The Pattern Scanning Laser (PASCAL®) Photocoagulator for Diabetic Retinopathy

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Abstract

For 40 years, laser photocoagulation has been the gold standard for the treatment of diabetic retinopathy (DR). Since receiving Food and Drug Administration (FDA) approval in 2005, the pattern scanning laser (PASCAL®) photocoagulator is emerging as a superior method of such treatment. PASCAL is a 532nm frequency-doubled neodymium-doped yttrium aluminum garnet (Nd:YAG) solid state laser that can be used for pan-retinal, focal, and macular grid photocoagulation in the setting of proliferative and non-proliferative DR. A more precise and predictable pre-determined pattern array may be delivered with more controlled spot spacing and predictable burn characteristics resulting in enhanced uniformity of laser treatment. Multiple spot delivery technique allows physicians to treat in a much shorter time, with less discomfort to the patient and diminished operator fatigue.

Retinopathy is one of the most feared complications of diabetes, severely compromising the quality of life in most affected patients. Diabetic retinopathy is the most common cause of vision impairment in people of working age in the developed world. Over a 20-year period, almost all patients with type 1 diabetes will develop retinopathy with approximately 30% going on to advanced disease. More than 60% of patients with type 2 diabetes will also develop retinopathy and often have retinopathy at the time of diagnosis of diabetes. With the global epidemic of type 2 diabetes, over 360 million people are projected to suffer from diabetes and its complications by 2030. While there is clear evidence that strict metabolic and blood pressure control can lower the risk for developing retinopathy and reduce disease progression, laser photocoagulation, and vitrectomy are often necessary and effective in preventing severe vision loss, particularly in the most advanced stages of the disease.

The concept of retinal laser photocoagulation as a treatment of diabetic retinopathy was introduced in the 1950s by Meyer-Schwickerath with the use of the xeon arc photocoagulator.[1] By the 1970s, the development of the ruby, argon ion, and krypton ion lasers and the coupling of these devices to a slit lamp (along with the use of contact lens, aiming beam, and movable joystick) ushered in the modern era of laser photocoagulation.[2] These enhancements permitted the precise creation of focused, single laser spots on the retina to achieve either focal, grid, or pan-retinal photocoagulation for the treatment of non-proliferative and proliferative diabetic retinopathy. Two large, prospective, randomized, multicenter trials (the Diabetic Retinopathy Study [DRS] and the Early Treatment Diabetic Retinopathy Study [ETDRS]) validated the effectiveness of laser photocoagulation and established the indications and parameters for the treatment of diabetic retinopathy.[3,4] These concepts persist, nearly unchanged, as the gold standard; laser photocoagulation remains one of the most common eye procedures performed by ophthalmologists.

Although fiber optic cables and air-cooled solid state lasers have replaced articulating arms and water-cooled gas tubes, from the standpoint of the patient and physician, until recently, little has evolved in the last 35 years in the general design and use of laser for retinal photocoagulation. Patients with proliferative diabetic retinopathy undergoing pan-retinal photocoagulation (PRP) generally receive between 1,200 and 1,800 laser spots in two or more sessions of 10–20 minutes each over the course of two to four weeks. This conventional photocoagulation uses a single application of laser energy per shot usually delivered as a 100–200 millisecond (ms) burn as recommended by the DRS and ETDRS.[3,4] Despite the use of different anesthesia and analgesia (e.g. peribulbar anesthesia or oral analgesia), many patients still find PRP a painful experience that may often lead to significant non-compliance and undertreatment.[5] Moreover, this treatment paradigm is not only cumbersome to the patient, it can also fatigue the physician. Patient comfort, and thus compliance, may be improved by using shorter exposure burns, avoiding red or infrared wavelengths with deeper penetration, and by decreasing overall treatment time.

The pattern scanning laser (PASCAL®) (OptiMedica, Inc., Santa Clara, CA) photocoagulator is a 532nm frequency-doubled neodymium-doped yttrium aluminum garnet (Nd:YAG) solid-state laser. It received US Food and Drug Administration (FDA) clearance for ophthalmic use in 2005. PASCAL uses a microprocessor-driven scanner to deliver, with a single foot depression, numerous operator-selected patterns (including squares, arcs, and full and subset grids) almost simultaneously. To achieve this, the pulse duration of each laser burn is reduced to 10–20ms (five to 10 times shorter than with conventional systems). Thus, PASCAL can deliver a pattern array of up to 26 laser spots in approximately 0.5 seconds at a 20ms pulse duration. By contrast, conventional photocoagulation, even in repeated mode, can only apply up to three shots per second at a 100ms pulse duration.

Given the significantly shorter pulse durations than those that had been previously used clinically, there was concern over the effects of the PASCAL photocoagulator on the retina. Pre-clinical animal experiments on the effects of reduced pulse duration (1–100ms) demonstrated the damage of light burns is confined to the outer retina and retinal pigment epithelium.[6] However, at pulse durations greater than 20ms, there is significant diffusion of heat with a less homogeneous lesion on histological examination.[6] The short-duration pulse of a PASCAL photocoagulator is associated with a more uniform and predictable burn dimension with minimal thermal boom compared with conventional photocoagulation.[6] This results in light burn lesions that are confined more to the outer retina with less energy spread laterally or in the direction of the choroid or nerve fiber layer. For a given burn intensity, significantly less total energy is required with PASCAL than with conventional photocoagulation.[6,8] In experimental models, pulse durations of approximately 20ms have been shown to represent an optimal compromise between the favorable impact of speed, spatial localization, and reduced collateral damage with a sufficient width of the therapeutic window.[8] The PASCAL photocoagulator uses an exposure time of 10ms for macular photocoagulation and 20ms for PRP.

In order to achieve the desired therapeutic lesion, the brief exposure time utilized by the PASCAL photocoagulator necessitates a higher laser power than that used in conventional photocoagulation.[7] In a published series of 75 procedures carried out in 60 diabetic patients, there was a statistically significant difference in the mean power required between the conventional laser and PASCAL photocoagulator groups in both the PRP and macular grid arms (235 versus 396mW for the PRP group; 100 versus 143mW for the macular grid group, conventional versus PASCAL, respectively; p<0.001).[7] A similar observation was noted in 20 patients undergoing PRP for proliferative diabetic retinopathy, central retinal vein occlusion or ocular ischemic syndrome.[8] The higher power levels required by the PASCAL laser have not resulted in any increase in observed long-term clinically significant complications.[7] This is to be expected as the threshold for a visible burn with pulse duration of 20ms in an experimental model was 110–120mW, while that for retinal hemorrhage was 600mW, providing a wide margin of safety.[6]

An unexpected advantage to PASCAL photocoagulation is the improved patient experience; clinically, patients experience less discomfort during PASCAL photocoagulation compared with conventional laser.[5] This may be related to the decreased total energy delivered and the limited thermal spread to the choroid. Importantly, the reduced exposure time and increased power used with PASCAL has not been associated with adverse effects and appears to be equally as effective as conventional laser photocoagulation parameters (with up to two years of published follow-up in treated patients with diabetic retinopathy).[5,7] The multiple spot delivery technique also allows physicians to perform PRP in a much shorter time period than with conventional laser (often in one session), further increasing patient comfort and lessening operator fatigue.

The PASCAL photocoagulator can deliver several treatment patterns including triple arcs and circles with variable radii of curvature and segment control, square arrays with variable spot spacing, and 2x2 to 5x5 spot patterns, customizable foveal encircling macular grids, and octant segments. Specific pattern and size can be tailored to particular disease and clinical conditions providing increased flexibility, efficiency, and margin of safety with more precisely spaced and more uniform burns than with conventional laser. For example, in conventional macular grid photocoagulation, each juxtafoveal laser spot delivered has an independent probability of inadvertently striking the foveal center. With the PASCAL photocoagulator, the pre-determined macular grid patterns with a fixed curvature radius and built-in controlled safety margins (with the smallest spot pattern diameter greater than 2,000μm) combined with the blinking fixation beam may increase the safety of macular grid laser. In order to minimize the risk associated with eye movements and blinking, the maximum number of spots in a pattern is limited to 26 with the PASCAL photocoagulator.

The use of the PASCAL photocoagulator may also improve the accuracy of implementing research protocols and improve the reliability of comparing treatment groups in clinical trials. A more precise and predictable pre-determined pattern array may be delivered with more controlled spot spacing and predictable burn characteristics, resulting in enhanced uniformity of laser treatment.

The PASCAL photocoagulator can be used for pan-retinal, focal, and macular grid photocoagulation in the setting of proliferative and non-proliferative diabetic retinopathy, and in branch and central retinal vein occlusion. Additional PASCAL applications include photocoagulation around retinal tears and detachments and focal treatment of juxtafoveal choroidal neovascularization. The PASCAL photocoagulator allows for multiple spot placement, short-duration burns, and more rapid and efficient delivery with less pain with similar clinical outcomes compared with conventional laser in a variety of posterior segment diseases. It represents a major advancement in the 35-year history of retinal photocoagulation. ■

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