Refractive and Visual Outcomes of Laser in Situ Kerato Mileusis for Moderate to High Myopia Using 213nm Solid State Laser - A Four Year Follow Up Study

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Abstract

Aims: To evaluate and report the visual, refractive outcomes and corneal integrity of conventional LASIK performed using 213nm solid laser to correct moderate to high myopia.

Design: Prospective case series

Methods: Present study analysed 53 eyes of 28 patients, with moderate to high myopia, who underwent conventional LASIK using PULZAR Z1 SOLID LASER, long term (4 year) visual refractive outcomes and the corneal integrity were studied. The patients were followed up for minimum of 48 months.

Results: There was a significant improvement in uncorrected distant visual acuity, post operatively (P value < 0.01). No significant change was detected in decimal notations in CDVA pre and post op (p=0.383). At the end of fourth year, post op logMAR UDVA was 0.30(20/40 or 0.50 decimal notation) in 87% of eyes and 85% of eyes achieved 0.18 logMAR (20/30 or 0.67 decimal notation). The post op logMAR CDVA 0.48(0.33 in decimal notation) was 100%, where as logMAR UDVA 0.48(0.33 in decimal notation) was 92%. The efficacy index was 1.11 and safety index was 1.19. In the long run, no serious complications pertaining to corneal integrity were noticed and 4% of eyes had complaints of haloes and night vision problems.

Conclusion: LASIK using PULZAR Z1 solid state laser, proved safe and effective providing predictable correction of moderate to high myopia.

Keywords: corrected distance visual acuity, uncorrected distance visual acuity, logMAR, RSBT, PRK and BCVA.

Introduction

Corneal photo ablation has been performed over the years using refractive excimer laser(193nm wavelength) safely and effectively. In recent times, solid state refractive laser platforms have been developed, providing an alternative to excimer lasers, with certain added advantages like smooth ablation patterns and less collateral corneal damage. The newer solid state laser is a quintupled Nd: Yag laser with a 213 nm wavelength, small spot size 0.6mm, high pulse to pulse energy stability. No need of dangerous or toxic gas, less noise levels in the operation theatre, less maintenance costs and the greatest advantage is its ready to use option anytime, unlike with excimer laser. There is a need to pool up the cases for using excimer laser for economy. The repetition rate of a solid state laser is 300 Hz. This is much higher than in the excimer lasers. This laser provides true Gaussian profile of the beam. The 213 nm wavelength is less sensitive to corneal hydration than 193 nm due to its better transmissibility in hydrated cornea. The hydrated state of the cornea has bearing on corrections. The over hydrated cornea results in frequent under corrections, dry stromal bed (under hydrated) results in over corrections. The solid state lasers are much more complex to manufacture and need frequent, meticulous maintenance. Earlier studies of refractive procedures performed with 213nm lasers have identified smooth ablation, clinical outcomes similar to excimer lasers. Few published studies indicate Photo Refractive Keratectomy (PRK) and LASIK using 213nm solid state laser are effective, safe and stable. The mechanical microkeratomes (different blades) to create flap thickness, varying from 100 microns to 140 microns are in use. The thin flaps facilitate the correction of higher errors with safety and stability.

Solid State Laser

The solid state laser technology analysed in this study uses the fifth harmonic of neodymium YAG laser. The laser is obtained through a system of three non linear crystals. The laser platform includes an eye tracker (z track, 25 hz). It adjusts the position of the laser beam, every frame during surgery according to eye moments. The eye tracker uses the position of the limbus, limbal blood vessels and the Iris pattern as references. Analog solid state, high speed eye tracking, 1 khz closed loop response and speed monitors these trackers. The Gaze tracker with 25 hz tracking speed is helpful in monitoring the patients gape position while maintaining fixation. This laser platform has the features for hinge protection and Cyclo rotation facility. The aim of the present study is to evaluate the stability of the visual and refractive outcomes and corneal integrity in cases of
conventional LASIK performed using the PULZAR Z1 laser (Custom Vis Solid State Laser presently known as CVC LASERS, Balcatta, Perth, Western Australia, Australia), in correcting moderate to high myopia, for a minimum follow up period of four years (Figure 1 & 2).

**Patients and Methods**

This prospective non-comparative study comprised of consecutive patients who underwent LASIK. Patients were informed about the nature of the treatment and the study, written consents were obtained, before undergoing treatment in accordance with the tenets of declaration of Helsinki. The surgeries were performed at a single center by a single surgeon (the presenting author). The center is a private practice setup. The solid refractive laser, PULZAR Z1 (CUSTOM VIS presently known as CVC LASERS, Balcatta, Perth, Western Australia, Australia), platform was used for stromal ablation. The inclusion criterion for study was moderate to high myopia, either in both eyes or single eye (Anisometropia). The exclusion criterion were low myopia, pre-op dry eye, pre-op suspected keratoconus, ectasia, corneas resulting in residual stromal bed thickness (RSBT) less than 270 μm (thin corneas), cataract, glaucoma, previous ocular surgeries, unstable refraction, patients aged below 18 years, pregnant and breast feeding women. This solid state laser does 12 μm of stromal ablation, for each dioptric power of the intended correction. Patients were instructed to stop using soft contact lens 2 weeks before and rigid gas permeable or hard lenses were stopped one month. Prior to surgery.

**Pre-operative Evaluation**

The pre-op ophthalmologic examination included visual acuity (corrected and uncorrected) using Snellen’s Visual Acuity Chart/logMAR charts. They were converted into logarithm of the minimum angle of resolution (LogMAR) and decimal notations. Cycloplegic (objective) and manifest (subjective) refraction was done, other examinations included Slit Lamp Bio Microscopy, Goldman’s Applanation Tonometry, Direct and Indirect Ophthalmoscopy, Corneal topography (The Vista Corneal Topography Unit, I-Trace Tracey Technologies, Tracey Technologies Corp,16720 Hedgécroft Drive, Suite 208 Houston, Texas 77060, USA) Ultrasonic Pachymetry (Nidek), Ocular Wavefront Aberrometry (I-Trace Tracey Technologies). Based on aberrometry, eyes with RMS value of less than 0.5 μm, were included in the study for the conventional LASIK treatment. On Slit Lamp Bio Microscopy, every case was examined for the signs of blepharitis, meibominitis, dry eye and other ocular conditions. Schirmer’s test and Tear film breakup time (BUT) were measured for all the cases.

**Surgical Techniques**

A single surgeon operated all the cases, using the same machine. The cases were performed under topical anaesthesia (proparacaine). They were performed between November 2008 and November 2009. All the cases were instructed for thorough face wash with soap and water. Disinfection of the lids and eye lashes were done using 10% povidone–iodine. Once thorough analgesia was attained, the Bausch & Lomb Xyoptix XP mechanical micro keratome was used for creating the Anterior Lamellar Corneal Flap of 120 μm thickness with nasal hinge and 8.5 mm to 9mm diameter. Before Lamellar keratectomy treatment centre of the laser ablation was selected. Once the Flap creation was over, Flap was lifted and stromal ablation done using solid state 213nm laser. After completing the stromal ablation, stromal bed was thoroughly washed to remove the tissue debris, epithelial cells and any protein particles, blood etc. After this the flap was repositioned back in its original position. The markings made pre-op with a marker pen on corneal epithelial surface are of great help in this manipulation. Then the flap edges were dried using the sterile merocel sponges. Once the drying of the cornea is ensured the lasik speculum was gently removed to flap wrinkles. Post operatively, topical gatifloxacin 0.3%, fluoro methalone and carboxy methyl cellulose sodium lubricant 0.5% w/v (Refresh tears, Allergan India) were prescribed. Antibiotic and low dose steroids were to be applied 4 times daily for 4 weeks. Lubricants were prescribed 3 hourly applications for six weeks.

**Post operative Follow Up**

All patients were examined on next post op day at the laser centre. The follow up was at one week, 2 weeks, 1 month, 3 months, 6 months and every year thereafter. On the first post op day Slit Lamp examination was done to examine the flap interface and corneal integrity. VAs were recorded. The study analysed for the visual refractive outcomes.
efficacy, safety stability at the end of fourth year. Slit Lamp Biomicroscopy and VAs were recorded, at every visit. Patients were enquired about the symptoms of haloes, ghost images and night vision problem.

**Statistical Analysis**

Data analysis was performed using SPSS for windows software (version 18.0) and Microsoft excel. Student t-test for paired data was used to compare pre-op data and post-op data. Wilcoxon Rank Sign Test was also used for non parametric analysis. Differences were considered statistically significant, when the p-value was less than 0.05. The efficacy index and safety index were calculated converting visual acuities into decimal notations. The Efficacy index was calculated as the ratio of the Post-op UDVA to pre-op CDVA. The Safety index calculated as the ratio of the post-op CDVA to pre-op CDVA. The post-op UDVA improved significantly (p-value). The Waring Protocol for refractive surgery outcomes, standard graphs and reporting systems is followed for the presentation of the study results.  

**Results**

In this series of 53 eyes of 28 patients studied, 3 eyes were unilaterally treated. One patient had high anisometropia (taken for lasik), for other two patients each eye was taken for lasik, other eyes were treated with lasik (lasek eyes excluded from study). Forty seven eyes were Plano targeted and 6 eyes were under corrected. The range of myopic corrections (stromal ablations done) were between -4.00 D sph to -10.00 D sph. The Astigmatic corrections treated were between the range of -0.25 D cyl to -2.00 D cyl. The mean age of the study group was 24 years. Minimum age was 19 years and maximum age 38 years. Female eyes were 26 (49%) and male eyes were 27(51%). The minimum follow up period was four years.

**Visual Acuity**

The post op visual acuity improvement in UDVA in decimal notations was statistically significant(P-value <0.01). No significant change was detected in decimal notations of CDVA pre and post op (p=0.383 paired T-test and 0.850 Wilcoxon Rank Sign Tests). At the end of fourth year, post op logMAR UDVA was 0.30(20/40 or 0.50 decimal notation) in 87% of eyes and 85% of eyes achieved 0.18 logMAR (20/30 or 0.67 decimal notation). The pre op logMAR CDVA 0.48(0.33 in decimal notation) was 100%, where as logMAR UDVA 0.48(0.33 in decimal notation) was 92%. (Figure 3) The efficacy index was 1.11 and safety index was 1.19. The (Figure 4) (histogram) shows the changes in CDVA post operatively when uncorrected. 81% of eyes show no change when uncorrected 4% of eyes shown one line gain, 9% of eyes showed loss of one line, 6% have shown loss of 3 lines, when uncorrected. 

**Refraction**

The post operative spherical equivalent refraction was within +/-1.00 D of emmetropia in 96% of eyes. (Figure 5)The figure 6 shows post-operative residual astigmatism (cylindrical changes) to be +/- 0.50D in 98% eyes. The figure 7 shows the achieved SE correction plotted against the intended correction. The myopia mean value -6.12 ± 0.46 D in the range of (-4.00D to -10.00 D). There is a strong correlation between achieved correction and attempted correction (R2=0.933). (Figure 7) The figure 8 shows the stability plot between achieved SE and SD spherical equivalent over the 48 months period.

**Complications**
Intra operative complications like minute bleeding were noted in two eyes (4%). Eccentric flap creation occurred in two eyes (4%). Flap lifting and washing the interface was done to remove the red blood corpuscles (RBCs). None of the cases underwent retreatment. However six eyes needed spectacle correction for best corrected visual acuity (BCVA) and the patients were happy with the spectacle correction. The patients, who were under corrected, were counselled before surgery. Among those 6 eyes, in two eyes RSBT was critically at 260 to 270 microns. These 2 eyes lost 2 lines of pre-op CDVA. There was no epithelial in growth or other serious complications like flap loss, diffused lamellar keratitis (DLK) and infectious keratitis. One case, two eyes (4%) reported the symptoms of night vision problem and haloes.

Discussion

Solid state lasers appear to be a promising solution for refractive surgeries. Applying less energy to the cornea and small flying spot size 0.6 mm, inducing less scarring and no collateral stromal damage. This technology has become an alternative in corneal refractive surgery, with some potential advantages over excimer lasers. There are few reports of the outcomes of the use of solid state 213 nm lasers for refractive correction. The visual outcomes in our cohort were excellent with a significant improvement in logMAR UDVA and maintenance of logMAR CDVA.

In our study, 85% of patients had UDVA of 20/30 (0.18 logMAR or 0.67 decimal notation) at the end of fourth year. Tsiklis et al in their study reported 90% eyes with UDVA of 20/25 or better. This is better than what is achieved in our study. However, present study included five amblyopic eyes and follow up is for longer duration. Pre-op CDVA of 20/20 (logMAR 0.00) is only 70%. David. P. Pinero et al. achieved 95% of UDVA of 20/25 or better in their study. In the present study, two eyes lost two lines, when the best correction is given, reason being development of minute Posterior Sub Capsular opacities of the lens. For the same patient (High myope) under correction was given. In spite of that, the Residual Stromal bed thickness was around 260 microns. Regarding refraction, 96% of the eyes are ≤ -1.00D post-op SE and 92% of eyes were ≤ -0.50D of emmetropia. This statistical figure shows excellent predictability of lasik performed using mechanical microkeratome and stromal ablation done by using solid state 213 nm refractive laser. This refractive predictability is equivalent to/or even better than reported with the excimer lasers (SE with ≤ -0.50D in 90% percent of eyes).10,16-20 The corneal flap of 120 microns thickness produced with Zyoptics XP microkeratome and the stromal ablation resulted in predictive refractive results, comparable to laser microkeratome.21 The astigmatic correction graph shows 98% of eyes are ≤ -0.50D. This study evaluated the symptomatology of glare haloes and night vision problems. Two eyes (4%) one patient reported the night vision problem. In the course of three years the patient got adjusted to it. Furthermore in this study, it was focused particularly on the stability of corneal flap. There was cases of flap injuries, flap dislocation, flap loss or flap wrinkle. This clearly confirms the long term safety of lasik performed using the mechanical microkeratome and newer generation solid laser. The eyes (patients) which were under corrected, were clearly counselled before the procedures performed and the overall satisfaction was excellent in this group. The solid state laser energy had no negative effect on the corneal endothelium.21 The conventional lasik performed using 213 nm laser achieved quiet predictable correction of moderate to high myopia. The post operative visual

53 eyes (47 eyes plano target), 48 months follow up

Figure 6: Refractive Astigmatism

Figure 7: Spherical Equivalent Attempted Vs Achieved

Figure 8: Stability of Spherical Equivalent Refraction
outcomes are good. This laser system should be considered as a best alternative option for laser vision correction. This laser needs no gas fillings or refilling (no cost for gas) and is convenient to use at any time and maintenance costs are reduced. This present study evaluated the refractive visual outcomes and long term stability and safety of moderate to high myopes, who underwent conventional lasik using 213 nm refractive laser. The overall satisfaction is excellent, even in high myopes because the under corrected patients were very well counselled for the future use of spectacles/contact lenses optionally whenever the need arises.

Regarding visual outcomes not only the visual acuities but contrast visual acuity changes and aberrometric changes should have been evaluated. As this setup possesses only the solid state refractive laser, to conduct a comparative study between excimer laser and solid refractive laser to corroborate the potential clinical equivalence of the said technologies was not possible.

In conclusion, the solid state laser (213 nm) is safe, effective and achieves stable results. This study confirms the long term stability and anatomical integrity of the eyes (moderate and high myopes, who underwent conventional lasik using 213 nm refractive laser. The overall satisfaction is excellent, even very well counselled for the future use of spectacles/contact lenses optionally whenever the need arises.

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**Its ability to achieve excellent satisfaction.**

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