a number of very new endeavors to surgically treat glaucoma that are not yet ready to be discussed in a volume such as this. Some will undoubtedly find their way “onto the radar” in the very near future.

We thank you who have purchased this book. We are both extremely interested in your feedback on this volume and hope that when you see us at glaucoma meetings you won’t hesitate to visit with us about what we could have done better or worse so that we can improve in the future.

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Part I

Considerations in Device Development
Introduction

Intraocular pressure (IOP) is maintained within a normal range from a dynamic balance between aqueous humor formation and drainage. Dysfunctional aqueous drainage results in elevated IOP, which is a causative risk factor for the development and progression of primary open-angle glaucoma (POAG) [1]. An understanding of how to lower IOP using microinvasive glaucoma surgery (MIGS) begins with an understanding of the normal anatomy of the structures related to the drainage of aqueous humor and changes in POAG. The major drainage structures for aqueous humor are the conventional or trabecular outflow pathway, which is comprised of the uveal and corneoscleral portions of the trabecular meshwork, the juxtacanalicular connective tissue, Schlemm’s canal, the collector channels, and the aqueous veins. Aqueous humor drains from the anterior chamber through progressively smaller channels of the trabecular meshwork into a circumferentially-oriented channel called Schlemm’s canal. From this canal, circuitous channels weave toward the surface of the sclera, ultimately joining the episcleral vasculature which drains into the venous system. Flow through this system is driven by a bulk-flow pressure gradient, and active transport is not involved as neither metabolic poisons nor temperature affects this system to any significant degree [2, 3]. 10–20 % of total aqueous outflow has been reported to leave the normal eye via the uveoscleral pathway [4, 5] which has become a primary target for medical intervention in glaucoma. However, this chapter will only focus on the conventional trabecular outflow pathway.

Normal Anatomy of Aqueous Outflow Pathway

Trabecular Meshwork

The trabecular meshwork (TM) is a triangular-shaped band of tissue encircling the anterior chamber angle (Figs. 1.1 and 1.2). The apex of the triangle is attached to the terminal edge of Descemet’s membrane of the cornea which is termed Schwalbe’s line. From this point of origin, the TM expands as it bridges the iridocorneal angle and ends posteriorly by blending with the stroma of the iris, ciliary body, and scleral spur. The scleral spur projects like a shelf onto the base of this triangle and also serves as a point of insertion for the longitudinal bundle of the ciliary muscle. The length of the TM from Schwalbe’s line to the scleral spur is 694.9 ± 109 μm in men and 713.2 ± 107 μm in women by histological assessment [8]. Using optical coherence tomography (OCT), the mean length of the TM was found to be 466.9 ± 60.7 μm in vivo [9]. An imaginary line drawn from Schwalbe’s line to the tip of the scleral spur separates the TM into two major parts. The portions of the TM external to the imaginary line include the corneoscleral meshwork, the juxtacanalicular tissue, and Schlemm’s canal. The portion of the TM closer to the anterior chamber internal to this imaginary line is termed the uveal meshwork because it extends from Schwalbe’s line to the stromas of the ciliary body and iris (Figs. 1.1 and 1.2). Uveal meshwork is readily viewed gonioscopically.

It is important to understand the relationship of the anterior chamber angle structures as viewed from at least two perspectives—the view obtained from meridional sections and the view obtained gonioscopically. These two views are compared in Figs. 1.3 and 1.4. Figure 1.3 shows a macrophotograph of the angle in a meridional view, while Fig. 1.4 depicts an en