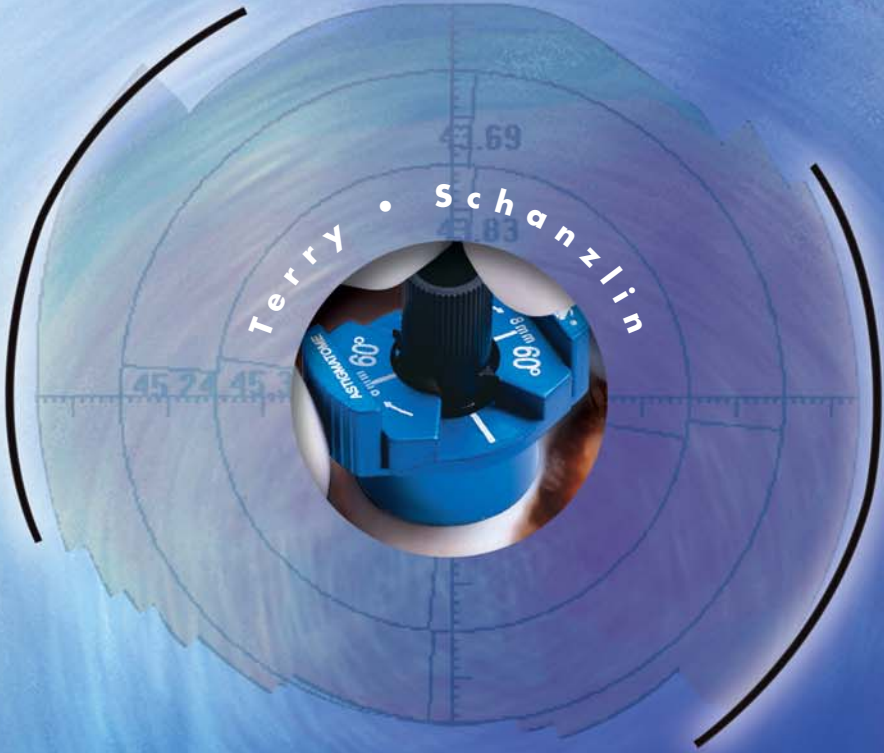


OASIS®



A S T I G M A T O M E™



*User's
Manual*



*Clifford M. Terry, MD
David J. Schanzlin, MD*

Instrumentation

The ASTIGMATOME Blade

Consistent Symmetry: Blade depth and Optical Zone (OZ) are preset to provide consistent depth and reproducibility. Preset depth options are 500, 550, 600, 650 and 700 μ for arcuate cuts at 8mm. Pachymetry is required to determine corneal depth. Measurements should be taken centrally and at the location of the incisions.

Double- or Single-blade Designs: The double-blade design is commonly used for the treatment of regular astigmatism where two simultaneous arcs are desired exactly 180° apart. A single-blade variation is available for non-orthogonal and asymmetric corrections.

External Blade Location Tabs: The external tabs provide visual indication of blade tip position throughout the procedure. They also provide a mechanical rotational stop when used with Preset Templates.

Safety: A blade guard protects the blades until retracted. Every ASTIGMATOME™ should be inspected to ensure exact blade depth.

Components

Vacuum Speculum: Provides fixation and lid separation. Fixation is achieved and maintained by a disposable vacuum syringe. A lid speculum may also be used as needed. The preset Templates or protractor template fit into the Vacuum Speculum.

Arc Templates: The Vacuum Speculum accommodates a range of interchangeable Arc Templates to assure consistent predetermined arc lengths. A template of a given arc length is selected according to your preferred nomogram and surgical plan. A protractor insert is also supplied for treating special cases such as non-orthogonal and asymmetrical astigmatism using variable arc length calculations.

Spring-loaded Vacuum Syringe: Provides the required level of vacuum for secure fixation throughout the procedure.



Patient Work Up

Surgical Worksheet

The Surgical Worksheet, illustrated on the following page, is useful for documenting pachymetry findings and other information needed. A *Procedure Summary*, a sequential overview of procedural steps and recommended medications, is included in this manual.

Pachymetry Notation Pattern (Circular Diagram)

The diagram illustrates both the relative position of the patient as well as the data obtained at each measurement point. Measurements are taken at five points — centrally and four points 90° apart at the incision. The five entry boxes permit the display of corneal thickness found at each location. As a universal reference, the patient's left ear, is 0°. The worksheet also emphasizes the need for plus cylinder notation to avoid treating the minus axis. Appropriate blade depth is based on the pachymetry reading. The selected blade depth should be up to 100% of the corneal thickness but no greater than.

Postop Medications

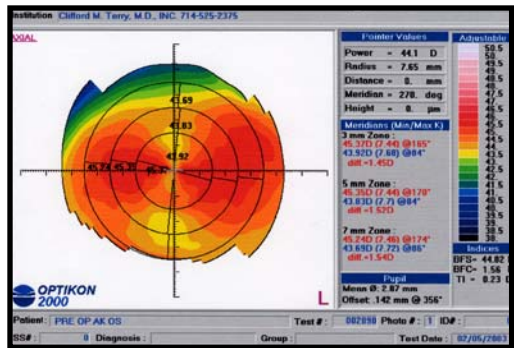
The patient's postoperative regimen consists of Fluoroquinolone once each waking hour and a mild corticosteroid four times a day. No ointments are used. For any discomfort, the patient may be directed to use a preservative-free, non-steroidal anti-inflammatory medication, four times per day. At the one-day postoperative visit, Fluoroquinolone is decreased to four times a day, and at one week postoperatively, all medications are discontinued.

Using the Corneal Map in Surgery

- Define a standard for the 0° reference point.
- Orient the map to match the position of the patient on the table.

This patient has approximately 3 diopters of plus cylinder at 145°

The correct axis of treatment is easily visualized if you think in plus cylinder. This avoids confusion and ensures that the cuts are correctly placed at the plus axis.



An inverted map orients the axis to the same position as the supine patient

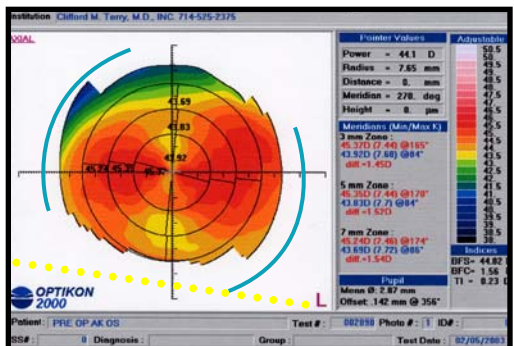
The map is marked twice

First

Mark the axis of the steep meridian.

Second

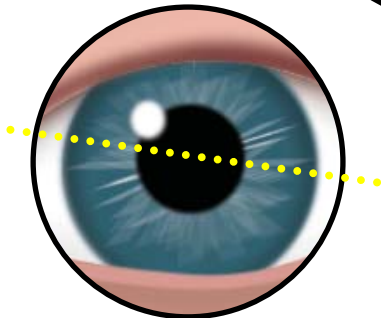
Mark the planned path of the blade(s) from start to finish based upon your preferred nomogram. Once marked, it is recommended that the map be placed within easy view throughout the case.



Marking the map for planned blade paths

Positioning the Alignment Speculum and Template on Axis

A central corneal mark is placed and the cornea dried. The vacuum tubing is attached to the port on the barrel of the Alignment Speculum. Based upon the surgical plan, the Template matching the desired arc length is placed into the Alignment Speculum. The Alignment Speculum is positioned so that the limbus is seen in all four notches and no conjunctiva is trapped under the footplate. The alignment index marks are matched to the previously placed scleral axis marks. Vacuum is applied by releasing the syringe piston and centration is verified by observing the central corneal mark in the center of the Template aperture.



● Illustration of plus cylinder scleral axis marks and the central corneal mark

Positioning the Alignment Speculum and Template on Axis *(continued)*

With the blade guard extended, the ASTIGMATOME™ blade unit is placed into the Template. This is done to protect the blade tips. The ASTIGMATOME blade indicators are placed at the starting point of the intended arc. Because the blades cut only in the clockwise direction, place the indicators against the most counter-clockwise walls of the Template as the starting point. Centration is again verified by viewing the central corneal mark visible through the ASTIGMATOME barrel.



Blade indicator placement at starting point

Prior to making the cuts, rock the ASTIGMATOME blades into the cornea to ensure maximum penetration. View the cornea to make sure that no aqueous is present, thus confirming that perforation has not occurred. Verify that both centration and vacuum have been maintained. You are now ready to place the cuts.

Maintain equal pressure on both blades using a single sweeping motion. Slowly rotate the ASTIGMATOME clockwise to the endpoint stop of the Template. This is best accomplished by using the arm and hand together in a smooth, sweeping motion as opposed to simply rolling the ASTIGMATOME between the finger and thumb. Once the endpoint is reached, vacuum is released and all instrumentation removed.



The endpoint stop and blade indicator position at the conclusion of the blade pass

Guidelines to Assure Success in Early Cases

- *Against the rule astigmatism of less than 3 diopters*
- *Normal pupil, IOP, and healthy cornea*
- *Pachymetry taken centrally and at four points 90° apart at the incision*
- *Corneal map is normal (regular bow-tie for double-blade procedure using preset templates)*
- *Completed Surgical Worksheet. Appropriate template selected*
- *Corneal map is marked and oriented in the same direction as the patient (i.e. invert map if working in a superior position, patient's legs ahead of/away from you)*
- *Preop medications given*
- *Axis verified using plus cylinder notation. Axis marks are placed on the sclera while patient is seated*
- *Perform the procedure under low magnification and coaxial illumination*
- *Mark the central cornea with a 4.75mm optical zone marker for intraoperative visual confirmation of precise alignment of instrumentation. View the central mark through the barrel of the ASTIGMATOME prior to initiating the cuts*
- *Normal vacuum is confirmed and sustained. No syringe piston movement following initial induction. Initial alignments remain secure*
- *Maintain equal pressure on both blades throughout the entire rotational pass. Blade pass should be a slow and even clockwise turning motion to the endpoint*
- *Compliance with postop medications*

Procedure Summary

Supplies

ASTIGMATOME™ Vacuum Alignment Speculum and Arc Template Set

ASTIGMATOME Vacuum Syringe Set

ASTIGMATOME Blade

Sterile Field

Eye Drape, Betadine Swabs

Topical Anesthesia (Tetracaine)

Fluoroquinolone

Lid Speculum

Upon arrival, the patient is prepped, keratometry is performed, and Corneal Topography is obtained. Pachymetry is measured along the surgical path at 12, 3, 6, and 9 o'clock as well as centrally. The patient is seated in front of the slit lamp for axis marking. Topical anesthesia and Fluoroquinolone are instilled at this time. A narrow slit lamp beam is adjusted to the appropriate axis. Marks representing the plus cylinder axis are placed on the sclera using a hockey stick foreign body spud and blue ink.

The patient is taken to the minor surgery suite, and the area around the surgical site is scrubbed with betadine. Topical anesthesia and Fluoroquinolone are instilled in the eye at this time. The patient is draped and the microscope is positioned above the operative eye. A central corneal mark is made using a 4.75mm optical zone marker. A lid speculum may be positioned as needed. The Vacuum Syringe Set is attached to the Alignment Speculum port. In accordance with the surgical plan, the appropriate Template is placed into the Vacuum Alignment Speculum and properly aligned. The cardinal alignment lines are aligned with the previously placed plus cylinder axis marks. Vacuum is applied by releasing the Vacuum Syringe Set spring-loaded

piston. Centration is confirmed by viewing the central corneal mark. The cornea is dried. An ASTIGMATOME blade of the correct blade depth and diameter is selected in accordance with the surgical plan. With its blade guard extended, the ASTIGMATOME blade is inserted into the Template. The ASTIGMATOME blade position indicators are aligned within the Template's most counter-clockwise starting point and the blades are rocked into the cornea to ensure full penetration. A dry cornea should be viewed through the ASTIGMATOME barrel and the absence of perforation should be confirmed. Using downward pressure, a gradual, even and uninterrupted clockwise rotation of the ASTIGMATOME is made to the endpoint. All instrumentation is removed and the patient is allowed to blink. The incisions may be inspected for depth and symmetry. A sterile preset groove blade may be used for enhancement depending upon keratometric findings.

The patient's postoperative regimen is Fluoroquinolone once each waking hour and a mild corticosteroid four times a day. No ointments are used. For any discomfort, the patient may be directed to use a preservative-free, non-steroidal anti-inflammatory medication, four times per day. At the one-day postoperative visit, Fluoroquinolone is decreased to four times a day, and at one week postoperatively, all medications are discontinued.

Sample Informed Consent

Authorization for/and consent to surgery

The surgicenter and your physician are required by law to obtain your consent to perform the surgical, medical or diagnostic procedure(s) listed below. Signing this form will acknowledge that you agree with and consent to your physician performing the recommended procedure(s). Your signature also confirms that your physician has explained to you the procedure(s), the risks of the procedure(s), the alternatives, if any, and the risks to the alternatives and the risks or consequences of foregoing all treatment. Please read this entire form carefully and then, before signing it, ask your physician any additional questions you may have. Your consent is valid until you withdraw it.

I, _____ hereby authorize Dr. _____, and whomever he may designate as his assistant(s), to perform the following operation or diagnostic procedure(s):
(Do not abbreviate).

Surgically Induced Astigmatic Keratotomy

I am aware that the practice of medicine and surgery is not an exact science and acknowledge that no guarantees or warranties have been made to me concerning the results of the procedure(s). I acknowledge that even though my physician has advised me of all known risks, that additional unforeseeable and unpreventable situations could arise in the course of my care which might result in injury. I have been informed that the treatment, operation or procedure to be performed on me may not necessarily improve or correct my condition, and that it is entirely possible that my condition may be worse following the treatment, operation or procedure.

I further consent to the administration of any necessary anesthesia to be applied by, or under the direction of Dr. _____.

I hereby state that I have read and understand this consent and that all my questions about the procedure(s), alternative procedure(s), and risks of each have been answered by my physician in a language that I understand and that all blanks were filled in prior to my signature, and inapplicable paragraphs, if any, were stricken before I signed.

Patient Signature _____ Date _____ Time _____
Witness _____

I have explained the surgical procedure(s), alternative(s), and risks to the person(s) whose signature is/are above.

Doctor Signature _____ Date _____ Time _____

Additional Sample Forms

Procedure Performed at the Time of Cataract Surgery

Dear Patient,

Your eye has an astigmatism, which after surgery will require eyeglasses to see as clearly as possible. However, we are able to correct your astigmatism surgically to get the best vision without glasses. Neither Medicare, HMOs or insurance companies cover this service which they deem as medically non-essential or cosmetic. We believe that when we restore vision to the eye, we should ensure the best eyesight possible. To achieve this excellent vision requires special testing, called corneal topography, and special depth measurements. A procedure called Precision Astigmatic Keratotomy is done to reshape the cornea using special instruments. Because insurance companies do not yet cover this procedure, there is a cost of _____ dollars to the patient, when performed at the time of your cataract surgery. This procedure is optional, but if it is not done you will need to wear stronger glasses that may not have been needed had this state-of-the-art procedure been provided.

In-office Procedure

AK Procedure Schedule Information

Patient Name _____

You have an Astigmatic Keratotomy scheduled for _____ (day), _____ (date).

A patient representative from my office will call you the day before the procedure with the exact time to arrive. You may eat breakfast and take any medications that you normally take in the morning, including eye drops. Do not wear any eye makeup, earrings, or fine clothing. You will be medicated prior to your procedure, and you must have a driver to take you home afterwards. In order to allow the medications to take affect, you will be here one hour after taking the medication, prior to the beginning of surgery. As each patient is different, one procedure may take longer than the next, due to special calculations that are performed. Your arrival time is not related to the procedure time, only to your procedure starting time.

Your Postoperative Appointments

One Day	Date _____	Time _____
One Week	Date _____	Time _____
One Month	Date _____	Time _____

These appointments are made prior to surgery to ensure your surgical experience with (your practice name) is a pleasant one. If you have any questions, please call _____.

Reimbursement Topics

Pre-existing Astigmatism

Pre-existing astigmatism is normally not reimbursable by insurance carriers and is not deemed “reasonable and necessary” by Medicare. However, because it is an “off schedule” procedure, you are permitted to charge a fee for the ASTIGMATOME™ procedure and collect it directly from the patient. The fee would include all testing and postop follow up. The fee may vary somewhat based upon whether or not it is to be done at the time of cataract surgery or as a separate procedure in the office (which requires added time and effort). For complete information regarding Medicare reimbursement, we strongly recommend obtaining a copy of *Medicare Reimbursement for Astigmatic Keratotomy* by Kevin J. Corcoran (Corcoran Consulting Group). They are supplied free of charge from OASIS™ MEDICAL at (800) 528-9786.

Surgically Induced Astigmatism

Correcting surgically-induced astigmatism is reimbursable by Medicare and most private insurance plans. This topic is covered thoroughly in the above paper from Corcoran Consulting Group. Hospital Out-Patient Departments are entitled to supply reimbursement, but an ASC is not.

Candidate Screening

**Patient categories that could benefit greatly
from the ASTIGMATOME**

Cataract/IOL patients (surgically-induced and pre-existing cylinder)

Patients whose spherical equivalent is plano

GPCL patients (high cylinder, low tolerance)

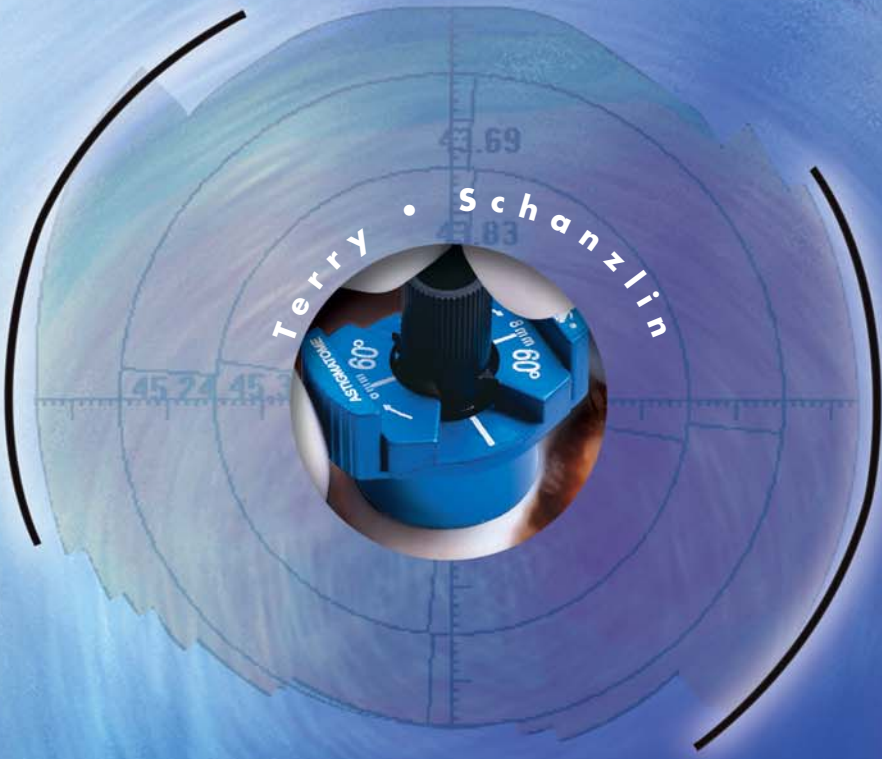
Toric Soft Lens patients (eliminates expensive care regimen)

Pre- and Post-LASIK patients (treating residual cylinder without lifting flap)

Prospective multifocal IOL patients

OASIS® 

ASTIGMATOME™



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The Terry-Schanzlin ASTIGMATOME was originally designed by Clifford Terry, MD with design modifications by David Schanzlin, MD.
Patent No. 5,938,675

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