Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

Description

Computer-assisted topography/photokeratoscopy provides a quantitative measure of corneal curvature. Measurement of corneal topography is being evaluated for the diagnosis and follow-up of corneal disorders such as keratoconus, difficult contact lens fits, corneal injury induced irregular astigmatism, and pre- and postoperative assessment of the cornea, most commonly after refractive surgery.

Background

Corneal topography was first used as a screening device for refractive surgeries such as PRK and LASIK. The indications for use in the management of corneal disease have become broader. Corneal topography describes measurements of the curvature of the cornea. An evaluation of corneal topography is necessary for the accurate diagnosis and follow-up of certain corneal disorders, such as keratoconus, difficult contact lens fits, and pre- and postoperative assessment of the cornea, most commonly after refractive surgery.

Various techniques and instruments are available to measure corneal topography:

- The keratometer (also referred to as an ophthalmometer), the most commonly used instrument, projects an illuminated image onto a central area in the cornea. By measuring the distance between a pair of reflected points in both of the cornea’s two principal meridians, the keratometer can estimate the radius of curvature of two meridians. The fact that the keratometer can only estimate the corneal curvature over a small percentage of its surface and that estimates are based on the frequently incorrect assumption that the cornea is spherical, are limitations of this technique.

- The keratoscope is older technology. It is an instrument that reflects a series of concentric circular rings off the anterior corneal surface. Visual inspection of the shape and spacing of the concentric rings provides a qualitative assessment of topography. A photokeratoscope is a keratoscope equipped with a camera that can provide a permanent record of the corneal topography.

- Computer-assisted photokeratoscopy is an alternative to keratometry or keratoscopy in measuring corneal curvature. This technique uses sophisticated image analysis programs to provide quantitative corneal topographic data. Early computer-based programs were combined
with keratoscopy to create graphic displays and high-resolution color-coded maps of the corneal surface. Newer technologies measure both curvature and shape, enabling quantitative assessment of corneal depth, elevation, and power.

In this policy the medical necessity of corneal topography in refractive surgery is not addressed.

**Regulatory Status**

A number of devices have received clearance for marketing through the U.S. Food and Drug Administration (FDA) 510(k) mechanism. The Orbscan (manufactured by Orbtek and distributed by Bausch and Lomb) received FDA clearance in 1999. The second generation Orbscan II is a hybrid system that uses both projective (slit scanning) and reflective (Placido) methods. The Pentacam (Oculus) is one of a number of rotating Scheimpflug imaging systems produced in Germany.

**Related Policies**

9.03.28 Corneal Collagen Cross-linking

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Computer-assisted corneal topography may be medically necessary in certain clinical settings:

2. Advanced keratoconus where a custom contact lens or scleral lens is being designed to avoid surgical intervention.
3. Corneal injury resulting in decreased vision where irregular astigmatism is suspected.
4. Decreased vision of unclear etiology where corneal ectasia is suspected but cannot be confirmed by keratometry.

Computer-assisted corneal topography is considered not medically necessary for routine evaluations to detect or monitor diseases of the cornea.

**Rationale**

**Literature Review**

_Detection and Monitoring Diseases of the Cornea_

Assessing corneal topography has been done for many years and is a part of the standard ophthalmologic examination of some patients. (1, 2) However, corneal topography can be evaluated and determined in multiple ways. Computer-assisted corneal topography has been used for early
Identification and quantitative documentation of the progression of keratoconic corneas, and evidence is sufficient to indicate that computer-assisted topographical mapping can detect and monitor disease.

Literature reviewed on PubMed through March 2013, identified two studies on quantitative evaluation of the corneal topography using computer-assisted corneal topography. Both studies reported utility for the diagnosis of corneal disorders and planning of treatment by evaluating the effects of corneal topographical abnormalities in diseased corneas more accurately and non-invasively. (3, 4)

Ginka and Zasshi showed optical characteristics of the anterior and posterior surfaces of the cornea in patients with keratoconus or transparent marginal corneal degeneration. (3) Their findings clarified the characteristics of serial alterations of high-order aberration in normal eyes, dry eye with tear deficiency and dry eye with tear evaporation. The effects of internal lubricating agents on soft contact lenses were also evaluated objectively. Corneal topographic analyses of the anterior and posterior surfaces in eyes with keratoconus or following keratoplasty were possible even when it was difficult for conventional corneal topographers to analyze accurately.

A study by Karnowski K, Kaluzny B J, Szkulmowski M, et al, reported quantitative analysis of corneas with pathological changes with three different instruments: The high-speed swept source (SS) optical coherence tomography (OCT), a Placido-based topographer, and a rotating Scheimpflug camera system. They demonstrated the applicability of the SS OCT for quantitative evaluation of the cornea. Based on their results they concluded SS OCT could be used for elevation-based topography and the evaluation of the corneal structure, to include the epithelium. Because a decrease in epithelial thickness masks the presence of an underlying cone on front surface topography, it was determined that SS OCT may be helpful in detecting keratoconus at an early stage.

**Contact Lens Fitting in Patients with Keratoconus**

A 2010 study was identified on computer-assisted corneal topography for the design of gas-permeable contact lens in 30 patients with keratoconus, who were recruited for the study in 2005-2006. (5) The report indicates that the subjects were consecutive, although patients whose topographical plots could not be used were excluded (number not described). The fit of the new lens was compared with the fit of the patient's habitual lens (randomized order on the same day). Clinical evaluation showed a good fit (no or minor modification needed) for more than 90% of the computer-designed lens. However, progression of keratoconus causes a bias favoring the most recently fitted lens, confounding the comparison between the new computer-designed lens and the patient’s habitual lens. This study has substantial limitations in both design and reporting.

**Corneal Astigmatism Measurements for Toric Intraocular Lens Implantation**

In 2012, Lee et al. reported a prospective comparative study of 6 methods of measuring corneal astigmatism for the purpose of toric intraocular lens implantation. (6) Astigmatism was evaluated in 257 eyes (141 patients) using manual keratometry, autokeratometry, partial coherence interferometry (IOLMaster®), ray-tracing aberrometry (iTrace™), scanning-slit topography (Orbscan), and Scheimpflug imaging (Pentacam). All measurements were masked to the results for the other
instruments. The study found no significant difference between the different instruments, indicating no advantage to computerized corneal topography compared to manual keratometry.

**Practice Guidelines and Position Statements**

The American Academy of Ophthalmology (AAO) Ophthalmic Technology Assessment titled Corneal Topography OTA (1999, Maintained 2008) the standard specific applications for corneal topography are as follows (7):

- “To screen patients for irregular astigmatism, corneal warpage, and keratoconus prior to refractive surgery; to evaluate the cornea after refractive and cataract surgery and to understand patients’ visual complaints; to direct management after penetrating keratoplasty; to plan astigmatic surgery; to fit contact lenses in patients with irregular astigmatism; to evaluate unexplained visual loss and to determine visual complications from corneal dystrophies, scars, pterygia, recurrent erosions, and chalazia.

Further research is needed to evaluate these and other clinical applications for the optimal use of corneal topography.”

In the 2010 AAO Preferred Practice Pattern publication from the AAO titled Comprehensive Adult Medical Eye Evaluation, lists the components of a comprehensive eye exam. (8) It goes on to state that, “Based on the patient’s history and findings, additional tests or evaluations might be indicated to evaluate further a particular structure or function. These are not routinely part of the comprehensive medical eye clinical evaluation. Specialized clinical evaluation may include the following”. A second list of specialized evaluations includes “Analysis of the corneal shape (e.g., keratometry and/or corneal topography”).

**Summary**

Analysis of a limited published research database indicates that there is clinical utility for corneal topography and that there are benefits in specific clinical situations:

2. Advanced keratoconus where a custom contact lens or scleral lens is being designed to avoid surgical intervention.
3. Corneal injury resulting in decreased vision where irregular astigmatism is suspected.
4. Decreased vision of unclear etiology where corneal ectasia is suspected but cannot be confirmed by keratometry.

Corneal topography is used as screening device in candidates for refractive surgery (a service not generally covered as a health insurance benefit).

For routine eye evaluations there is a lack of scientific evidence from appropriately constructed clinical trials that confirm improved health outcomes using computer assisted corneal topography. Therefore
this procedure is considered **not medically necessary** for routine evaluations to detect or monitor diseases of the cornea.

References


Policy History

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<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, reference 6 added; policy statement unchanged.</td>
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Corneal topography
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 19, 2015 and is effective July 15, 2015.

Signature on File

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