The Alpins Method:

A Breakthrough in Astigmatism Analysis

Refractive surgery is an emerging subspecialty of ophthalmology. About half of the world's population are candidates for corneal refractive surgical correction of nearsightedness (myopia) or farsightedness (hyperopia), and about half of these people have astigmatism of sufficient amount to warrant concurrent correction. A new method, developed by Noel Alpins, MD, assists in the planning and evaluation of corneal refractive surgery on people with astigmatism. The Alpins method determines a goal for astigmatism correction and a vector (steepening force) required to achieve that goal. From this, the method allows the calculation of the principal components by which an operation fails to achieve its goal, and other components that assist in the comparative analysis of the results of astigmatism surgery for individuals and groups of individuals.

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The ideal cornea of the eye is a perfect dome with a base that is a perfect circle. For people with astigmatism, the dome is not spherical and the base is elliptical to one degree or another.

The cornea (the clear front window of the eye) has a major role in focusing light on the retina (the light-sensitive tissue in the back of the eye which can be likened to the film in a camera). Any distortion of the cornea results in the defocusing of light and a blurred image on the retina.

Since the late 1970s, eye surgeons have been taking advantage of the refractive power of the cornea to correct nearsightedness (myopia) and farsightedness (hyperopia). The ophthalmic subspecialty that has emerged is called refractive surgery. Refractive surgery represents a growing market worldwide with a huge potential impact both in economic and human terms.

THE COMPLICATING FACTOR

The various corneal refractive procedures that have been developed over the past two decades have one thing in common: to correct myopia, they flatten the dome of the cornea; to correct hyperopia, they steepen the dome of the cornea.

The most common corneal refractive procedures are photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK). In PRK, an excimer laser is used to ablate the surface of the cornea, steepening or flattening it as appropriate for the individual patient. In LASIK, the surgeon first uses an instrument called a microkeratome to cut a flap on the front of the cornea. The flap is folded back, the excimer laser is used to make an ablation on the corneal bed (steepening or flattening as appropriate), and the corneal flap is returned to its original position. In essence, LASIK is PRK performed under a corneal flap.

Myopia and hyperopia in the absence of astigmatism are said to be spherical. The correction of spherical myopia and hyperopia by changing the shape of the cornea is a relatively straightforward process. In myopia, the focal point of converging light rays lies in front of the retina. In hyperopia, the focal point is behind the retina. A flattening of the cornea reduces its refractive power, which in the myope pushes the focused image back to the retina where it belongs. Similarly, steepening the cornea increases its refractive power, moving the focal point forward to the retina.

When astigmatism is thrown into the equation, however, refractive surgery becomes immensely more complicated. In planning, implementing and analyzing refractive surgery, astigmatism has challenged the

best minds in ophthalmology. This article describes Noel Alpins' method of astigmatism analysis. 1,2,3,4

GETTING WITH THE PROGRAM

In its use of vector analysis, the Alpins method built on the work of others (see References 5, 6 and 7). Alpins finalized the method in 1991 and, seeing its commercial applications, began development of a computer program that incorporated the mathematics. He called the program ASSORT, which stands for Alpins Statistical System for Ophthalmic Refractive surgery Techniques. The ASSORT program is built on the Paradox database, a product of the Borland company. ASSORT allows the compilation of patient data and the statistical outcomes analysis not only of refractive surgical procedures, but the treatment of cataract and glaucoma, two common ophthalmic conditions.

The ASSORT program is designed to apply the Alpins astigmatism-analysis method to patient data entered by the surgeon or the surgeon's staff. For refractive surgery patients, the data consist of measurements that are routinely taken in association with refractive surgery by instruments and techniques commonly found in the offices of refractive surgeons — i.e., standard refraction, keratometry and corneal topography. The Alpins method can be seen as an additional level of the software. In fact, the method is employed within a number of specific components of the program, which the ASSORT company describes as modules. In short, the program applies conventional statistical analyses to the entered data, but can also subject the data to the Alpins method of analysis. Notably, while the Alpins method will forever retain the purity of the mathematical construct it is, the accuracy of its results are invariably tied to the accuracy of the measurements fed into it (topography, keratometry and refraction) and the tools used to perform the surgery. Highlights of the ASSORT program are shown in Table 1.

REFRACTIVE ERRORS IN THE POPULATION

Astigmatism can be divided into three main types: (1) naturally occurring regular astigmatism; (2) naturally occurring irregular astigmatism; and (3) irregular astigmatism associated with disease, trauma or prior ocular procedures. This article deals mainly with the first two.

The amount of myopia, hyperopia and astigmatism is expressed using a unit of measurement called a diopter (D), which describes the ability of a lens to bend (refract) light. By convention, myopia is reported in negative diopters, hyperopia in positive diopters. Corneal refractive surgical procedures exist that can effectively treat myopia from approximately -1 D to -16 D, according to a survey of 30 leading surgeons reported in the September 1997 issue of EyeWorld (upper limit of -16 D represents the average of all respondents). Corneal refractive surgical procedures for hyperopia, not widely used in the United States, appear to have a more limited range: from +1 D to +6 D, according to reports.

A zero refractive error, called emmetropia, is for the most part the desired state. Intraocular procedures beyond the scope of this article exist that can treat higher amounts of both myopia and hyperopia. People with refractive errors within 1 D of emmetropia (refractions between -1 D and +1 D) ordinarily are not considered candidates for refractive surgery.

People with refractions between -1 D and -16 D, and those with between +1 D and +6 D, therefore can be considered candidates for corneal refractive surgery, given

TABLE 1 — Highlights of the ASSORT program.

The ASSORT program:

- Is provided on diskettes or CD-ROM and operates on Windows 3.1, Windows 95 or Windows NT.
- Accepts patient data related to refractive surgery, as well as cataract surgery and the medical and surgical treatment of glaucoma.
- Employs the patented Alpins astigmatism-analysis methodology to plan and analyze the results of cataract and refractive surgery.
- Identifies and enables correction of errors in technique or laser operation that result in overcorrections, undercorrections, or off-axis astigmatic treatment in refractive surgery.
- Determines the customized "surgeon factor" in selecting intraocular lens power at cataract surgery, and helps plan the size and location of cataract incisions to minimize postoperative astigmatism.
- Produces statistical tables, charts and scatter plots for use in presentations and publications.

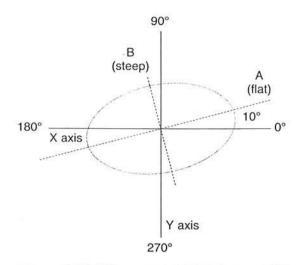


FIGURE 1. The base of a cornea with regular astigmatism is an ellipse. The long axis of the ellipse (A) at 10° is perpendicular to the short axis (B). In the otherwise normal astigmatic human eye, the long axis can be found anywhere from 1° to 180°. However, astigmatism with the long axis near 180°, called "with-therule" astigmatism, is considered "better" — i.e., people having with-the-rule astigmatism can see better and report less handicap than people with similar degrees of against-the-rule astigmatism.

that they qualify in other respects. A report by the consulting firm Arthur D. Little establishes the "vision-wear population" of the United States at 150 million citizens (EyeWorld, July 1997, page 30). From this, one might estimate that about half of the country's population falls into these two ranges, and thus perhaps half of the world's population as a whole.

The incidence of greater than 1 D of naturally occurring astigmatism in U.S. studies has been reported at 56%, 39.5%, and 32%. One study estimated that astigmatism greater than 0.5 D was present in 44.4% of the population, with 8.44% of the total having astigmatism of 1.5 D or greater. In one Australian PRK series, 70% of patients required an astigmatic correction as part of their treatment.

One might therefore conclude that as many as half of the patients who are candidates for corneal refractive surgery, who may constitute half of the world's population, have astigmatism sufficient to be of concern to the refractive surgeon.

THE ASTIGMATIC CORNEA

The ideal corneal dome, viewed from above, is a circle. The cornea with regular astigmatism is an ellipse. The astigmatic cornea complicates analysis because an ellipse has two primary meridians, one long and one short. The meridians are at right angles to one another and, superimposed on an X-Y axis, can assume various orientations in the human eye (Figure 1).

The slope of the astigmatic corneal dome on the short meridian is steeper than the slope of the corneal dome along the long meridian. One can think of the bowl of a dinner spoon, which also has short (steeper) and long (flatter) meridians. If we use the flat meridian as a reference, on an X-Y axis the flat meridian can be found, in the otherwise normal human eye, at any point between 1° and 180°.

When the flat meridian is at or near 180°, the astigmatism is said to be "with the rule." When the flat meridian is at or near 90°, the astigmatism is said to be "against the rule." With-the-rule astigmatism is more common and is said to provoke less disruptive visual effects than against-the-rule astigmatism of similar magnitude. 12,13,14

Because regular astigmatism is symmetrical, it can be defined by its magnitude (steepness) and its meridian (axis). The range between 1° and 180° is sufficient to describe regular astigmatism because it is symmetrical — that is, 3 D of astigmatism at the 10° axis, for example, describes the same situation as 3 D of astigmatism at the 190° axis, so by convention practitioners define regular astigmatism as occupying axes between 1° and 180°.

To correct myopic astigmatism and achieve a perfect dome, the procedure must flatten the cornea as a whole to correct the myopia, but flatten the steeper axis of astigmatism a little more (or, seen another way, relatively steepen the flatter axis). To correct hyperopic astigmatism, a procedure must steepen the cornea as a whole, but relatively steepen the flatter axis of astigmatism a little more.

One can now imagine that various amounts of spherical flattening or steepening can be accompanied by various amounts of astigmatic flattening or steepening, which can be accompanied by axis shifts to any point between 1° and 180°. The situation presents an extremely complicated analytical challenge. Traditional methods of reporting refractive surgical correction of astigmatic patients fall short mainly in their inability to convey axis shifts and handle aggregate data. The Alpins method, as will be described, determines a goal for

astigmatism correction, and a vector (steepening force) required to achieve that goal. From this, the method allows the calculation of the principal components by which an operation fails to achieve its goal, and other components that assist in the comparative analysis of the results of astigmatism surgery for individuals and groups of individuals.

Here is an additional confounding factor we will revisit: Astigmatism as measured by refraction (the well-known test where various lenses are placed in front of the eye while the doctor asks, "Which is better, this or this?") often differs from astigmatism as measured by keratometry and corneal topography, tests considered more objective and quantitative.

THE GOLF ANALOGY

Fundamental concepts of the Alpins method are demonstrated by a golf putt performed on a flat green with no outside forces such as wind (Figure 2).

A golf putt is a vector, possessing magnitude (length) and axis (direction). The intended putt (the path from the ball to the hole) corresponds to Alpins' target induced astigmatism (TIA), which is the astigmatic change (by magnitude and axis) the surgeon intends to induce in order to correct the patient's pre-existing astigmatism. The actual putt (the path the ball follows when hit) corresponds to Alpins' surgical induced astigmatism (SIA), which is the amount and axis of astigmatic change the surgeon actually induces. If the golfer misses the cup, the difference vector (DV) corresponds to the second putt — that is, a putt (by magnitude and axis) that would allow the golfer to hit the cup on the second attempt.

Alpins' "Correction Index" is determined by the ratio of the SIA to the TIA (what the surgery actually induces versus what the surgery was meant to induce), and is preferably 1 (it is greater than 1 if an overcorrection occurs and less than 1 if there is an undercorrection). It is calculated by dividing SIA (actual effect) by TIA (target effect).

Alpins' "Coefficient of Adjustment" is the inverse of the Correction Index and quantifies the modification needed to the initial surgery plan to have achieved a Correction Index of 1, the ideal correction. If the surgeon achieves an overcorrection, for example, the Coefficient of Adjustment might be .90, indicating that the surgeon should have

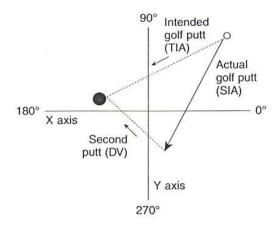


FIGURE 2. Vector mapping of a golf putt demonstrates fundamentals of the Alpins approach to astigmatism analysis.

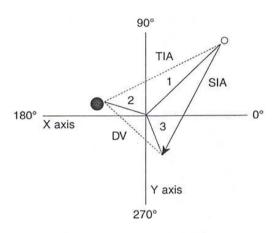


FIGURE 3. The target induced astigmatism (TIA), surgical induced astigmatism (SIA), and difference vector (DV) correspond to the golf putt analogy in Figure 2, and are calculated from (1) the patient's preoperative astigmatism; (2) the targeted astigmatism the surgeon plans to achieve; and (3) the actual achieved effect of the surgery in this double-angle vector diagram (DAVD).

selected a correction 90% of what was actually selected. The Coefficient of Adjustment can be used to refine future procedures.

The Alpins method also includes concepts such as the "Magnitude of Error" (intended correction minus actual correction) and "Angle of Error" (the angle described by the vectors of the intended correction versus the achieved correction). The Angle of Error is

positive if the achieved correction is on an axis counterclockwise to where it was intended, and negative if the achieved correction is clockwise to its intended axis.

Alpins' "Index of Success" is calculated by dividing the DV (how far you miss the target effect) by the TIA (the original target effect). The Index of Success is a relative measure of success. Going back to our golf analogy: If golfer John attempts a long putt and golfer Bob a shorter one, and each golfer's ball lands the same distance from the cup, John's putt can be considered more successful because he had the longer initial putt. The Index of Success constitutes a valuable new measure of the relative effectiveness of various surgical procedures, and even of the surgeons themselves.

Unlike other available approaches to astigmatism, the indices Alpins describes can be subjected to conventional forms of statistical analysis, generating averages, means, standard deviations, etc., for each individual component of surgery.

THE DOUBLE-ANGLE VECTOR DIAGRAM

Figure 3 is a double-angle vector diagram (DAVD) used by Alpins to allow calculations in a 360° sense and permit the use of rectangular coordinates. It is an analytical technique that simplifies interpretation of differences among preoperative, desired and achieved astigmatic values, and allows the calculation of the magnitude and direction of surgical vectors. The trigonometry is described in detail in References 1-4.

Line 1 defines a patient's preoperative astigmatism by magnitude (length of the line) and axis (an angle from the x axis representing twice the patient's measured axis of preoperative astigmatism). Line 2 defines the target astigmatism — that is, the magnitude and axis of the correction the surgeon is determined to achieve. Line 3 represents achieved astigmatism — that is, the magnitude and axis of the postoperative astigmatism. The dashed lines are the TIA, SIA and DV, as described above. The TIA, SIA and DV, and the description and calculation of their various relationships, comprise the essence of the Alpins method.

The method can be applied to irregular astigmatism. Although irregular astigmatism is commonly associated with prior ocular surgery, it is also naturally occurring ¹⁵ and prevalent. ⁴ Corneal topography, a technique that produces an image map based on the refractive power of the cornea at many

discrete points on its surface, reveals that irregular astigmatism comes in various configurations: the two steep hemimeridians, 180° apart in regular astigmatism, may be separated by less than 180° (a situation called *nonorthogonal*); and the two steep hemimeridians may be asymmetrically steep — that is, one may be significantly steeper than the other, as shown by a larger magnitude value.

Unlike other available astigmatismanalysis approaches, the Alpins method can independently analyze the two hemimeridians of irregular astigmatism. This capability becomes more important as refractive lasers gain the ability to treat discrete parts of the cornea.

TOPOGRAPHY VERSUS REFRACTION

Most refractive surgeons perform corneal topography, keratometry and refraction before and after refractive surgery. As mentioned, corneal topography provides an image map based on the refractive power of the cornea at thousands of separate points on the corneal surface. Keratometry does the same at only a few points at an optical zone away from the center of the cornea. Corneal topography and keratometry are considered "objective" measures of corneal refractive power. Since corneal topography has come to be more widely used, 16 keratometry will be disregarded for the purpose of this discussion.

Refractive measurements are based on the subjective response of the patient to various lenses placed in front of the patient's eyes. A refraction identifies the myopic or hyperopic correction, as well as the magnitude and axis of astigmatic correction needed for clear vision.

Most people with astigmatism demonstrate differences in magnitude and axis between topographic astigmatism (T) and refractive astigmatism (R).2 In other words, refractive power as measured at the surface of the cornea does not coincide with the refractive power that these people perceive as supplying good vision. The phenomenon may be related to the internal optics of the eye and the visual perception of the brain; clinicians sometimes refer to it as "lenticular astigmatism" (related to the lens of the eye). It presents a significant problem to current efforts to couple real-time corneal topography and laser treatment in an effort to "sphericize" the cornea. It also poses a common clinical quandary.

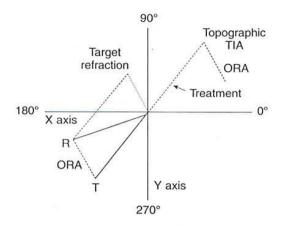


FIGURE 4A. This DAVD shows a patient having a discrepancy between refractive astigmatism (R) and corneal topographic astigmatism (T), whose targeted treatment is based 100% on T. The vector between R and T is the ocular residual astigmatism (ORA), the minimal amount of astigmatism that can remain in the optical system of this eye. The target refraction is the amount of refractive astigmatism remaining after treatment to eliminate topographic astigmatism — that is, the cornea would be spherical but the patient would have a remaining refractive astigmatism equal to the target refraction (and ORA) shown. The treatment is shown as a vector of equivalent magnitude to T, but 180° away from T on the DAVD (actual steepening treatment on the cornea would be 90° away).

Faced with a discrepancy between T and R, most refractive surgeons treat the patient's spectacle astigmatism in the belief that reshaping the cornea to the patient's refractive preference will produce better visual results. It is apparent, however, that treating R may do nothing to alleviate T, and in fact can result in increased corneal topographic astigmatism. Increasing the corneal astigmatism violates fundamental principles of corneal surgery and may lead to spherical aberration. The for these reasons, Alpins does not dismiss the discrepancy so lightly, and offers a system for its management.

Figures 4A, 4B and 4C demonstrate how the Alpins method can be used to approach a patient who has a discrepancy between T and R. Alpins describes the vector between T and R as ocular residual astigmatism (ORA), and sees ORA as an irreducible minimum astigmatism that can be achieved in any individual eye that has such a discrepancy. If a surgeon chooses to treat the topographic astigmatism, the refractive astigmatism remains, and vice versa.

The ORA is equivalent in magnitude to the refractive (Figure 4A) and topographic (Figure 4B) targets. The maximum correction of astigmatism is achieved when the remaining astigmatism is at its minimum

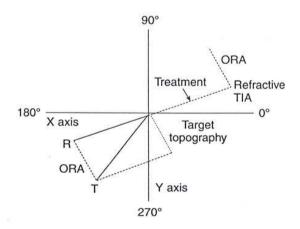


FIGURE 4B. DAVD shows same patient as in Figure 4A, but with correction targeted 100% on correcting refraction. Target topography is the corneal topographic astigmatism remaining after treatment to eliminate refractive astigmatism. The treatment vector has an equivalent magnitude to *B*, but is 180° away from *B* on the DAVD (actual steepening treatment on the cornea would be 90° away).

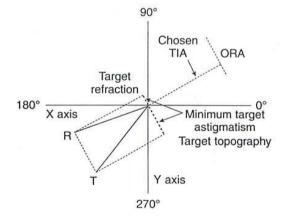


FIGURE 4C. An intermediate TIA can be chosen between the boundaries of the topographic TIA and refractive TIA. The relative proximity of the intersection to either the topographic or refractive endpoints (heavy dashed line) is determined by the emphasis of treatment required (total will equal 100%). Any TIA that achieves the minimum target astigmatism for the prevailing topographic and refractive parameters will terminate on the ORA line.

(the minimum target astigmatism) and is equal to the ORA. This remaining astigmatism will be refractive, topographic or a combination. The Alpins approach enables surgeons to calculate the ORA as well as the parameters (laser settings) for eliminating 100% of T, 100% of R, or any combination of T and R equaling 100%, while leaving the absolute minimal amount of astigmatism in the eye's optical system. The Alpins method also helps surgeons choose these treatment parameters through the use of Alpins "optimal treatment."

Alpins' optimal treatment is based on calculations that put more surgical emphasis on topographic astigmatism the more unfavorably the astigmatism falls on the cornea (toward an against-the-rule orientation). The surgical emphasis graph shown in Figure 5 assumes a linear relationship (the heavy V-shaped lines); however, a non-linear relationship may exist.

Alpins performed an as-yet-unpublished study where astigmatic patients were randomly assigned to optimal treatment or the more conventional approach of treating only the refractive astigmatism. Optimal treatment produced better visual results even though it did not aim to treat 100% of the refractive astigmatism. The reasons cited above — that is, the more physiologic orientation of with-the-rule astigmatism, the spherical aberration introduced by corneal astigmatism, etc. — probably underlie these

TABLE 2 — The Alpins method in a laser or corneal topography machine.

Incorporation of the Alpins method would allow a refractive laser or corneal topography machine to display the following information:

- Preoperative measurements sphere and astigmatism by topography and refraction.
- Target induced astigmatism (TIA).
- · Ocular residual astigmatism (ORA).
- Treatment emphasis laser settings based on the surgeon's choice of eliminating 100% refractive astigmatism, 100% topographic astigmatism, or any combination of the two equaling 100%.
- Optimal treatment suggested laser settings that allow greater treatment emphasis on refractive astigmatism the closer the remaining corneal astigmatism is to 90° (against-the-rule).
- Treatment vector graphs graphs of refraction, topography and TIA vectors, and how they change as treatment emphasis changes.
- Nomogram of adjustment coefficients applied to laser settings based on past experience; for example, to correct for hyperopic shift or consistent spherical over- or undercorrection by a particular laser.
- Designer cornea the Alpins methodology applied independently to both hemidivisions of the cornea in a case of irregular astigmatism, featuring a calculated vector value of irregularity called topographic disparity (TD) useful for topographic descriptions.

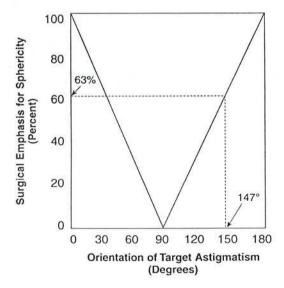


FIGURE 5. Alpins' "optimal treatment," which is the optimal point of termination of the TIA with the ORA line, is determined from the surgical emphasis graph shown here. In this example, the meridian of target topography is 147°. As it lies 57° from a with-the-rule orientation of 90°, the surgeon may decide to apportion 57 of 90, or 63% emphasis, to a topographybased goal of zero astigmatism (and the remainder, 37%, to refractive astigmatism). If the meridian of target topography is 90°, a physiologically more favorable orientation, 100% of the treatment will be devoted to the correction of refractive astigmatism. If the meridian of target topography is 180°, or against-therule, 100% of the treatment will be devoted to correcting the topographic astigmatism ("sphericizing" the cornea and eliminating the unfavorable against-therule astigmatism).

results. With optimal treatment, one appears to gain the advantage of less remaining corneal astigmatism without the penalty of increased refractive astigmatism.

LASERS AND CORNEAL TOPOGRAPHERS

Refractive lasers and corneal topography machines could include the Alpins method either as planning and analysis "add-ons" to their current software (Table 2), or as a basis for the development of custom applications. For lasers, it makes sense to consider use of the Alpins method in the programming of a laser's operating system. In this way, treatment parameters calculated by the Alpins method could directly guide the ablation pattern of a laser, as opposed to the operator having to manually enter settings into the laser after using the Alpins method to calculate the settings.

Corneal topography machines, while benefiting from the add-on functions of the Alpins method, could use it to simulate prior to surgery the corneal image map that might be expected after any proposed refractive surgical correction. This would be especially helpful and dramatic for those patients in whom treatment of refractive astigmatism alone would actually exacerbate existing corneal astigmatism.

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