Optical Coherence Tomography (OCT) of the Anterior Eye Segment

Effective: August 1, 2017

Next Review: June 2018
Last Review: June 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Optical coherence tomography (OCT) is a noncontact diagnostic imaging tool for conditions of the anterior segment of the eye such as angle-closure glaucoma and pathological processes (e.g., infections).

MEDICAL POLICY CRITERIA

Anterior segment optical coherence tomography is considered investigational for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Anterior segment optical coherence tomography (OCT) is a non-contact scanning
computerized ophthalmic imaging method for obtaining real-time, high-resolution, cross-sectional imaging of the anterior eye chamber and the ciliary body, which includes the cornea, pupil, lens, and iris. In this technique, a reflected light beam interacts with a reference light beam. The coherent (positive) interference between the two beams (reflected and reference) is measured by an interferometer, allowing construction of an image of the ocular structures. This method allows cross-sectional imaging at a resolution of 6 to 25 microns. Ultrahigh resolution OCT can achieve a spatial resolution of 1.3 microns, allowing imaging and measurement of corneal layers. Since this is a non-invasive procedure it can be conducted by a technician and eliminates patient discomfort and inadvertent compression of the globe.

Currently, gonioscopy or ultrasound biomicroscopy are the methods most often used for clinically assessing the anterior chamber angle. Both of these techniques require placement of a probe under topical anesthesia. OCT is also being evaluated as a noninvasive alternative for the following uses:

- Rapid detection and diagnosis of eyes at risk for angle closure glaucoma
- Assessment of corneal thickness and opacity
- Assessment of lens thickness and calculation of intraocular lens power
- Evaluation of pre- and post-surgical anterior chamber anatomy
- Guidance tool in laser-assisted cataract surgery
- Imaging of phakic intraocular lenses and intracorneal ring segments
- Assessment of postoperative complications
- Detection of pathological processes such as dry eye syndrome, ocular surface conditions, tumors, uveitis, and infections

Also being investigated is the possibility that the 0.8-micron wavelength Stratus OCT may provide sufficient detail for routine clinical assessment of the anterior chamber angle in glaucoma patients. The width of the angle is one factor affecting the drainage of aqueous humor. A wide unobstructed iridocorneal angle allows sufficient drainage of aqueous humor, whereas a narrow angle may impede the drainage system and leave the patient susceptible to angle closure glaucoma.

REGULATORY STATUS

A number of systems have received 510(k) approval by the US Food and Drug Administration (FDA), including but not limited to the following:

- The Zeiss Visante OCT™ system (Carl Zeiss Meditec Inc.), is designed specifically for imaging of the anterior eye segment
- Predicate devices for the Zeiss Visante OCT were the Stratus OCT™ (Carl Zeiss Meditec Inc.)
- Orbscan II™ Keratometer (Orbtek, Inc./ Bausch & Lomb Surgical)
- The Slit-Lamp OCT (SL-OCT, Heidelberg Engineering) is intended as an aid for the quantitative analysis of structures and the diagnosis and assessment of structural changes in the anterior segment of the eye
- RTVue® (Optovue) is a Fourier-domain OCT system for posterior segment imaging and has a lens available to allow anterior segment imaging. FDA Product Code: OBO
- LenSx® (Alcon), Catalys (Optimedica), and VICTUS (Technolas Perfect Vision) laser systems include OCT to provide image guidance for laser cataract surgery.
- Ultrahigh resolution OCT devices include Bioptigen Envisu (Bioptigen) and the SOCT
Copernicus HR (Optopol Technologies).

The possibility of using posterior imaging systems with add-on lenses for the assessment of the anterior segment is also being investigated. Several posterior imaging systems received FDA 510(k) approval.

The AC Cornea OCT (Ophthalmic Technologies) from Canada is not cleared for marketing in the United States.

**EVIDENCE SUMMARY**

Validation of the clinical use of any diagnostic test focuses on three main principles:

- **Analytic validity** of the test, which refers to the technical accuracy of the test compared with a gold standard or compared with results taken with the same device on different occasions (test-retest). While there is no absolute gold standard for anterior segment imaging in the screening, diagnosis, or treatment of glaucoma, gonioscopy and ultrasonography are the techniques currently used for measurement of the anterior chamber angle.

- **Clinical validity**, which refers to the diagnostic performance of the test (i.e., sensitivity, specificity, and positive and negative predictive values), in detecting clinical disease. The sensitivity of a test is the ability to detect a disease when the condition is present (true positive). The specificity is the ability to detect the absence of a disease or outcome when the disease is not present (true negative).

- **Clinical utility** is a key aspect in evaluating clinical test performance. Clinical utility is defined as the ability of test results to guide decisions in the clinical setting related to treatment, management, or prevention, and improve health outcomes as a result of those decisions.

Numerous studies have used optical coherence tomography (OCT) to evaluate the anatomy of the anterior segment and report qualitative and quantitative imaging and detection capabilities; these studies provide evidence for the technical performance of OCT. The focus of this review is on evidence for the clinical validity and clinical utility of optical coherence tomography (OCT) compared with gonioscopy and/or ultrasound biomicroscopy.

**CLINICAL VALIDITY**

Assessment of the clinical validity of OCT depends on evidence that any additional eyes identified as having narrow angles by OCT compared with current alternatives (i.e., gonioscopy, ultrasonography, or slit-lamp biomicroscopy) are more likely to progress to primary angle closure glaucoma. Therefore, studies that did not include comparison of OCT with gonioscopy, ultrasonography, or slit-lamp biomicroscopy were excluded from this review.

**Optical Coherence Tomography Compared with Gonioscopy**

Several studies have compared OCT with gonioscopy for the detection of primary angle closure in patients with known glaucoma or eye conditions known to increase glaucoma risk such as angle closure, ocular hypertension, and cataracts.[1-8] These studies have suggested comparable or superior sensitivity but poor specificity for OCT compared with gonioscopy. For example, Nolan and colleagues assessed the ability of a prototype of the Visante OCT to detect primary angle closure in 203 Asian patients.[1] A closed angle was identified in 152 eyes with gonioscopy and 228 eyes with OCT; agreement was obtained between the two methods.
in 143 eyes. In reporting this low specificity for OCT, the authors noted that while gonioscopy is used as a reference standard, it is not considered to be a gold standard. The authors also suggested the following possible reasons for the increase in identification of closed angles with OCT:

- Lighting is known to affect angle closure, and the lighting conditions are different for the two methods (gonioscopy requires some light);
- Placement of the gonioscopy lens on the globe may cause distortion of the anterior segment;
- Landmarks are not the same with the two methods.

OCT as a screening method in the general population was studied by investigators at the Singapore National Eye Centre. The 2,047 subjects were 50 years of age or older with no history of any eye disorders or procedures that could influence the quality of angle imaging by OCT. In one article[5] the authors reported poor diagnostic performance compared with gonioscopy, with a reasonable sensitivity of 89% but a poor specificity of 68% while another article[9] reported the opposite findings, with fair sensitivity of 46% and high specificity of 87%. In addition, a notable limitation to use of OCT for angle closure glaucoma screening was the inability to locate the scleral spur, an essential landmark in angle measurement, in 25% of the study population.[10]

No studies were found that included follow-up data to determine whether eyes classified as closed angle by OCT but not by gonioscopy were at risk of developing primary angle closure glaucoma (true positive).

**OCT Compared with Ultrasound Biomicroscopy**

Few studies were found that compared the diagnostic performance of OCT with ultrasound biomicroscopy (UBM). These studies are limited to case series and retrospective reviews that do not permit conclusions due to methodological limitations, including but not limited to small sample size, and the heterogeneity of study subjects and reported outcomes. For example, Garcia and Rosen studied 80 eyes to determine the indications for OCT and UBM. While both techniques provided clear images of the cornea, conjunctive, iris, and anterior angle, UBM was reported to have provided superior visualization for cataracts, anterior tumors, ciliary bodies, haptics, and intraocular lenses, while OCT was superior at detecting a glaucoma tube and a metallic corneal foreign body.[11] Bianciotto et al.[12] and Garcia-Medina et al.[13] also found UBM superior to OCT for tumor visualization and for central corneal thickness in patients with primary open-angle glaucoma, respectively. The remaining studies compared various measurements of ocular structures and angles. The reported interpretations of the outcomes were conflicting. One preliminary study of an OCT prototype reported similar mean values, reproducibility, and sensitivity-specificity profiles for quantitative anterior chamber angle measurement.[14] However, two more recent studies found OCT and ultrasound measurements to be correlated but to have poor agreement.[15,16] The authors of both studies concluded that the two techniques cannot be used interchangeably and OCT cannot replace ultrasound for quantitative anterior chamber angle assessment. A 2016 prospective study compared the use of OCT to UBM following canaloplasty to detect changes in anterior chamber structures. 15 patients who underwent canaloplasty were included and the presence of Schlemm’s canal was identified in all patients using UBM and 93% of patients using OCT. The conclusion of the study was that OCT offers a high-resolution imaging of superficial structures whereas UBM is able to detect deeper structures.[17]
OCT Compared with Slit-Lamp Biomicroscopy

Only one study was found that included comparison with slitlamp biomicroscopy. Jiang et al. reported a cross-sectional, observational study of the visualization of aqueous tube shunts by high-resolution OCT, slitlamp biomicroscopy, and gonioscopy in 18 consecutive patients (23 eyes).[18] High resolution OCT demonstrated the shunt position and patency in all 23 eyes. Compared with slitlamp, 4 eyes had new findings identified by OCT. For all 16 eyes in which the tube entrance could be clearly visualized by OCT, growth of fibrous scar tissue could be seen between the tube and the corneal endothelium. This was not identified in the patient records (retrospectively analyzed) of the slitlamp examination. The results of this small study must be validated in additional studies.

CLINICAL UTILITY

Evaluation of the clinical utility of anterior segment OCT for any condition depends on demonstration of an improvement in clinical outcomes. Outcomes are considered to be improved when published evidence has demonstrated that additional true positive cases are identified, and these identified cases are successfully treated.

Angle-closure Glaucoma

The clinical utility of OCT for diagnosing glaucoma is closely related to its ability to accurately diagnose glaucoma since treatment is generally initiated upon confirmation of the diagnosis. Therefore, if OCT is more accurate in diagnosing glaucoma than alternatives, it can be considered to have clinical utility above that of the alternative tests. No studies were found that provided direct evidence on the clinical utility of OCT for diagnosing narrow angle glaucoma.

Other Uses

The current literature consists of small, nonrandomized trials on the use of OCT to clarify a variety of diagnoses in pediatric patients,[19], to predict primary failure following Descemet stripping automated endothelial keratoplasty (DSAEK)[20] and Descemet membrane endothelial keratoplasty (DMEK)[21,22], and to detect the inflammatory reaction in uveitis.[23]

Two-year results from the prospective PIONEER (Prospective Intraoperative and Perioperative Ophthalmic ImagIng with Optical CoherEncE TomogRaphy) study were published by Ehlers et al. in 2014.[24] Intraoperative scanning was performed with a microscope-mounted portable OCT system. In the first 24 months, 531 eyes were enrolled, including 275 AS cases. A surgeon feedback form, which was part of the study protocol, indicated that intraoperative OCT (iOCT) informed surgical decision making by visualizing fluid in the graft/host interface in 48% of lamellar keratoplasty cases. This group has also reported preliminary results with a prototype OCT system (RESCAN 700) that is integrated with a microscope and has a heads-up display, video display, and foot pedal control of the OCT scanner.[25] AS images in this initial phase included iOCT evaluation of corneal incisions, scleral closure, phacoemulsification groove depth, and intraocular lens position.

The criterion standard for the diagnosis of ocular surface tumors such as squamous neoplasia (OSSN) is histologic examination of tissue specimens from excisional biopsy.[26] In a 2014 review, Thomas et al. noted that noninvasive methods of diagnosing OSSN will be increasingly important as treatment moves toward medical therapy, although future studies will be needed to evaluate technical performance and diagnostic accuracy for this indication.[27]
In 2012, Cauduro et al. provided a retrospective review of 26 eyes of 19 pediatric patients (range, two months to 12 years) who presented with a variety of anterior segment pathologies. OCT was used to clarify the clinical diagnosis. No sedation was needed for this non-contact procedure, and only one eye of a two month-old patient required topical anesthesia. The impact of the procedure on patient care was not reported.

In 2011, Moutsouris et al. reported a prospective comparison of anterior segment OCT, Scheimpflug imaging, and slit-lamp biomicroscopy in 120 eyes of 110 patients after Descemet membrane endothelial keratoplasty (DMEK). All slit-lamp biomicroscopy and OCT examinations were performed by the same experienced technician and all images were evaluated by two masked ophthalmologists. From a total of 120 DMEK eyes, 78 showed a normal corneal clearance by all of the imaging techniques. The remaining 42 eyes showed persistent stromal edema within the first month, suggesting partial graft detachment. Biomicroscopy was able to determine the presence or absence of a graft detachment in 35 eyes. Scheimpflug imaging did not give additional information over biomicroscopy. In 15 eyes, only OCT was able to discriminate between a “flat” graft detachment and delayed corneal clearance. Thus, out of the 42 eyes, OCT had an added diagnostic value in 36% of cases. This led to performance of a secondary DSAEK for total graft detachment, while partial graft detachments were rebubbled or observed for corneal clearing. There were no false negatives (graft detachment unrecognized) or false positives (an attached graft recognized as a graft detachment).

This evidence is insufficient to permit conclusions regarding the effectiveness and utility of OCT for evaluating other conditions. Larger, randomized, trials of longer duration and follow up are needed to determine whether any detection of additional conditions by OCT results in improved health outcomes.

PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines from U.S. professional societies were found that recommend the use of anterior segment optical coherence tomography.

SUMMARY

There is not enough research to show that anterior segment optical coherence tomography improves health outcomes or guide treatment decisions. No clinical guidelines based on research recommend anterior segment optical coherence tomography. Therefore, anterior segment optical coherence tomography is considered investigational.

REFERENCES


15. Mansouri, K, Sommerhalder, J, Shaarawy, T. Prospective comparison of ultrasound biomicroscopy and anterior segment optical coherence tomography for evaluation of anterior chamber dimensions in European eyes with primary angle closure. *Eye (Lond)*. 2010 Feb;24(2):233-9. PMID: 19444291


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**CODES**

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