SOLID-state lasers may offer a safe alternative

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in London

SOLID-STATE UV lasers offer a safe and effective alternative to excimer lasers for use in refractive surgery procedures, according to several studies presented at the XXIV Congress of the European Society of Cataract & Refractive Surgeons.

Marc Tay MD of Singapore, reported his outcomes performing LASIK with the 213nm, diode-pumped Nd:YAG Pulzar Z1 (CustomVis) flying spot laser to correct high myopia and myopic astigmatism. That laser has a 300 Hz pulse rate, a 0.6nm Gaussian shaped flying spot, and two eye-tracking systems. He used the Evolution microkeratome (Moria) for flap creation.

His series included 34 eyes with pre-operative sphere ranging from -6.00 to -17.00 D and up to -4.00 D of astigmatism. More than half of the eyes had a pre-operative SE of at least -10.00 D.

At the one-month follow-up visit, 23 eyes (68 per cent) were corrected to within 0.5 D of intended SE, while 31 eyes (88 per cent) were within 1.0 D. Uncorrected acuity was 20/20 or better in 88 per cent of eyes and 6/12/20/40 or better in all eyes, and there were no cases with loss of more than two lines of BCVA.

“Our clinical evaluation shows that this 213nm laser creates a clean, clear, and smooth ablation surface, and compared with the excimer laser it has several advantages. Warm-up time is reduced using the solid state laser, its performance is less sensitive to environmental factors, the treatment time is fast and its beam is less absorbed by fluids so that my requirement for careful hydration monitoring of the corneal surface is reduced,” noted Dr Tay.

“The preliminary results achieved in the treatment of high myopia and myopic astigmatism are very encouraging. So far, the outcomes are surpassing the FDA grid requirements and support the efficacy, predictability and safety of this solid-state laser. However, this is short-term experience in a small population. Now, larger studies are needed as well as further work to refine the nomogram.”

Marco Rossi MD, has been using the diode-pumped, 210nm solid state LaserSoft laser (Katana Technologies) for three years at Ospedale di Circolo di Busto Arsizio, Busto Arsizio, Italy. The laser features a 0.2nm Gaussian spot, a peak fluence of 350 mJ/cm2, a repetition rate up to 1.0 kHz, and an eye-tracking with a 1.0ms latency.

An outcomes analysis based on data collected in 959 procedures led Marco Rossi MD and colleagues to conclude that the LaserSoft laser represents a safe and effective alternative to the excimer laser for use in refractive surgery.

“There are advantages for using this laser because the treatment is associated with less inflammation, less pain, and faster visual recovery compared with excimer laser vision correction. In addition, with its small spot diameter and true Gaussian beam shape, it generates a very smooth surface and the potential for very precise ablation and enhanced correction of higher-order aberrations in customised treatments,” said Dr Rossi.

“Results achieved with this laser have been very favourable, although there is a tendency for overcorrection in treating very high myopia. We believe this latter drawback is due to the longer treatment time needed for the higher levels of correction. The manufacturer tried to develop a higher frequency machine to resolve that problem, but unfortunately the programme has to be stopped because of financial problems that cannot allow the Katana laser GMBH to survive anymore. “The 959 eyes in his study population included 759 eyes treated for myopia or myopic astigmatism (mean SE -2.61; maximum SE -12.5 D) and 154 eyes with hyperopia or hyperopic astigmatism (mean SE +1.97 D; maximum SE +6.13 D). In addition, there were 46 eyes with mixed astigmatism (mean SE -0.25 D; maximum sphere +2.28 D and cylinder -5.50 D).

Prior to surgery, 85 per cent of eyes had BCVA of 1.0 or better. By three months after surgery, BCVA was 1.0 or better in 84 per cent of eyes, and that proportion rose to 92 per cent after 12 months and remained at the same level after three years.

“If the data are analysed with the eyes divided based on type of pre-operative refractive error, the results are the same showing an improvement in BCVA over time in all treatment subgroups,” Dr Marco Rossi said.

The UCVA data also showed a steady improvement over time with the same trend observed in analyses of the treatment subgroups. At 15 days after surgery, UCVA was 0.5 or better in 94 per cent of eyes, 0.8 or better in 72 per cent of eyes, and 1.0 or better in 45 per cent. By three months, those rates had risen to 98 per cent, 82 per cent, and 71 per cent, and increased further to 99 per cent, 94 per cent, and 82 per cent at one year.

“The FDA targets require only 50 per cent of eyes to achieve UCVA of 1.0 or better and 85 per cent to be 0.5 or better,” noted Dr Rossi.

The refractive results were very stable overall with mean SE for the entire group being 0.01 D by day 15 and remaining at that level through one year. However, there were differences among the three groups.

“The myopes showed a very slight myopic shift with mean SE changing from just 0.08 D at day 15 to 0.01 D at one year. Among the hyperopes, there has been a more marked shift in the hyperopic direction, with mean SE rising from -0.31 D at day 15 to +0.13 D at one year, while the refractive outcomes in the mixed astigmatism group showed variability through six months, but stability between six months and one year when the mean SE has been around plano,” reported Dr Rossi.

Dr Rossi also compared predictability and safety outcomes achieved with the LaserSoft laser against the FDA approval criteria to show that they exceeded all of the targets at six months. In his LaserSoft population, 94 per cent of eyes had achieved MRSE within 0.5 D of intended and 98 per cent were within 1.0 D. No eyes had a BCVA worse than 0.5 and only two per cent lost more than two lines of BCVA.

Solid-state may be safer

The solid-state UV lasers could offer a safety advantage over the conventional 193nm excimer laser. Paul van Saarloos PhD, a laser physicist and CEO of CustomVis, Perth, Australia, reviewed data on the absorption characteristics of the 213nm wavelength and studies investigating its potential carcinogenic and mutagenic activity. He explained that while the 213nm and 193nm laser wavelengths are absorbed similarly in corneal collagen, the two wavelengths are absorbed very differently by BSS or saline.

“The longer 213nm wavelength is absorbed less and penetrates much better through those fluids compared with the 193nm wavelength. Those data suggest that the performance of the 213nm laser is unlikely to be influenced significantly by variations in corneal hydration or environmental humidity, and so we believe the 213nm laser ablation should be more reliable and predictable. Furthermore, the 213nm treatment is a colder ablation with less energy wasted heating water, and that factor should increase its efficiency,” Dr van Saarloos said.

Dr van Saarloos noted that a previously published study investigating the action spectra for cell inactivation and DNA changes in UV radiation-exposed bacterial and yeast cells show they are less sensitive to radiation in the range of 190-220nm compared with longer wavelengths.

“It is thought that surrounding cytoplasmic components may protect the nuclear DNA from UV light in the 190 to 220nm range,” Dr van Saarloos noted.

However, a study by Kaido et al. comparing the mutagenic and cytotoxic effects of 193nm and 213nm radiation determined that the longer wavelength had a more damaging effect on cultured mammalian cells. Technical issues with the methods used in that in vitro study may confound its results, said Dr van Saarloos.

“The 213nm beam was likely contaminated with 266nm radiation, which is known to be mutagenic and cytotoxic. Furthermore, the cells used in that study were wet and the laser fluences used for their irradiation were too low to cause drying. Therefore, it can be postulated that the moisture present provided a shielding effect against the 193nm radiation but not the 213nm treatment. On that basis, an alternative conclusion from this study is that the results are confirmation that the 213nm wavelength achieves better transmission through fluid,” Dr van Saarloos said.

An in vivo study conducted by Dr van Saarloos and colleagues demonstrates the 213nm wavelength offers similar safety compared with the 193nm wavelengths with respect to the potential for causing DNA damage. That study was performed in 15 rabbits that were divided into three groups to undergo a 300-micron ablation bilaterally using either a 213nm wavelength from an Nd:YAG laser, a 266nm wavelength, or a 193nm wavelength from an argon fluorescent excimer laser.

Approximately 30 per cent of epithelial cells and keratocytes exhibited unscheduled DNA synthesis among eyes treated with the 266nm wavelength. In contrast, there was minimal DNA damage in eyes treated with either the 213nm laser or the 193nm excimer laser as evidenced by the presence of unscheduled DNA synthesis in only about 3.4 per cent of cells in those groups.

“A study now under way is using TUNEL staining to evaluate apoptosis in rabbit corneas undergoing PRK, and at three days after treatment, we are seeing no difference between eyes treated with the 213nm and 193nm lasers with respect to the presence of dying cells under the ablated zone,” Dr van Saarloos said.

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