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Optical Coherence Tomography (OCT) of the Anterior Eye Segment

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Next Review: June 2024
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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 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

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

- Anterion (Heidelberg Engineering GmbH)
- Pentacam AXL Wave (Oculus Optikgerate GmbH)
- Xephilio OCT-A1 (Cannon)
- 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

Systematic Reviews

Desmond (2021) performed a systematic review (SR) with meta-analysis of anterior segment optical coherence tomography (AS-OCT) compared to gonioscopy in detecting eyes with angle closure.[1] A literature search was performed in April 2020 resulting in the inclusion of 23

studies (N=5663). Only studies that provided enough data to determine the sensitivity and specificity of AS-OCT and assessed the ability to detect an eye with angle closure were included. Eighteen studies were conducted in Asia, three in the United States, and two in the United Kingdom. There was substantial variation in the assessed parameters and methodology among the studies including the use of different optical coherence tomography devices, gonioscopy diagnostic criteria, and AS-OCT positivity threshold. The sensitivity of AS-OCT ranged from 46% to 100% (median, 87%) with a specificity ranging from 55.3% to 100% (median, 84%). Of the four studies with the best diagnostic accuracy for AS-OCT, all used a case-control study design with a high risk of bias. Overall, the authors concluded that AS-OCT demonstrates "good sensitivity for detecting angle closure"; however, it is not yet "able to replace gonioscopy" and further studies are required to better determine its utility.

Jindal (2020) published the results of a Cochrane SR with meta-analysis of non-contact tests including AS-OCT for the detection of an occludable angle.[2] A total of 47 studies (N=23,440) were included, of which 27 studies (N=15,580) evaluated AS-OCT compared to the reference standard of gonioscopy. AS-OCT (subjective opinion of occludability) was evaluated across 13 studies (9,242 eyes) and found to have a sensitivity of 0.85 (95% CI 0.76, 0.91) and specificity 0.71 (95% CI 0.62, 0.78) (moderate-certainty). Comparisons of sensitivity and specificity between index tests and limbal anterior chamber depth (LACD) (≤ 25%) as the reference found AS-OCT had a statistically significant lower specificity.

Nonrandomized Studies

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.[3-10] These studies have suggested comparable or superior sensitivity but poor specificity for OCT compared with gonioscopy. For example, Nolan (2007) assessed the ability of a prototype of the Visante OCT to detect primary angle closure in 203 Asian patients.[3] 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[7] the authors reported poor diagnostic performance compared with gonioscopy, with a reasonable sensitivity of 89% but a poor specificity of 68% while another article[11] 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.[12]

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 (2008) 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.[13] Bianciotto (2011)[14] and Garcia-Medina (2013)[15] also found UBM superior to OCT for tumor visualization and for central corneal thickness in patients with primary open-angle glaucoma, respectively. Vizvári (2018) reported that OCT was superior to UBM in the visualization of conjunctival melanocytic nevi structures, but that UBM performed better than OCT in highly elevated and pigmented nevi.[16]

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.[17] However, two more recent studies found OCT and ultrasound measurements to be correlated but to have poor agreement.[18, 19] 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. Fifteen 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.[20]

OCT Compared with Slit-Lamp Biomicroscopy

Only one study was found that included comparison with slitlamp biomicroscopy. Jiang (2012) 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).[21] High resolution OCT demonstrated the shunt position and patency in all 23 eyes. Compared with slit-lamp, four 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 mainly of small, nonrandomized trials on the use of OCT for a variety of indications, including plaque observation,[22] preparation for eye surgery,[23] clarification of diagnoses in pediatric patients,[24] prediction of primary failure following endothelial keratoplasty,[25-27] and detection of inflammatory reaction in uveitis.[28]

Two-year results from the prospective PIONEER (Prospective Intraoperative and Perioperative Ophthalmic ImagiNg with Optical CoherEncE TomogRaphy) study were published by Ehlers (2014).[29] Intraoperative scanning was performed with a microscope-mounted portable OCT system. In the first 24 months, 531 eyes were enrolled, including 275 anterior segment (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.[30] 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.[31] In a review, Thomas (2014) 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.[32]

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

AMERICAN ACADEMY OF OPHTHALMOLOGY

In 2020, the American Academy of Ophthalmology published a preferred practice pattern on primary angle closure disease.[33] The Academy stated that gonioscopy of both eyes should be performed on all patients in whom primary angle closure disease is suspected to evaluate the angle anatomy, including the presence of iridotrabecular contact and/or peripheral anterior synechiae, and plateau iris configuration and that anterior segment (AS) imaging may be a useful adjunct to gonioscopy and is particularly helpful when the ability to perform gonioscopy is precluded by corneal disease or poor patient cooperation. Although anterior segment optical coherence tomography can be very useful, it has limitations in evaluating the angle. Neither the posterior aspect of the iris nor the ciliary body are well imaged with anterior segment

optical coherence tomography, reducing the utility of this approach in evaluating plateau iris configuration or ciliary body abnormalities. Isolated peripheral anterior synechiae or small tufts of neovascularization may be missed if not in the plane imaged by 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

1. Desmond T, Tran V, Maharaj M, et al. Diagnostic accuracy of AS-OCT vs gonioscopy for detecting angle closure: a systematic review and meta-analysis. *Graefe's archive for clinical and experimental ophthalmology = Albrecht von Graefes Archiv fur klinische und experimentelle Ophthalmologie.* 2022;260(1):1-23. PMID: 34223989
2. Jindal A, Ctori I, Virgili G, et al. Non-contact tests for identifying people at risk of primary angle closure glaucoma. *Cochrane Database Syst Rev.* 2020;5:CD012947. PMID: 32468576
3. Nolan WP, See JL, Chew PT, et al. Detection of primary angle closure using anterior segment optical coherence tomography in Asian eyes. *Ophthalmology.* 2007;114(1):33-9. PMID: 17070597
4. Kalev-Landoy M, Day AC, Cordeiro MF, et al. Optical coherence tomography in anterior segment imaging. *Acta Ophthalmol Scand.* 2007;85(4):427-30. PMID: 17355288
5. Pekmezci M, Porco TC, Lin SC. Anterior segment optical coherence tomography as a screening tool for the assessment of the anterior segment angle. *Ophthalmic Surg Lasers Imaging.* 2009;40(4):389-98. PMID: 19634744
6. Sakata LM, Wong TT, Wong HT, et al. Comparison of Visante and slit-lamp anterior segment optical coherence tomography in imaging the anterior chamber angle. *Eye (Lond).* 2010;24(4):578-87. PMID: 19521435
7. Lavanya R, Foster PJ, Sakata LM, et al. Screening for narrow angles in the singapore population: evaluation of new noncontact screening methods. *Ophthalmology.* 2008;115(10):1720-7, 27 e1-2. PMID: 18486215
8. Wong HT, Lim MC, Sakata LM, et al. High-definition optical coherence tomography imaging of the iridocorneal angle of the eye. *Arch Ophthalmol.* 2009;127(3):256-60. PMID: 19273787
9. Hu CX, Mantravadi A, Zangalli C, et al. Comparing Gonioscopy With Visante and Cirrus Optical Coherence Tomography for Anterior Chamber Angle Assessment in Glaucoma Patients. *Journal of glaucoma.* 2014. PMID: 24844543
10. Tay EL, Yong VK, Lim BA, et al. Agreement of angle closure assessments between gonioscopy, anterior segment optical coherence tomography and spectral domain optical coherence tomography. *Int J Ophthalmol.* 2015;8:342-6. PMID: 25938053
11. Campbell P, Redmond T, Agarwal R, et al. Repeatability and comparison of clinical techniques for anterior chamber angle assessment. *Ophthalmic Physiol Opt.* 2015;35(2):170-8. PMID: 25761580

12. Narayanaswamy A, Sakata LM, He MG, et al. Diagnostic performance of anterior chamber angle measurements for detecting eyes with narrow angles: an anterior segment OCT study. *Arch Ophthalmol.* 2010;128:1321-7. PMID: 20938002
13. Garcia JP, Jr., Rosen RB. Anterior segment imaging: optical coherence tomography versus ultrasound biomicroscopy. *Ophthalmic Surg Lasers Imaging.* 2008;39(6):476-84. PMID: 19065978
14. Bianciotto C, Shields CL, Guzman JM, et al. Assessment of anterior segment tumors with ultrasound biomicroscopy versus anterior segment optical coherence tomography in 200 cases. *Ophthalmology.* 2011;118:1297-302. PMID: 21377736
15. Garcia-Medina JJ, Garcia-Medina M, Garcia-Maturana C, et al. Comparative study of central corneal thickness using Fourier-domain optical coherence tomography versus ultrasound pachymetry in primary open-angle glaucoma. *Cornea.* 2013;32(1):9-13. PMID: 22495027
16. Vizvari E, Skribek A, Polgar N, et al. Conjunctival melanocytic naevus: Diagnostic value of anterior segment optical coherence tomography and ultrasound biomicroscopy. *PloS one.* 2018;13(2):e0192908. PMID: 29444155
17. Radhakrishnan S, Goldsmith J, Huang D, et al. Comparison of optical coherence tomography and ultrasound biomicroscopy for detection of narrow anterior chamber angles. *Arch Ophthalmol.* 2005;123:1053-9. PMID: 16087837
18. 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;24(2):233-9. PMID: 19444291
19. Pinero DP, Plaza AB, Alio JL. Anterior segment biometry with 2 imaging technologies: very-high-frequency ultrasound scanning versus optical coherence tomography. *J Cataract Refract Surg.* 2008;34:95-102. PMID: 18165088
20. Fuest M, Kuerten D, Koch E, et al. Evaluation of early anatomical changes following canaloplasty with anterior segment spectral-domain optical coherence tomography and ultrasound biomicroscopy. *Acta ophthalmologica.* 2016;94(5):e287-92. PMID: 26648049
21. Jiang C, Li Y, Huang D, et al. Study of anterior chamber aqueous tube shunt by fourier-domain optical coherence tomography. *Journal of ophthalmology.* 2012;2012:189580. PMID: 22778909
22. Takezawa Y, Suzuki T, Shiraishi A. Observation of Retrocorneal Plaques in Patients With Infectious Keratitis Using Anterior Segment Optical Coherence Tomography. *Cornea.* 2017;36(10):1237-42. PMID: 28704321
23. Venincasa MJ, Osigian CJ, Cavuoto KM, et al. Combination of anterior segment optical coherence tomography modalities to improve accuracy of rectus muscle insertion location. *J Aapos.* 2017;21(3):243-46. PMID:
24. Cauduro RS, Ferraz Cdo A, Morales MS, et al. Application of anterior segment optical coherence tomography in pediatric ophthalmology. *Journal of ophthalmology.* 2012;2012:313120. PMID: 22934156
25. Shih CY, Ritterband DC, Palmiero PM, et al. The use of postoperative slit-lamp optical coherence tomography to predict primary failure in descemet stripping automated endothelial keratoplasty. *Am J Ophthalmol.* 2009;147(5):796-800, 00 e1. PMID: 19232563
26. Moutsouris K, Dapena I, Ham L, et al. Optical coherence tomography, Scheimpflug imaging, and slit-lamp biomicroscopy in the early detection of graft detachment after Descemet membrane endothelial keratoplasty. *Cornea.* 2011;30(12):1369-75. PMID: 21993458

27. Steven P, Le Blanc C, Velten K, et al. Optimizing descemet membrane endothelial keratoplasty using intraoperative optical coherence tomography. *JAMA Ophthalmol.* 2013;131:1135-42. PMID: 23827946
28. Agarwal A, Ashokkumar D, Jacob S, et al. High-speed optical coherence tomography for imaging anterior chamber inflammatory reaction in uveitis: clinical correlation and grading. *Am J Ophthalmol.* 2009;147(3):413-16 e3. PMID: 19054493
29. Ehlers JP, Dupps WJ, Kaiser PK, et al. The Prospective Intraoperative and Perioperative Ophthalmic ImagiNg with Optical CoherEncE TomogRaphy (PIONEER) Study: 2-year results. *Am J Ophthalmol.* 2014;158(5):999-1007. PMID: 25077834
30. Ehlers JP, Kaiser PK, Srivastava SK. Intraoperative optical coherence tomography using the RESCAN 700: preliminary results from the DISCOVER study. *The British journal of ophthalmology.* 2014;98:1329-32. PMID: 24782469
31. Medina CA, Plesec T, Singh AD. Optical coherence tomography imaging of ocular and periocular tumours. *The British journal of ophthalmology.* 2014;98 Suppl 2:ii40-6. PMID: 24599420
32. Thomas BJ, Galor A, Nanji AA, et al. Ultra high-resolution anterior segment optical coherence tomography in the diagnosis and management of ocular surface squamous neoplasia. *The ocular surface.* 2014;12(1):46-58. PMID: 24439046
33. American Academy of Opthalmology Primary Angle Closure Preferred Practice Pattern [cited 6/28/2023]. 'Available from:' https://www.aao.org/preferred-practice-pattern/primary-angle-closure-disease-ppp.

CODES

Codes	Number	Description
CPT	92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral
HCPCS	None	

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