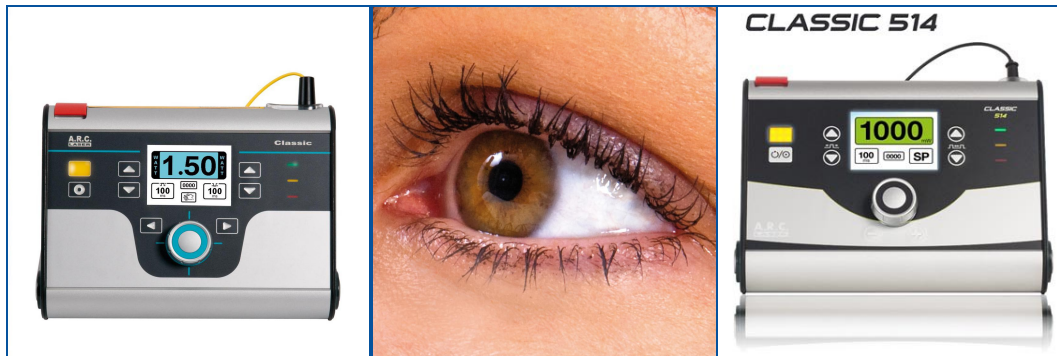


Ophthalmology

Application manual for the Classic laser



532 / 514 nm wavelength



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WARNING

For your own safety follow all
guidelines for handling the
equipment and follow the safety
instructions in this manual.

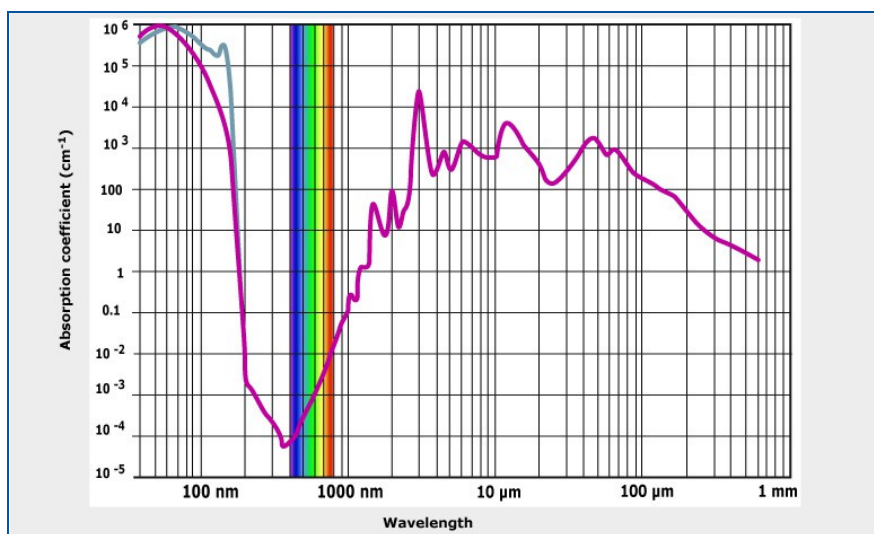
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1) Laser safety

Laser radiation emitted by the Classic laser can cause severe damage to the patient as well as to the user and third persons accompanying the laser use. The Classic laser is classified in the laser class IV. This means that the radiation can cause damage when it is directly applied to any tissue and also if the radiation is scattered or reflected.

The Classic laser radiation is intense and efficient to coagulate and evaporate tissue. The most serious injuries occur, when laser radiation is unintended exposed to sensitive parts of the eye, e.g. the macula. Even low laser power is able to damage the macula of the eye, which is not reversible. This may cause permanent blindness.



Water absorption

Laser radiation in the wavelength range between 400 and 1400 nm is most dangerous to retinal structures. The cornea as well as the anterior chamber, the lens and the vitreous body of the eye contain mainly water. Between 400 and 1400 nm wavelength water has very low absorption. Therefore the laser radiation is transmitted very well and nearly the full power reaches the retina, where it is absorbed by the blood and the retinal pigment epithelium.

The Classic laser emits visible laser radiation and it is absolutely necessary to wear eye safety goggles when using the Classic laser system. For lasers combined with slit lamps or indirect ophthalmoscopes (LIO), such systems are normally equipped with eye protection filters, which allows the surgeon to resign eye goggle use. Also in case of endo laser systems, the microscope in the theater can be equipped with eye protection filters and then the surgeon can work without eye goggles.

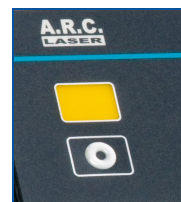
With its intensity (e. g. focused beam), the Classic laser radiation can also do harm to skin or other tissue. The radiation can light up inflammable material.



Safety instructions

To avoid any injuries it is important to follow the laser safety instructions:

1. Any user of the Classic laser system has to be trained by A.R.C. Laser authorized personal or by someone trained by A.R.C. Laser authorized personal.
2. The room / the area, where the laser system is used has to be signed with the laser warning symbols in a way that everyone can easily see that there is a laser area, which should not be entered without the adequate protection while the laser is in use.
3. Do not use the system whenever you are not sure that every component works in the dedicated way. Keep an eye on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur. You may test this by using a light paper and holding an endo probe (e.g. HS01001 / LL13009s), in a distance of about 5 cm (you have to put the laser on Ready mode / laser safety goggles!). The same should be visible when using the Classic in combination with a slit lamp or indirect ophthalmoscope (LIO); the aiming beam spot should be clearly visible and round.
4. Whenever the laser is on Ready mode (yellow Ready-LED on) every person within the area where radiation from the laser can occur (laser treatment area / laser room) has to wear laser safety goggles which is suitable to protect the eyes from Classic laser radiation.
5. The laser has to be used only for the defined application; never irradiate any other material / tissue beside the intended use.
6. Special care should be taken to avoid irradiating reflecting materials. Reflected laser radiation can cause the same harm as direct application.
7. Switch off the Ready mode of the laser when the laser is not in use; e. g. during operation breaks or at the end of the surgery.



Ready-LED

2) Basics of laser application

The intended effect of the laser application is based on the interaction of the radiation with the tissue components. The laser radiation is absorbed, scattered or reflected by the tissue. Air has only little influence on the Classic radiation and therefore the interaction between air and the Classic radiation can be neglected. Reflection plays a major role with metal, glass and other reflecting surfaces.

Whenever the Classic radiation is applied to tissue the reflection is not dominant. Nevertheless it is not zero! When the radiation is scattered in the tissue, it does not influence the absorption. Absorption is mainly responsible for the efficiency of the laser radiation. Absorption means that the Classic laser radiation is converted mainly into heat, which causes the desired effects (coagulation / vaporisation).

With low energy density (big laser spot or low power) the heat which is achieved in the tissue can cause heating of the tissue. The smaller the spot size is, or the higher the power is set, the warmer it gets. There is a limit, when the tissue does no longer tolerate the heating, tissue proteins denature, coagulation occurs. The next limit is achieved when tissue water (intra- and extracellular water) suddenly evaporates ($> 300^{\circ}\text{C}$). Tissue is fragmented and destroyed. Cutting / evaporation is achieved.

Temperature effect	
Temperature	Effect
$> 40^{\circ}\text{C}$	enzyme induction, membrane disaggregation, edema
$45^{\circ} - 65^{\circ}\text{C}$	tissue damage, reversible or irreversible, dependent on the irradiation time
$> 65^{\circ}\text{C}$	coagulation
$> 100^{\circ}\text{C}$	dehydration
$> 150^{\circ}\text{C}$	carbonisation
$> 300^{\circ}\text{C}$	vaporisation, ablation (removal of tissue)
some 1000°C	ionisation, immediate burn (shock wave formation)

Tissue cutting always needs high energy densities (high power or small spot size). At the cutting edges, respectively beside the evaporation zones the tissue is always affected by the heat (coagulation). The positive effect and advantage of the Classic laser use in iridectomy e.g. is, that this can stop bleeding.

In continuous mode the laser permanently emits radiation. In pulse mode the tissue can cool down between each laser pulse and therefore the side effects of the heating can be reduced.

The micropulse-mode causes no denaturation of nerve cells in case of adequate energy settings. This mode can selectively have an effect in the RPE layer and underlying Bruch-Membrane and choroid. It works "sub-threshold" without coagulating the retina visible.

3) Application

Indications / Contraindications

Retina by endocoagulation	
indications	contraindications
<ul style="list-style-type: none"> · securing pre-existing retinal breaks · iatrogenically produced retinal breaks · retinotomies · panretinal photocoagulation · coagulation of bleeding retinal surface neovascularization · diabetic retinopathy 	<ul style="list-style-type: none"> · existing decreased transparency of the optics (e.g. cataract, cloudy vitreous) · direct application to the macula

Retinal coagulation via slit lamp or indirect ophthalmoscope	
indications	contraindications
<ul style="list-style-type: none"> · securing pre-existing retinal breaks · retinotomies · panretinal photocoagulation · coagulation of bleeding retinal surface neovascularization 	<ul style="list-style-type: none"> · existing decreased transparency of the optics (e.g. cataract, cloudy vitreous)

Retinal micropuls application via slit lamp	
indications	contraindications
<ul style="list-style-type: none"> · panretinal laser application · alternative application to photocoagulation of retinopathia centralis serosa and diabetic retinopathy and also diabetic macula edema 	<ul style="list-style-type: none"> · existing decreased transparency of the optics (e.g. cataract, cloudy vitreous)

Glaucoma (ALT / trabeculoplasty)	
indications	contraindications
<ul style="list-style-type: none"> · treatment of non responders to medication and pre-surgical failures · non compliance patients with medically not satisfied IOP control · medication allergic patients · treatment of non responders to medication and bad surgical prognosis 	<ul style="list-style-type: none"> · narrow chamber angle with bad visibility · low pressure glaucoma disease

The Classic can be used "stand alone" for retinal treatments with endo probes, as well as in combination with different slit lamp versions (PCL 5 ZL or PCL5 SHL) and in combination with a Q-Las laser (old model).



Technique

For the use of the Classic laser, the laser has either to be equipped with a laser fiber (endo use), it has to be coupled to the LIO by connecting the laser fiber to the LIO or the laser is already coupled to a slit lamp. The endo fibers have a fiber plug on one side, which has to be inserted into the fiber coupler of the Classic laser. In case of LIO use the laser fiber, which connects the Classic to the optical system of the slit lamp has to be removed from the slit lamp and has to be connected to the LIO.



The laser versions vary, there are versions with only one port or only fixed fiber for slit lamp adaptation (e.g. Classic 514nm).

Pre-treatment tests

The Classic laser does an automatic internal testing on the power output before the device can be used. Keep an eye on the system components. Especially take a look on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur.

Treatments

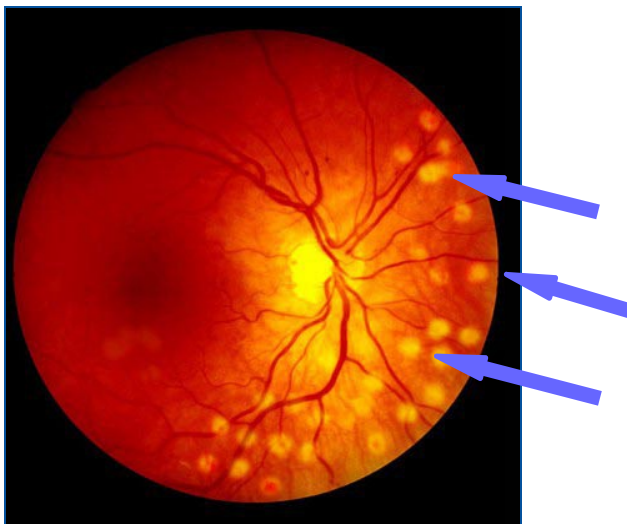
Therapy advice

This chapter gives detailed information on the laser applications. Of course, this chapter cannot compensate for intensive studies of appropriate literature, personal experiences and critical consideration of facts. Nevertheless, this should help every "beginner" as well as each one who is not working on a regular base with the laser. The following indications are average values – no guidelines! They are based on the fundamental experiences of several medical doctors, who are using our lasers every day. Despite all caution from our side, each medical doctor needs to set their parameters individually, observing the indication and the patient to be treated. Changing the parameters may possibly require a change of other settings. Neither author nor manufacturer is liable for treatment failures.

Retinal Photocoagulation

For treating retinal diseases, the laser can be used in the theater as an endo laser or via slit lamp in the doctors office or via LIO.

Photocoagulation can be performed to fix the retina, e.g. in case of detachments, or to destroy unwanted tissue components, e.g. in case of neovascularisation. Photocoagulation is achieved when the tissue alters and changes its structure permanently. A visible indication on the retina is a grey or white tissue appearance right where the radiation of the laser has been applied.



Retinal coagulation with Classic laser

Endo coagulation treatments maybe carried out using trocars or not.

Treatment parameter:

The effect of the laser radiation on the tissue has to be recognized and observed! Never treat in case of disturbed or hindered visibility to the area treated!! The tissue alteration (coagulation with light grey or white tissue surface appearance) arises from heating. About 65-70°C are needed to achieve the desired tissue effect. Such warming and heating can be achieved with different parameters:

Shorter pulse time → less heating (longer pulse time/ continuous radiation results in more heating)

Bigger spot size → less heating (smaller spot size → more heating)

With the Classic laser and slit lamp use at a power level of 200 mW and with a spot size of 200 micrometer, a laser pulse of 200 ms should normally result in good coagulation.

The following facts may change the required power, pulse length or spot size!:

- target chromophore: blood, retinal pigment epithelium (more or less pigment), the darker the structure is the more chromophore it has and the less power is normally needed.
- the use of a lens/ contact lens can improve the visibility and reduce the power needed for the treatment through optical magnification/ better focusing.

Different companies (e.g. Ocular Instruments) offer contact lenses for retina coagulation.



The retina lens comparison chart (Ocular Instruments) shows different lenses and their performance and suitability.

RETINA LENS COMPARISON CHART									
Lens	PRP 165	Wide Field	PDT 1.6X	ProRetina 120 PB ⁽³⁾	Reichel-Mainster 1X	Reichel-Mainster 2X	Focal/Grid (Standard) ⁽⁴⁾	High Mag	
Static Field of View	165°	118°	120°	120°	102°	117°	90°	75°	
Dynamic Field of View	180°	127°	133°	136°	133°	142°	121°	88°	
Image Magnification	.51x	.68x	.63x	.50x	.95x	.50x	.96x	1.25x	
Laser Spot Magnification Factor ⁽²⁾	1.96x	1.50x	1.60x	2.00x	1.05x	2.00x	1.05x	.80x	
Retinal Disorder ⁽¹⁾	Procedure	+++ Optimal ++ Very useful + Useful - Not useful							
NVD, NVE, NVI	PRP - Clear Media	+++	++	++	++	++	+	-	
	PRP - Vitreous Hemorrhage	++	+++	+++	+++	++	+	-	
Macular Edema	Focal + Grid	+	+	+	+	+++	+++	+++	++
CNV in ARMD	Focal	-	-	-	-	+++	+++	+++	+++
or OHS	PDT, TTT	+	+++	+++	+	+++	+++	+++	+++
Retinal Holes	Peripheral	+++	+	+	+	+	+	-	-
Ocular's Laserlight® high efficiency, broad band, anti-reflective coating provides optimal image contrast, minimizes bothersome reflections and maximizes visible and diode laser transmission.		⁽¹⁾ NVD, NVE, NVI: neovascularization - disc, retina elsewhere, iris; CNV: choroidal neovascularization; ARMD: age-related macular degeneration; OHS: ocular histoplasmosis syndrome							
		⁽²⁾ Multiply the laser photocoagulator spot size setting by this magnification factor to calculate the retinal spot size produced by each lens.							
		⁽³⁾ The ProRetina's tubular design facilitates examination and treatment of patients with prominent brows. It also allows easy lens manipulation for examination and treatment of the retinal periphery.							
		⁽⁴⁾ Focal/Grid is the new name for the Mainster Standard.							

For panretinal photocoagulation (example⁽¹⁾), the following remarks can be given:

Laser system via slit lamp, LIO or hand piece (endo use):

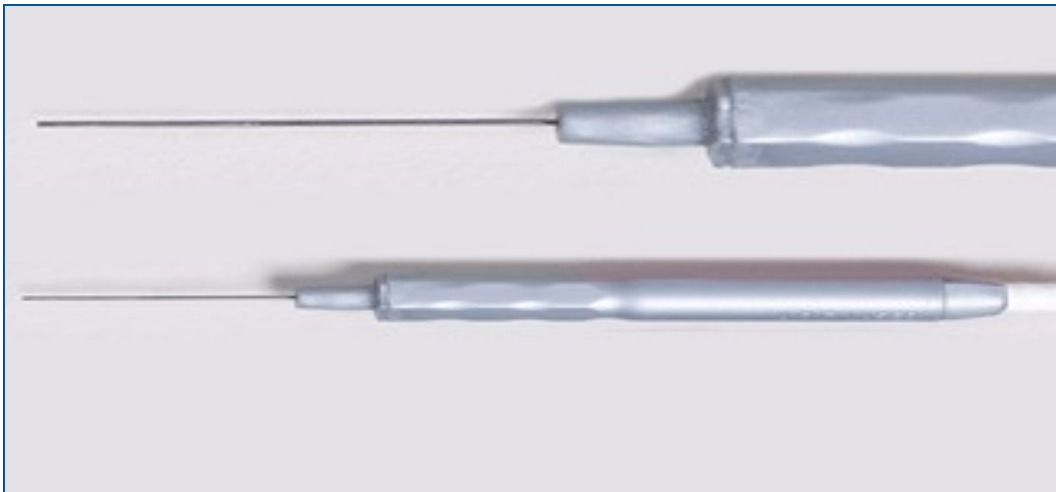
- Spot size: 200 – 500 µm
- Pulse length: 0.05 – 0.2 sec
- Medium to heavy white spots separated by 1-2 burn widths.
- 1500-2000 spots in total applied in several sessions (some weeks in between the treatments)

(1) S. Boyd, A. Agarwal, Laser Surgery of the Eye, The Art of Lasers in Ophthalmology, Highlights of Ophthalmology International, ISBN 9962-613-34-5, page 257, 2005

Endocoagulation

Endo coagulation should never be done in contact to the retina. Keep a small

distance to the retinal surface, however, at too big distances the effect drops or is no longer achievable, because scattering occurs and the spot size of the laser beam widens because of the divergence of the laser delivery!



Endo probe hand pieces

hand piece	
single use	reusable
LL13009s (19 G, straight)	on request
LL13011s (20 G, straight)	
LL13006s (23 G, straight)	
LL13010s (25 G, straight)	
LL13014s (20 G, curved 30°)	
LL13015s (25 G, curved 30°)	

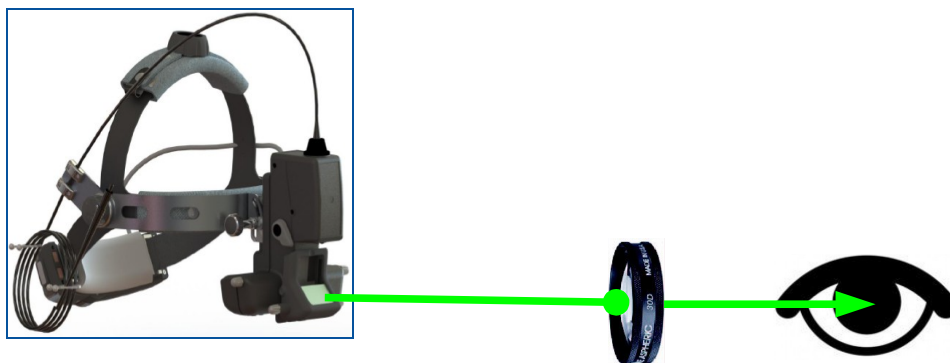
Retina coagulation by indirect ophthalmoscope

For photocoagulation of the retina with indirect ophthalmoscope a lens has to be used between LIO and patients eye to focus the radiation onto the retina. The power of the lens should be between 20 and 40 dpt. User parameters below are based on the use of a 28 dpt. Lens*.

Power: 200 – 350 mW, Pulse length: 200 ms, frequency: 2,5Hz*



*Haidong Shan, Yinqing Ni, Kang Xue, Jia Yu, Xin Huang^{1,2}; Type 1 Retinopathy of Prematurity and Its Laser Treatment of Large Preterm Infants in East China; PLOS ONE | DOI:10.1371/journal.pone.0144313 December 16, 2015



Schematic LIO laser use

Micropulse treatment of the retina

A micropulse treatment of the retina is a relatively new treatment option. The aim of using micropulses is not to coagulate the target tissue completely and destroy the nerve cells, but to achieve a limited effect in the RPE layer and underlying Bruch-Membrane and choroid. Activation of cell function only is a future goal. Therefore the laser spot is visually not recognizable any more and the energy has to be set precisely. To do this, a peripheral area of the retina, not, or negligible relevant for the visual acuity of the patient can be used to adjust the right energy setting. There are various suggestions published in literature* to adjust the power. Energy (power at fixed pulse length) titration is performed mostly by applying energy up to the level where coagulation is visible (in normal pulse mode) and then changing to micro pulse mode and e.g. multiplication of the power by 2-3**. Another advise is to set 15% duty cycle and triple the power***. To set the right energy dose, the pulse length (e.g. between 100 to 200ms) has to be kept constant. After setting the right energy dose (completed power titration process) the treatment can be performed at the same spot size.

*Paula Scholz. Lebriz Altay. Sascha Fauser, A Review of Subthreshold Micropulse Laser for Treatment of Macular Disorders, *Adv Ther* (2017) 34:1528–1555

**Fawwaz Al Mamoori, IQ 532 Micropulse green laser treatment for refractory chronic central serous retinopathy, *Eye Care Vis*, 2017 doi: 10.15761/ECV.1000102 Volume 1(1): 1-3

***http://retinatoday.com/pdfs/0317RT_Cover_Luo.pdf, (Online archive of Retina Today); Caesar K Luo, Melissa D Neuwelt, Exploring two photocoagulation modes for DME, continuous-wave and subthreshold capabilities in a single laser, *Retina Today*, March 2017, 62 - 64

Glaucoma treatment

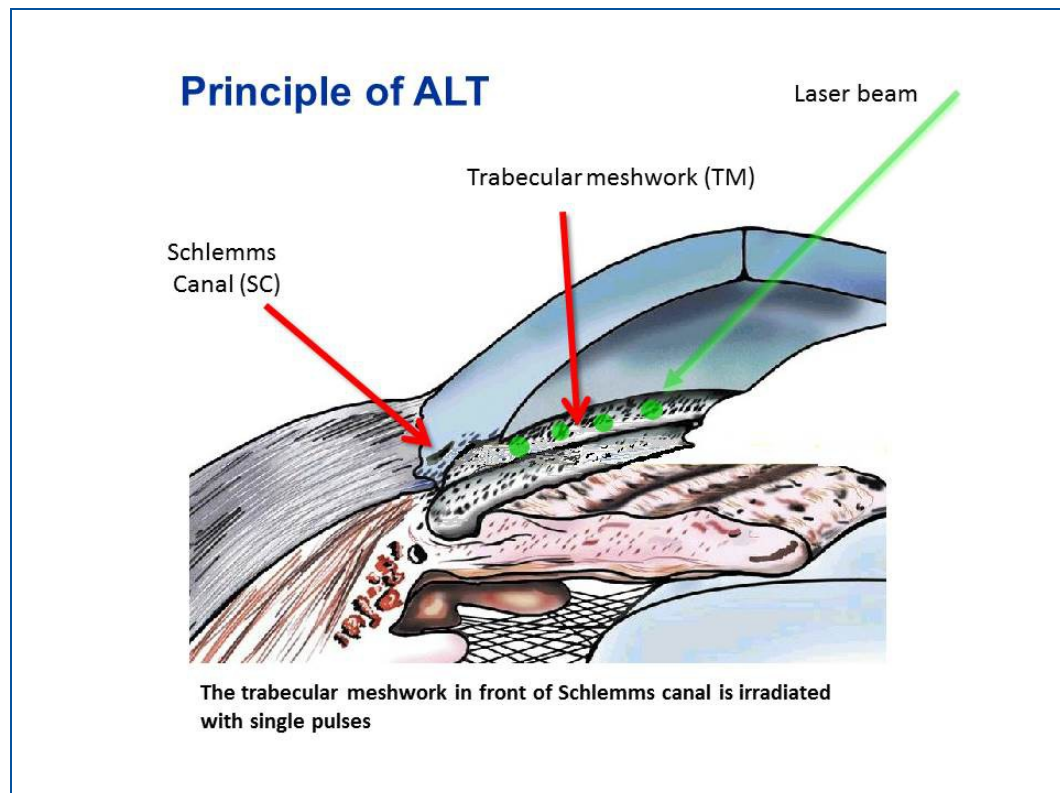
Iridectomy

For achieving an opening in the iris, the following advice can be given⁽¹⁾:

- use of a iridectomy contact lens
- use a spot size of 50 μm and 1.5 W and 0.1 sec pulse duration

(1) S. Boyd, A. Agarwal, Laser Surgery of the Eye, The Art of Lasers in Ophthalmology, Highlights of Ophthalmology International, ISBN 9962-613-34-5, 2005

ALT / Trabeculoplasty

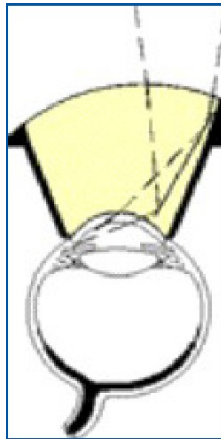


Open angle Glaucoma can be treated by irradiating the chamber angle and partly coagulating the trabecular meshwork. The area to be treated is the trabecular meshwork between scleral spur and Schwalbes line.

In a study⁽²⁾ the treatment parameters were the following:

50 laser spots on 180° of the meshwork circumference with 400-600mW power and a spot size of 50 μm . They used an antireflection coated Goldmann lens to direct the laser beam via the lens mirror to the chamber angle.

The best way is to use a special trabeculoplasty lens (e.g. SLT lens).



(2) Karim F Damji, Kirtida C Shah, William J Rock, Harkaran S Bains and William G Hodge, Selective laser trabeculoplasty v argon laser trabeculoplasty: a prospective randomised clinical trial; Br. J. Ophthalmol. 1999;83;718-722

Methods in case of unwanted effects

The application of laser radiation can cause vaporisation if the energy density is high enough. This may result in unwanted tissue fragmentation (cutting). Tissue fragmentation instead of coagulation can occur if the surgeon applies laser radiation at the same position for a too long time, the same as with too much power. Even less power may cause extended necrosis and unwanted tissue alteration leading to inflammation, especially in the eye, when too high power or too long exposure is used.

The treatment has to be stopped and anti inflammatory medication has to be delivered.

Treatment related issues

The amount of irreversible damaged tissue depends on the time and extend of the radiation. Discomfort from the heating which is generated by the laser may occur. All persons in the treatment room have to wear eye protection goggles, this may lead to decreased vision regarding contrast and color by the personal and surgeon. For endo coagulation, the eye protection filter for the microscope has to be mounted. The eye protection filter in the microscope protects the surgeon, who is not wearing goggles in this case.

Behavior in case of a system error

In case of any failure in the power generation of the laser, the power which is delivered to the patient decreases. Overpower cannot occur as the current for the laser diode is limited by a fuse. Less power than expected results in less effect. When this occurs, the user can check for the fiber delivery first and then for the laser. Any damage to the fiber results in a decrease of the power. The user should not continue the use of the laser and call the service to check the system.

A restart results in a new check of the system at the beginning. When the laser measures too low or too high power, the system does not start.

Any error message displayed by the system can be checked in the operation manual. In case of any insecurity or questions please contact your local A.R.C. Laser representative.

Treatment parameters

Retina coagulation via slit lamp

Power, pulse length and spot diameter according to the effect, therefore watch the effect!

200mW at 200ms with 200 micrometer spot size normally give good coagulation

Endocoagulation

Watch the effect! Power, pulse length and spot diameter influence the effect.

The spot size maybe larger due to the distance of the hand piece to the retina and the divergent laser beam, therefore more power maybe needed to achieve coagulation compared to slit lamp use in case of larger distance.

Micropuls application via slit lamp

Energy, spot size and treatment duration per application should be set according to the indication. The energy for the treatment has to be set to a so called "sub-threshold" power level. The determination is done setting the power limit (at a fixed pulse length) to achieve coagulation (minimal value) and then double or triple this value. After that, the micropulse program should be activated (duty cycle 5 to 15%***, see also page 16).

*Fawwaz Al Mamoori, IQ 532 Micropulse green laser treatment for refractory chronic central serous retinopathy, *Eye Care Vis*, 2017 doi: 10.15761/ECV.1000102 Volume 1(1): 1-3

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Iridectomy

Use a iridectomy contact lens; use a spot size of 50µm and 1.5W and 0.1sec pulse duration⁽¹⁾.

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Trabeculoplasty

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A.R.C.
LASER