



PROCEDURE GUIDE: VITREOUS OPACITIES

IMPORTANT: The following Procedure Guide pertains to the use of Reflex Technology™ (Ellex, Australia) for Posterior Membranectomy i.e. severing vitreous opacity from the collagen matrix to move the opacity from the visual axis using laser energy. The Procedure Guide is provided for information purposes only. Ellex recommends that physicians new to the technique undertake education and training prior to commencing the procedure.

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Treatment options for vitreous strands/opacities include:

1. Do nothing. Reassure: “try to live with it”.
2. Perform Laser Treatment for the Vitreous Opacity.
3. Perform Floater-Only Vitrectomy (Note: rarely offered due to high risk profile).

A. EQUIPMENT REQUIREMENTS:

Nd:YAG laser optimized for use in both the posterior segment and in the anterior segment.

Not all YAG lasers are suitable for use in the vitreous cavity. It is important that the laser is able to visualize and fire in both on-axis and off-axis positions (Figure 1) in order to optimize treatment.

“Coaxial” or “on-axis” illumination permits visualization from the lens to the retina and is essential in order to visualize vitreous strands or opacities located in the middle and posterior vitreous. With on-axis illumination the illuminating light source is positioned on the same vertical optical axis as the oculars and the laser energy beam.

For example, if light enters the eye at an angle that differs markedly from the visual axis of the operating physician, it will only illuminate the anterior portion of his/her field of view. Consequently, vitreous strands or opacities positioned in the posterior vitreous will be difficult to visualize. In contrast, a raised illumination tower can overcome these issues.

(Refer to section “Treatment Pearls”, “Utilizing On-Axis and Off-Axis Illumination” for further reading.)

A lens specially designed for treating in the vitreous.

The choice of lens will depend on the position of the vitreous strand or opacity to be treated. It is important to note that the commonly available Goldmann (3-mirror) lens is not suitable for treating vitreous strands or opacities.

(Refer to Appendix 1 for detail regarding available lenses.)

B. PATIENT SELECTION:

Patients presenting with persistent complaints regarding the negative effect of vitreous strands or opacities on their daily visual functioning and/or quality of vision. Common complaints include moving shadows or spots in the patient's vision due to vitreal condensations, fibers, strands, and/or clouds. Clinically significant vitreous opacities that reside outside the central visual axis but intermittently through the center.

It is important to take note of the following:

- a. Patient should not have active retinal pathology or active inflammation.
- b. Patient symptoms should be present for at least three months and be stable in behavior. For new onset of symptoms defer any considerations of treatment and recheck the retina and symptoms after a minimum of 3 months.
- c. Patient should not complain of peripheral flashes of light. (Peripheral flashes of light would suggest an incomplete posterior vitreous detachment, or untreated tear and hence pose a risk of further retinal tear or detachment.)
- d. Older patients (>45) with sudden-onset symptoms will most likely have experienced a posterior vitreous detachment (PVD). Many of these patients present with a Weiss-ring type opacity.
- e. Young patients may complain of vitreous strands or opacities, but they are generally not considered to be ideal candidates for treatment: they often have microscopic opacities located within 1-2 mm of the retina or lens.
- f. Patients with high myopia are not considered to be ideal candidates for treatment: they may be at higher risk of retinal tear or posterior detachment.
- g. Patients should exhibit realistic expectations.
- h. Importantly, vitreous opacities must be easily visualized by the physician – irrespective of how obvious they are to the patient, and must correlate with the patient's complaints
- i. Patients should not under go simultaneous laser procedures ie. YAG capsulotomy plus laser vitreolysis.

In addition to the aforementioned considerations, it is recommended to take note of the following for your first patients:

- a. Limit initial treatment to pseudophakic patients to avoid any risk of causing a traumatic cataract. Only after you are sufficiently accustomed to the technique and the visualization system i.e. on-axis and off-axis illumination for spatial context (Figure 1), you may choose to perform treatment in phakic patients.
- b. Treat the well-defined, fibrous, Weiss-ring type opacity caused by a PVD. These fibrous strands or opacities often behave as if “tethered” by the sheet of vitreous cortex of which they are a part. Because they are fibrous, they absorb the laser energy well and can be vaporized more efficiently. In addition, they are usually located safely away from the crystalline lens and the retina. They are also easily visualized and correlate with patient's symptoms. The end point of complete vaporization is more easily achieved and visualized with these types of visual strands or opacities.
- c. It is recommended to not treat the diffuse, cloud-like syneresis type of opacities, which are more difficult to visualize and to treat effectively; they often take multiple sessions and a larger number of shots per session.
- d. Patients with multi-focal IOL lenses are candidates for treatment, but may be more difficult to treat due to the refocusing of the aiming beams by the IOL.
- e. Although the risk of an acute elevation of IOP is rare, it is wise to avoid treating patients undergoing treatment for glaucoma or those with elevated IOP or advanced glaucoma.
- f. Avoid performing too many shots in pseudophakic post-YAG capsulotomy patients with anterior opacities located close to the posterior capsule, who can present a higher risk for developing an IOP-spike post treatment.

C. BEFORE GETTING STARTED:

It is very important to manage patient expectations and to set realistic treatment outcomes:

- The goal of treatment is to achieve a “functional improvement”. That is, to allow the patient to return to their “normal, day-to-day” activities with reduced hindrance from their vitreous strands or opacities.
- The patient should not expect to achieve a 100% clear vitreous (as can sometimes be the outcome with vitrectomy).
- Some vitreous strands or opacities can be easily and efficiently treated; some vitreous strands or opacities cannot be treated.
- More than one treatment session may be necessary to achieve a satisfactory result. The duration of each treatment session will also vary, depending on the density, location, size, and number of opacities.
- Practice visualization with the specific vitreolysis lenses (Appendix 1) to train your eye to correlate the vitreous opacity image from the slit lamp view during the consult with the view using the laser. Try this on a few patients before starting your first treatment case.

D. PRE-TREATMENT:

1. Discuss anticipated treatment outcomes and risks with the patient.
2. Ensure patient completes a signed consent form.
3. Undertake a full (dilated) eye examination with attention to the retina and periphery. Aggressive dilation with both tropicamide and phenylephrine is recommended; every millimeter of dilation is beneficial. The recommended minimum size of pupil is 6 mm, but it is recommended to dilate to as large of a size as possible.
4. Perform OCT and/or retinal photography to establish base line documentation of the patient’s current condition and to rule out retinal pathology. If retinal pathology is noted, the patient should not be treated with laser vitreolysis.
5. Apply topical anesthetic with 2-3 instillations a few minutes apart.

E. TREATMENT:

The treatment spot size and pulse width are fixed at approximately 8 microns and 4 ns respectively. The only parameters that will significantly vary are the energy of the pulse and the number of pulses fired in one shot i.e. single, double, or triple.

The offset of the treatment laser beam in respect to the aiming beam can also be set anterior through to posterior (refer to “Treatment Pearls”).

F. TREATMENT STEPS:

1. Prior to commencing treatment, explain to the patient that he/she will hear the sound of a shutter opening with each laser shot, and that this is a normal part of the laser system's operation. Further, the sound may differ depending on whether the laser is fired in the "on-axis" or the "off-axis" position (Figure 1).
2. Anesthetize the eye and place the contact lens on the patient's cornea using a coupling agent of your choice. It is recommended considering an anesthetic drop in the non-operative eye also, to help decrease the blink reflex.
3. Place the patient's chin and head on the chinrest and headrest respectively. Ensure they are comfortable before commencing the procedure. It is often recommended to have an assistant hold the back of the patient's head to remind him/her to keep it forward against the headrest.
4. Adjust height of table to maximize view and provide additional user comfort. Adjust oculars and set pupillary distance, as well as focusing, prior to starting.

G. POST-TREATMENT:

1. Generally, post-treatment medications are not necessary.
2. In very rare cases, inflammation of the anterior segment can occur. In the unlikely event that this does occur, treat with non-steroidal anti-inflammatories (ketorolac), or a steroid (prednisolone acetate) for a few days. Patients may see small, dark specks in their lower field of vision in the initial few hours following the procedure. These are small micro-gas bubbles at the roof of the globe. They dissolve quickly and disappear within a day or so.
3. There are no restrictions on patient activities.
4. Patients cannot adequately assess the treatment results until the pupils have constricted back to normal.
5. It is recommended that the patient be followed up the next day to 1 week for visual acuity and IOP testing. A dilated exam should be performed within 4-6 weeks to assess outcome as well as retina evaluation.
6. Follow-up treatments can be undertaken on consecutive days, although it may be advantageous to wait a few days for the eye's condition to stabilize. Patient symptomatic improvement can vary depending on the type of clinically significant vitreous opacities. It may take up to a month to truly assess if another session is necessary based on their symptoms.

H. SIDE EFFECTS AND COMPLICATIONS:

Reported side effects and complications are rare. Possible side effects may include, but not be limited to:

- Accidental retina hit or shock wave contusion of retina or sub-retinal tissues. In the periphery, this could be asymptomatic. Avoid treating over the macula in the posterior third of the vitreous.
- Traumatic cataract. Patients may experience a rapid onset of symptoms if there is a breach of the posterior capsule. It may make cataract surgery more urgent and more complicated if the posterior capsule is compromised.
- Increased intraocular pressure. Rare, but more likely in older patients with compromised trabecular meshwork drainage combined with treatment of dense, vitreous strands/opacities in the anterior vitreous. Also pay close attention to those patients with anterior vitreous/ opacity behind a post YAG capsulotomy pseudophakic lens. IOP increases have been reported in this sub set of patients. In these patients, we recommend limiting the number of shots to 300-400 shots per session.
- In phakic patients possible damage to natural lens or posterior capsule resulting in a cataract. In pseudophakic patients a possible pitting of an IOL. Both are avoidable by observing the recommended safety zone; ensure adequate distance between the vitreous opacity and natural lens/IOL before undertaking treatment.
- Uveitis. Although possible, this has not been noted with laser vitreolysis. Treat with anti-inflammatory medications as needed.
- Retinal detachment. There is an increased risk of retinal detachment related to laser vitreolysis. This should be disclosed to the patient prior to the procedure and listed on the consent form accordingly.
- Patients should be warned if they suddenly develop symptoms from a new vitreous opacity, flashing lights with eye movement or a visual field defect they should report immediately to their physician.

TREATMENT PEARLS

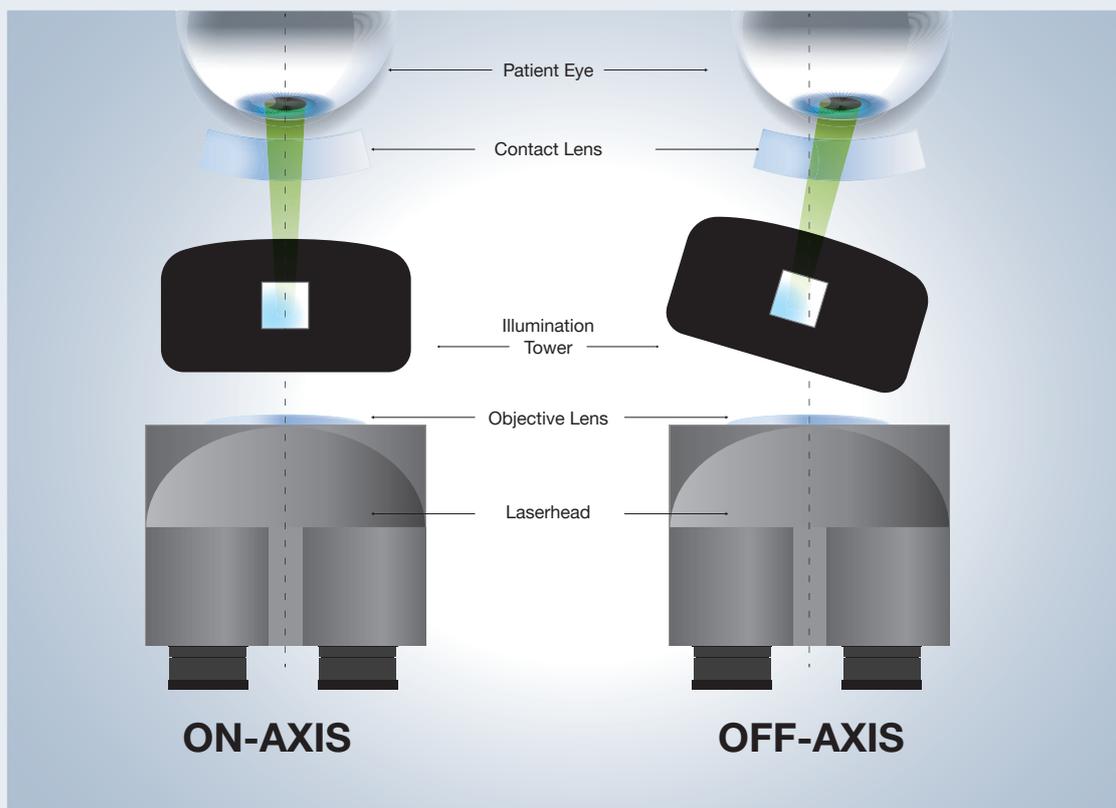
1. Utilizing On-Axis (Coaxial) and Off-Axis Illumination

1. It is important to obtain a clear view of the vitreous strand or opacity as well as the surrounding structures with 100% confidence in three-dimensional space. Accidental shots to the lens or the retina may occur if the physician does not appreciate spatial context.
2. At the start of the procedure, use on-axis illumination to view the retina, before coming anteriorly to use off-axis illumination i.e. slit lamp in the oblique position (Figure 1). This will enable you to appreciate the anterior vitreous and posterior lens capsule and will provide the necessary spatial context in order to identify the vitreous opacity(s) and surrounding structures – and to determine if it is safe to proceed with treatment.
3. **On-axis mode, vitreous opacity(s) located in the middle and posterior vitreous:** if the vitreous opacity is in focus and the retina is not in focus, you will have sufficient “space” to fire the laser. If the retina and the opacity are both in focus, or both close to being in focus at

the same time, then it is recommended not to fire the laser.

4. **Off-axis mode, vitreous opacity located in the anterior vitreous:** it is strongly recommended to use off-axis illumination to help visualize the posterior lens capsule in determining if there is sufficient distance between the opacity and the lens. Further, off-axis illumination can provide additional contrast of the opacity by removing the red glow and thus causing it to appear white in front of a black background.
5. Toggle back and forth between off-axis and on-axis modes to achieve the optimal visualization of the vitreous strand or opacity and surrounding structures throughout the procedure. You can also titrate the amount of “glow” by settling the laser in between “on-“ and “off-“ axis.
6. Throughout the procedure recheck the position of the vitreous strand or opacity in relation to the retina and lens to ensure constant feedback r.e. spatial context.

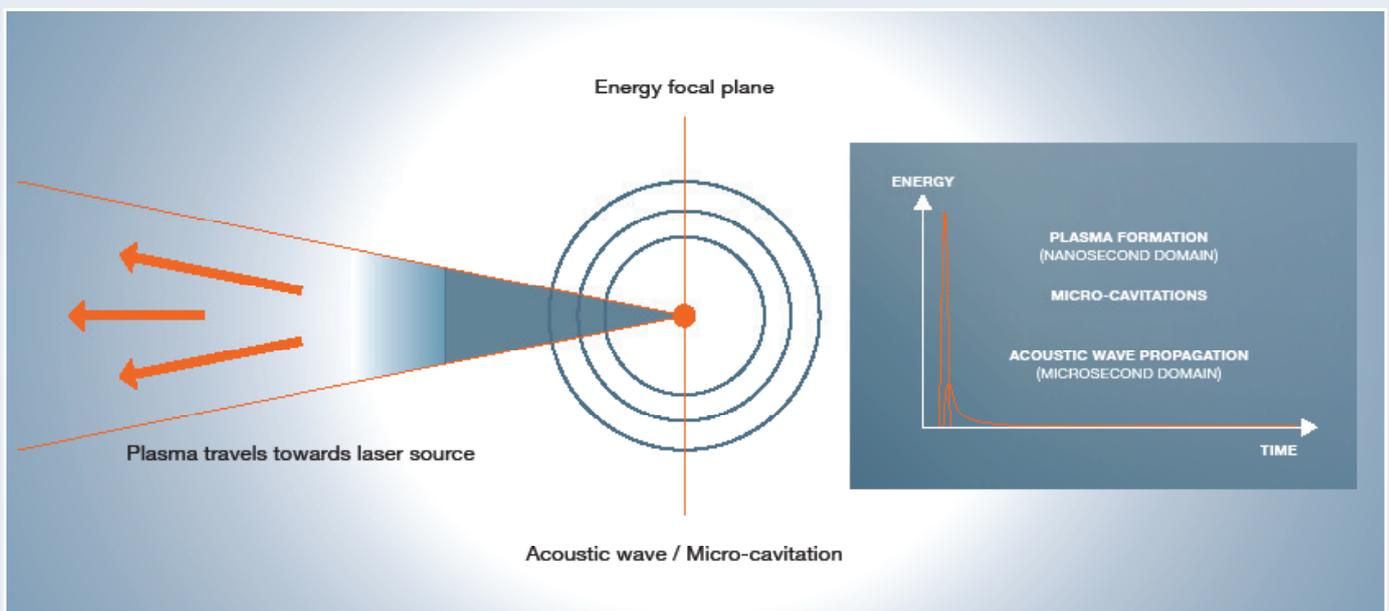
Figure 1



TREATMENT PEARLS (continued)

2. Energy to Use; Number of Pulses; Number of Shots

1. Because the laser energy used requires passage through more optical media than during capsulotomy treatment, more energy will typically be required to perform the procedure as compared to standard YAG laser procedures. Regardless, always start with a lower level of energy and titrate upwards until there is adequate optical breakdown and vaporization of the vitreous collagen.
2. Commence treatment with a single pulse per shot. Set energy at the minimum level required to create the optical breakdown in the vitreous cavity (typically 3-4 mJ). Most treatments can be performed at approx. 5 mJ per shot. It is not uncommon, however, for surgeons to use higher energy levels of approx. 8-10 mJ. It is important to note that you should titrate the power up, rather than starting at the higher energy levels.
3. More energy will be required if the vitreous opacity is located deep in the posterior vitreous. For example, the same may be vaporized at 4 mJ in the anterior vitreous, at 5 mJ in the mid-vitreous and 6 mJ in the posterior vitreous.
4. The number of shots required will vary depending on the type of vitreous opacity. For physicians new to the technique, it is recommended to limit the number of shots per treatment session to a maximum of 300-400 shots, single pulse (Note: refer to pulse counter on laser remote display).
5. There is no limit to the maximum energy or number of shots, but most physicians limit each procedure to a maximum of 1000 shots. This is largely due to the fact that, after a significant number of shots, gas bubbles can build up and make visualization difficult.
6. It is possible to enhance the vaporization effect by using burst mode (2 or 3 pulses per shot) but it is important to note that the total energy delivered per shot will be higher than in single burst mode.
7. It is important to note that there is a non-linear relationship between the increased dispersion of energy in the eye and energy setting on the laser. In other words, increasing the energy from 5 mJ to 10 mJ does not double the amount of dispersed energy; instead, it represents an approx. 40% increase. This non-linear relationship is what allows for increased energy settings to be used in the vitreous.



TREATMENT PEARLS (continued)

3. Vision and Aiming Beams

1. It is important to maintain an adequate distance of more than 3-4mm from the lens and more than 3-4 mm from the retina at all times. This is referred to as the “safe zone”. (Note: When starting out, consider observing a wider margin of safety and treat only in the central third of the vitreous and always avoid the direction of the macula.)
2. If the aiming beam is not clearly in focus, avoid firing. If in doubt, focus on the vitreous strand/opacity and pull back the joystick slightly: this will enable you to clearly visualize the two aiming beams before refocusing them to one spot.
3. The vitreous strand/opacity may be seen to move or become mobile during vitreolysis due to the shock wave introduced with each shot fired. When firing directly at a mobile opacity, always wait for it to settle into position before continuing with treatment. This avoids unnecessary energy delivery into the eye.

4. Direction of Treatment

1. In the presence of multiple vitreous opacities, commence treatment anteriorly and proceed to the posterior. This will enable you to first remove those vitreous opacities that may impede your vision of the posterior structures. Likewise, try and treat from the top down as gas bubbles may impede vision of higher vitreous opacities if the lower ones are treated first. Although, it is important to treat the vitreous opacities that are easiest to see first.
2. If the opacity is over the macula and the retina is also in focus, do not fire. If you are not sure of the distance between the vitreous opacity and retina, move the eye up and down to try and move the vitreous opacity to a different position.
3. Moving the eye up and down, or left and right, can also be a very useful tool to help move hard to reach opacities into a more easily treatable position. If the opacity is too far in the periphery of the contact lens, the laser energy will not achieve the necessary therapeutic effect.

5. Anterior and Posterior Offset

1. It is possible to position the optical breakdown in front of (anterior offset) or behind (posterior offset) the structure to be vaporized. When the energy is increased, the optical breakdown and resulting plasma move closer to the operating physician. This offset capability permits greater accuracy in positioning the optical breakdown.
2. When working deeper in the posterior vitreous, chromatic aberration will focus the treatment beam further behind the aiming beam. Use the anterior offset to position the optical breakdown in the same plane as the aiming beam focus. This is particularly critical when working close to the retina where extreme care must be taken, particularly when working at higher energies.

Note: Some physicians prefer to manually defocus the system with the joystick rather than via the Anterior/Posterior Offset control and keep the offset at zero accordingly. If using Anterior/Posterior Offset control, the recommended offset is 100-200 microns.

Please refer to the Operator Manual for the proper use of the Ellex Ultra Q Reflex™ and Tango Reflex™ lasers.

APPENDIX 1: RECOMMENDED LENSES

LENSES AVAILABLE FROM VOLK

	Product Code	Image Mag.	Contact OD	Lens Height
Singh MidVitreous Lens	# VSMV	1.16X	15.5mm	24mm

- Designed specifically for the visualization of vitreous strands or opacities in the near and central mid-vitreous during vitreous opacity removal.
- With a 1.16x image magnification, and .86x laser spot, the lens offers a high-degree of resolution and focusing ability.
- A 30-mm ring diameter and short 24-mm lens body allow for easier slit lamp handling, with slightly more imaging depth range than a taller lens.
- The direct contact lens requires the use of viscous coupling fluid during laser treatment.

LENSES AVAILABLE FROM HAAG STREIT

	Product Code	Image Mag.	Contact OD	Lens Height
CGVL Vitrectomy Contact Lens	CGVL	1.4X	16mm	13mm

- Designed for photodisruptive YAG laser procedures in the posterior vitreous.
- While structures in the anterior to mid-vitreous may be treated with the CGPL or without any contact lens, safety and efficacy of photodisruption are increased in the deeper vitreous with the CGVL contact glass.
- The magnifying effect and the possibility to visualize the retina allow for improved aiming accuracy.

	Product Code	Image Mag.	Contact OD	Lens Height
CGPL Capsulotomy Contact lens	CGPL	1.5X	15.5mm	13mm

- Designed for the dissection of opacified posterior lens capsules and membranes in the pupillary and retropupillary space.
- Enhances the safety and efficacy of YAG laser procedures; lowers the minimal laser energy that is needed for disruption of the capsule and thereby significantly reduces risk to the IOL.
- The magnifying effect allows for improved aiming accuracy. Beam handling is facilitated by the large diameter.

LENSES AVAILABLE FROM OCULAR INSTRUMENTS

	Product Code	Image Mag.	Contact OD	Lens Height
Ocular Karickhoff 21mm Vitreous Lens	OJKY-21	1.39X	15.5mm	16mm

- Designed for laser treatment of vitreous opacities.
- Good coning of laser beam.
- Small flange prevents lens being squeezed off eye by patient; small exterior diameter enables lens to be inserted into an eye with small lid fissures.
- Lightweight, plastic helps to retain lens on eye; serrated edge for easy grip.
- Lens allows surgeon to view retina clearly in most patients during procedure to check for hemorrhage.

	Product Code	Image Mag.	Contact OD	Lens Height
Ocular Karickhoff Off-Axis Vitreous Lens	OJKPY-25	1.36X	15.5mm	16mm
	OJKPY-30	1.25X	15.5mm	16mm

- Designed for treating off-axis vitreous opacities
- Rotating the lens allows surgeons to look for opacities without the patient moving their eye.
- OJKPY-30 improves the treatment of vitreous opacities deeper in the eye than the OJKPY-25.
- Small flange prevents lens being squeezed off eye by patient; black mark in lens indicates the direction of peripheral view.
- Anterior lens surface design reduces image astigmatism and image degradation when tilting the lens.

	Product Code	Image Mag.	Contact OD	Lens Height
Ocular Peyman Wide Field YAG Laser Lens	OPY-12.5	1.40X	15.5mm	16.5mm
	OPY-18	1.41X	15.5mm	16.5mm
	OPY-25	1.36X	16mm	14.7mm

- The Peyman Wide Field YAG Laser Lens series features three lenses:
 1. The 12.5mm anterior radius lens is for treating the region of the anterior chamber to the posterior capsule.
 2. The 18.0mm anterior radius lens is for mid vitreous.
 3. The 25.0mm anterior radius lens is for deep vitreous.
- These lenses provide high image quality and beam control when treating structures from the posterior capsule to deep vitreous by either mode-locked or Q-switched YAG lasers.

APPENDIX 2: FURTHER READING

PEER-REVIEWED LITERATURE

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BOOKS/CHAPTER

Laser Treatment of Eye Floaters by John R. Karickhoff, MD
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