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ORIGINAL ARTICLE

LASER ASSISTED SUB EPITHELIAL KERATECTOMY FOR HYPEROPIA USING 213 NM WAVELENGTH SOLID STATE LASER, 3 YEAR FOLLOW UP STUDY OF REFRACTIVE AND VISUAL OUTCOMES

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ABSTRACT: PURPOSE: To evaluate the visual and refractive outcomes, using 213 nm solid lasers for the correction of broad range of hyperopia, covering pediatric age group to presbyopic age group. **MATERIALS AND METHODS:** The Present study is a prospective case series in a private practice setup, analysed series of eyes, with low to high hyperopia, who underwent conventional LASEK. Long term (3 year) visual and refractive outcomes and overall patient satisfaction studied. **RESULTS:** This cohort study of 37 eyes included broad range of hyperopia between +1.5 D to +7.5 D. For 70.27% of eyes, there was no change in CDVA post operatively and there was a significant Gain of one line in 21.62% of eyes and the paediatric eyes (4) gained one line. The post-op improvement in logMAR UDVA/decimal notations is statistically significant (P value <0.01). No significant change was detected in logMAR CDVA/Decimal notations. The post op log MAR UDVA is +0.30 (20/40) in 78.4% of eyes, +0.48 (20/60) visual acuity in 95% of eyes. Post op LogMAR UDVA 0.00 (20/20) in 40.54% of eyes is equal to pre-op logMAR CDVA. The efficacy index is 1.01 and safety index is 0.99. Post op 3 eyes (8.11%) lost 1 line of CDVA and 8 eyes (21.62%) gained one line of Snellen's visual acuity. **CONCLUSION:** The conventional LASEK can be performed using solid laser, safely and effectively for hyperopia covering broad age groups and it can achieve effective visual outcomes with excellent overall patient satisfaction.

KEYWORDS: LASEK, CDVA, UDVA, logMAR and PRK.

INTRODUCTION: Corneal photo ablation has been performed over the years using refractive excimer laser 193nm wavelength safely and effectively.[1-4] In recent times, solid state refractive laser platform has been developed,[5-6] providing an alternative to excimer lasers with certain added advantages. The newer solid state laser is a quintupled Nd: Yag laser with a 213nm wavelength, small spot size 0.6mm. Experimental studies indeed found that solid lasers (213nm wavelength) don't induce thermal damage or collateral damage in deep corneal layers.[6-7] Photo ablation of the stromal tissue within the wavelength ranging from 190nm to 220nm is with high degree of accuracy and minimal collateral damage.[4-5] This laser has higher pulse to pulse energy stability.

There is no need of using toxic gas and it has least noise levels in the operation theatre, less maintenance costs and the greatest advantage is its ready to use option anytime unlike with excimer laser. The repetition rate of solid state laser is 300hz, much higher than in the excimer laser. 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.[8] The hydrated cornea has bearing on corrections. The over hydrated cornea results in frequent under corrections, dry stromal bed (under hydrated) results in over corrections.[9] The solid state lasers are more complex to manufacture and needs frequent and meticulous maintenance of the machine.

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There are few earlier studies using commercially available solid state lasers in correcting refractive errors. Earlier studies of refractive procedures performed with 213nm lasers have identified smooth ablation, clinical outcomes similar to excimer lasers.[5 & 10] Few published studies indicate Photo refractive Keratectomy (PRK) and LASIK using 213 nm laser are effective, safe and stable.[10-13]

The solid state laser technology analysed in this study uses the fifth harmonic of neo dynium Yag laser. The laser is obtained through a system of three non-linear crystals. The laser platform includes an eye tracker (z track, 25hz). 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, 1khz closed loop response and speed monitors these trackers. The Gaze tracker with 25 hz tracking speed is helpful in monitoring the patients' gaze 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 results of visual and refractive outcomes in performing Laser Assisted Sub Epithelial Keratectomy (LASEK) using the Pulzar Z1 laser (Custom Vis Solid State Laser presently known as CVC Lasers, Perth, Australia) in correcting low to moderate hyperopia, with a minimum follow up of 3 years.

MATERIALS AND METHODS: This prospective non-comparative study comprised of 37 eyes that underwent LASEK. In this series, patients' age groups ranging from 12 years to 52 years are included. The parents of the pediatric patients were well counseled about the potential advantages and also about the possibility of regression, however the cases were taken because of superficial amblyopia, extremely poor compliance and frequent loss of glasses. The presbyopic patients were well explained about the correction, only for distant vision and the need to use the presbyopic glasses thereafter. In this series, the range of powers from +1.5D to +7.5D, were corrected. Patients were informed about the nature of the treatment and study. Written consents were obtained before undergoing treatment, in accordance with the tenets of declaration of Helsinki. The surgeries were performed at a single centre by the single surgeon, the presenting author.

The centre is a private practice setup. The solid state 213 nm laser platform is used for stromal ablation. The inclusion criterion for this study is low to moderate hyperopia either single eye (in case of Anisometropia) or both eyes. The patients' age is ranging from 12-52 years. The exclusion criterion were pre-op dry eye, pre op Ectasia and deep seated amblyopic eyes without any visual acuity (VA) improvement pre operatively, ocular diseases and Anterior segment disease, Herpetic keratitis, Atopic conditions, Auto Immune and System Connective tissue diseases. The patients were instructed to stop using soft contact lenses before two weeks and hard lens, Rigid Gas Permeable (RGP) lenses before one month.

The pre-op examination included visual acuity recordings on Snellen's visual acuity charts/logMAR charts, uncorrected and corrected, however converted into logarithm of the minimum angle of resolution (logMAR) and decimal notations. Cyclopegic (Objective) refraction, Manifest (subjective) refraction is done for every case. Other examinations included are Slit Lamp Biomicroscopy, Gold Man's Applanation Tonometry, Direct and Indirect Ophthalmoscopy, Corneal Topography (The Vista Corneal Topography Unit, I-Trace Tracey Technologies, Tracey Technologies Corp, 16720 Hedgecroft Drive, Suite 208 Houston, Texas 77060, USA) and Nidek's Ultrasonic Pachymetry, Ocular Wavefront Abberometry (I-Trace Tracey Technologies). On Slit Lamp

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Biomicroscopy, every case was examined for the signs of Blepharitis, Meibominitis, dry eye and other ocular conditions. Schirmer's Test and Tear Break Up time were measured.

The cases were performed between March 2009 and March 2010. Topical anaesthesia (Pro-paracaine drops) was instilled ten minutes before surgery. All the cases were instructed for thorough face wash with soap and water. Disinfection of the lids and eye lashes were done using 10% Povidine-Iodine. Once the refractive parameters were entered into the laser software, the treatment centre of the laser ablation is selected. Epithelial separation is achieved by using 20% iso propyl alchohol (Instilled into the well) for 45 seconds. Then the alcohol is sucked by using the merocel sponge and epithelium is separated as a layer. Utmost care was taken not to spill any drop of alchohol in to the conjunctival culdesac. The ablation is set for 6.5 mm optical and 2.5 mm blend zone (Overall 9 mm). The standard LASEK procedure was performed.[14] Mytomycin-C 0.02% was applied for 30 seconds to all the eyes, then thorough irrigation was done.

EPITHELIAL flap is repo sited back and over it bandage soft contact lens is used. Soft contact lenses are left over for the period of one week till the reepithelialisation is completed. Post operatively patients received topical flouro metholone eye drops four times a day, gatifloxcin 0.3% eye drops four times a day and Carboxy methylcellulose sodium lubricant 0.5% w/v (Refresh tears, Allergan India) drops per three hourly installations. In addition to these topical medications, the oral analgesic Tab. Diclonac SR (Tab. Reactin plus) are also prescribed for two days. Artificial tears and flouro metholone were continued for three months. Post op follow up was conducted on immediate post op day, One week, three weeks, one month, three months, six months and at the end of one year and every year. Post Op follow up included Slit Lamp Biomicroscopy, VA recordings (UDVA & CDVA) manifest and subjective refraction. Each patient was given a validated questionnaire enquiring the symptoms of dry eye and visual fluctuations. The study analysed visual refractive outcomes, efficacy, safety and stability at the end of three years.

The SPSS (version 18.0) and Microsoft excel were used for the data analysis. Student t-test for paired data was used to compare pre-op and post-op data. Wilcoxon signed rank test was used for non-parametric analysis. Differences were considered statistically significant, when the P-value < 0.05. The efficacy index and safety index were calculated, converting visual acuities into decimal notation. The efficacy index was calculated as the ratio of the post-op Uncorrected Distant Visual Acuity (UDVA) to pre-op Corrected Distant Visual Acuity (CDVA). The cumulative proportion of eyes within each visual acuity group for pre-op CDVA and post-op UDVA are plotted in histogram. The safety index is calculated as the ratio of the post-op CDVA to pre-op CDVA. The post-op UDVA improved significantly (P value <0.01) calculated in decimal notations. Accuracy was calculated by plotting the intended change in SE against the achieved change in SE at the end of three years. The resulting linear regression line shows the trend and allows observation of under and over corrected eyes. The stability of treatment is analysed by comparing the mean post-op SE at three months and three years. The Waring protocol for refractive surgery outcomes, standard graphs and reporting systems is followed for the presentation of the study results.[15]

RESULTS: The Present study enrolled 37 eyes of 20 patients with a mean age of 29 years ranging from 12 years to maximum age of 52 years. The mean attempted SE power is +4.75 ± 1.86 D with the range of +1.5 D to +7.5 D. The minimum follow up period is 36 months.

The post-operative improvement in UDVA (in decimal notations) is statistically significant P value <0.01, with both paired t-test and Wilcoxon Sign Rank Test. No significant change was detected

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in logMAR CDVA/Decimal notation, P=0.811 for paired t-test and P=0.546 for Wilcoxon Signed rank test. The post-operative logMAR UDVA is +0.30 (20/40) in 78.4% of eyes, logMAR UDVA is +0.48 (20/60) visual acuity in 95% of eyes and logMAR UDVA is +0.80 (20/125) in all the post-op cases. LogMAR post op UDVA 0.00 (20/20) in 40.54% of eyes is equal to pre-op logMAR CDVA Figure 1 shows overall efficacy and safety indices. The efficacy index is 1.01 and safety index is 0.99. Figure 2(b) shows the changes in pre-op CDVA in Snellen's lines, post operatively. Post LASEK, three eyes (8.11%) lost 1 line of CDVA and 8 eyes (21.62%) gained 1 line of Snellen's visual acuity.

At the end of three years the mean SE in all the eyes corrected are +0.54±0.06D. The R^2 between the intended SE and achieved SE is 0.98% (Figure 3). This represents the accuracy of the treatment. The refractive astigmatism correction shown in the figure 5, shows 97% of eyes showing residual cylindrical value of ≤+0.50D and the residual spherical equivalent value within ≤+1.0D are 92% of eyes (Figure 4). The stability plot Figure 6 shows 5 eyes, 14% show change in refraction between 3 months to 36 months.

DISCUSSION: This cohort study of 37 eyes included broad range of hyperopia between +1.5 to +7.5 D. This study included paediatric age eyes (4) aging 12 & 14 years. There was no change in 70.27% of eyes, CDVA post operatively and there was a significant gain of one line in 21.62% of eyes and the paediatric eyes (4) gained 1 line. Out of 37 eyes, 32 eyes (86.5%) were Plano targeted. Five eyes (14%) were under-corrected because of the high Hyperopia more than +7.5D. In the paediatric eyes, one line gain is quiet encouraging and significant. The paediatric cases were taken for refractive LASEK as there was a compliance problem and frequent loss of glasses. The parents were fully explained about the regression and future changes in refractive status, but at the end of three years, the visual acuity and refractive status is quiet stable. The complications noticed in our study are the peripheral stromal haze (5%) and in another two eyes (5%), there were the symptoms of dryness and visual fluctuations in the day. Both stromal haze and dry eye symptoms decreased at the end of one year. In this study, the wide age group of patients is taken and all of them are very happy, including the Presbyopes. The Presbyopes were very clearly explained about the correction for the distant vision only. The under corrected subjects were also very happy, as they became less dependent on glasses and the cosmetic problem was resolved. Through validated questionnaire, the level of satisfaction and symptomatology were studied. The recently published papers on LASEK using excimer laser in hyperopes and myopes have shown refractive stability between 6 months and 12 months. These studies found only 1% incidence of refractive change.[16,17]

The previous study by McAlinden C, with Excimer laser, showed results at 1 year, 100% eyes within ±0.50D[17] and the present study shows the residual spherical equivalent value within ≤ + 1.0D in 92% eyes. However in this study, amblyopic eyes are included. Studies by Shah et al using solid state 213 nm Laser for correcting broad range of refractive errors concluded that 97.9% intended SE were within ±1.00D at the end of six months. Solid (213 nm) laser with Gaussian beam producing 0.6mm flying spot is smaller than 0.95mm spot size of excimer lasers and larger spot diameters known to increase stress on the cornea.[18] This laser causes less damage to corneal collagen and cellular changes.[19] Pulzar Z1 is safe with high pulse to pulse stability, gaze track and Z1 tracker. No gas fillings or re-fillings are required. With less maintenance costs and its ready to use option, it's a good economical choice. Despite numerous advantages of this laser, there are relatively few published reports, about the refractive visual outcomes, using this laser. Earlier studies on PRK and LASEK, using this laser treatment proved to be effective and safe.[20]

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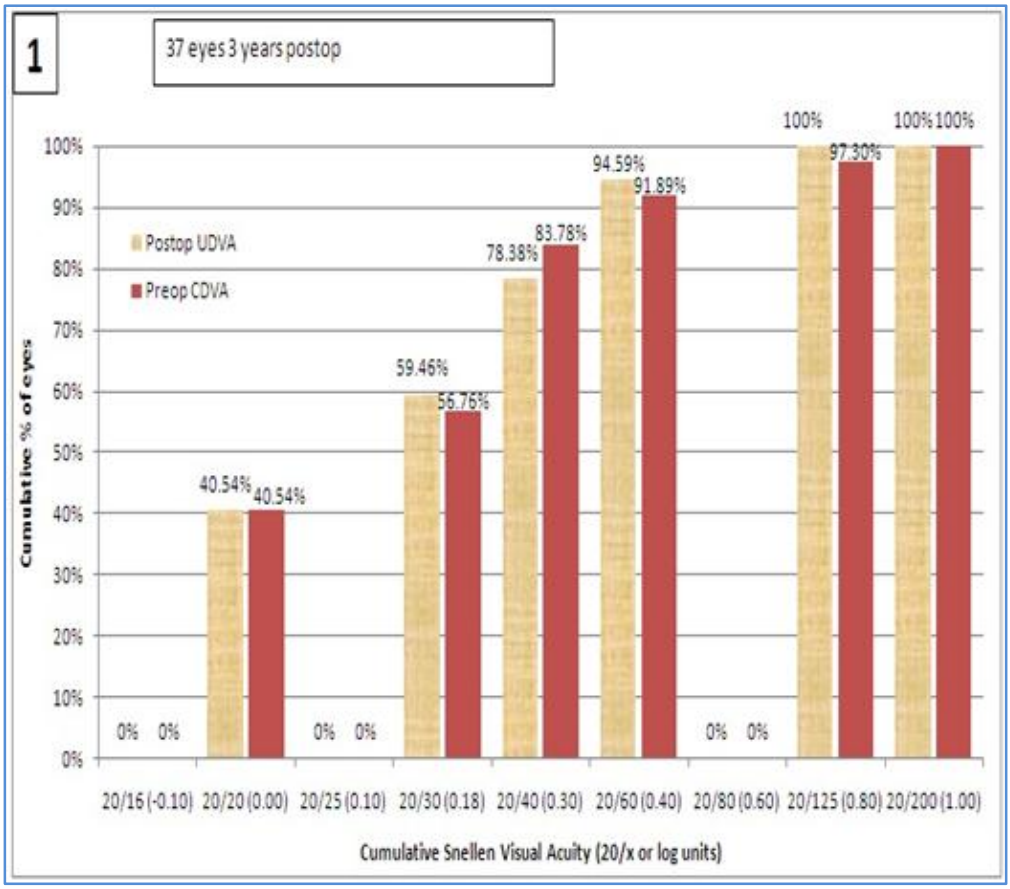
The present study has a follow up for a minimum of 3 years covering wide age range, with good efficacy, safety and accurate results comparable with reported excimer laser ablations, wave front guided or conventional.[21,22] This study results are quiet comparable to the earlier study.[20] Few studies have this length of follow-up. This study included the pediatric cases as well as presbyopic eyes. The paediatric eyes with some amount of amblyopia have improved (one line gain) and became independent of glasses. Few previous studies are available, conducting LASIK and PRK in children using Excimer Laser,[23-26] but this study included paediatric eyes for LASEK using solid state laser. It proves that it is easy to perform LASEK for the paediatric patients (12-14 years). There was no fixation problem during laser ablations, post-operative care was easy and procedures were done under topical anaesthesia.

This study has shown very good results, but the limitation is, it is not a comparative study showing comparative results using excimer laser in control group and the sample size is small. In this study, aberrometric changes and contrast visual acuities were not included. The Presbyopic age group patients were very happy, as they were not dependent on glasses for distant vision and adult patients are happy as well. The key to success in these two age groups (high level of satisfaction), is thorough counseling before surgery, explaining advantages and limitations. In conclusion the broad range of Hyperopic power and age groups were studied, performing the conventional LASEK using 213nm solid state laser results were safe, effective and stable, with high level of satisfaction, over a period of three years.



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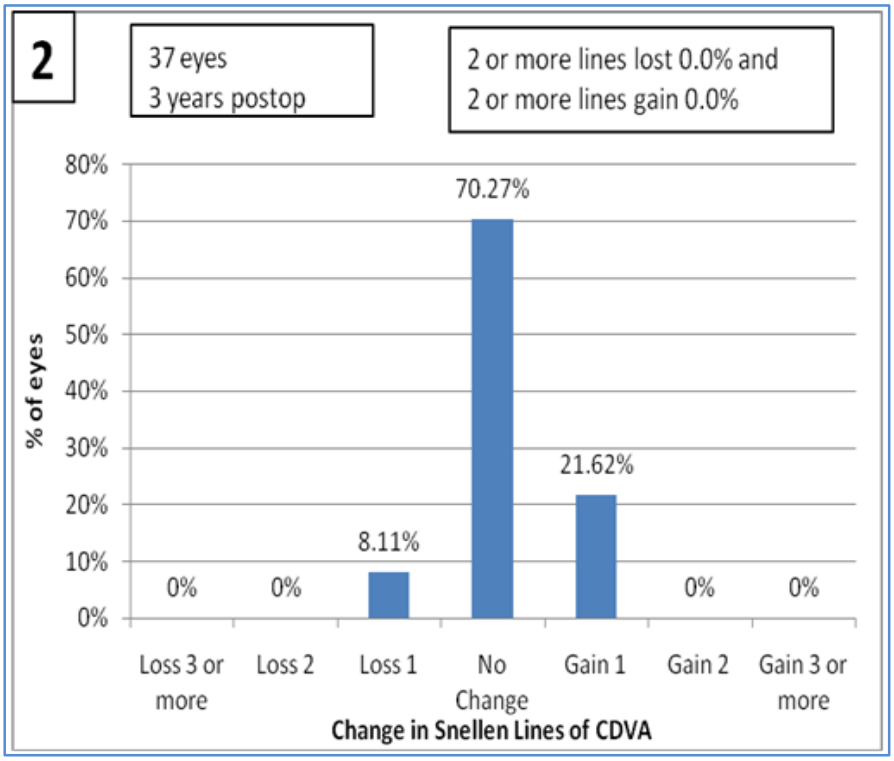

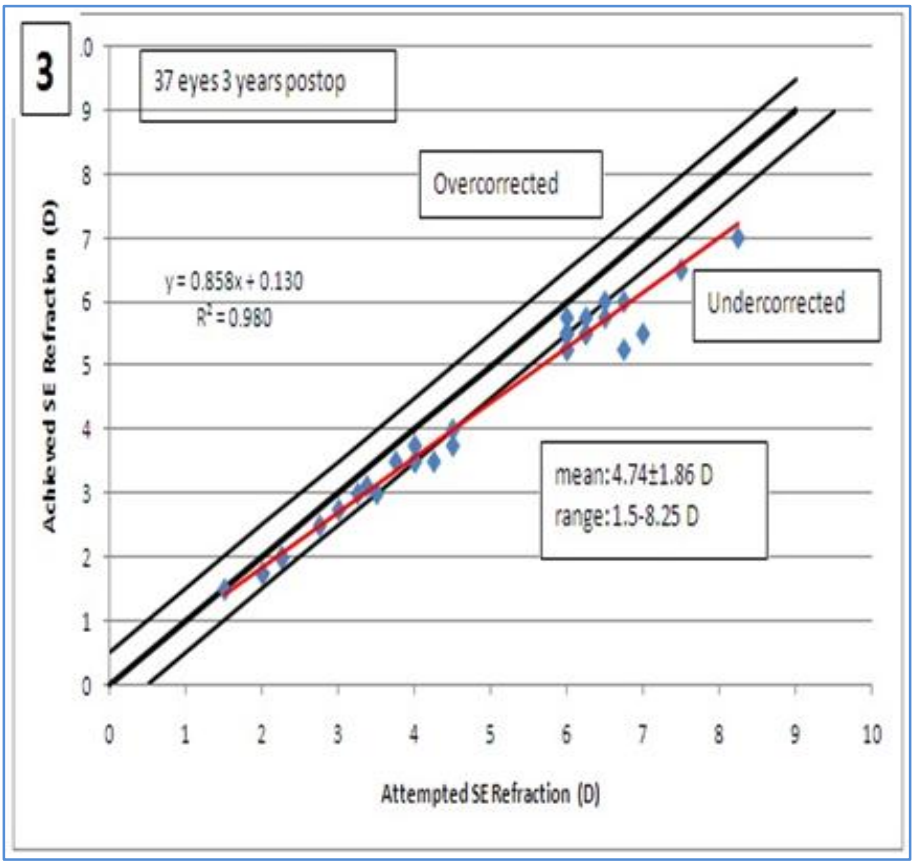

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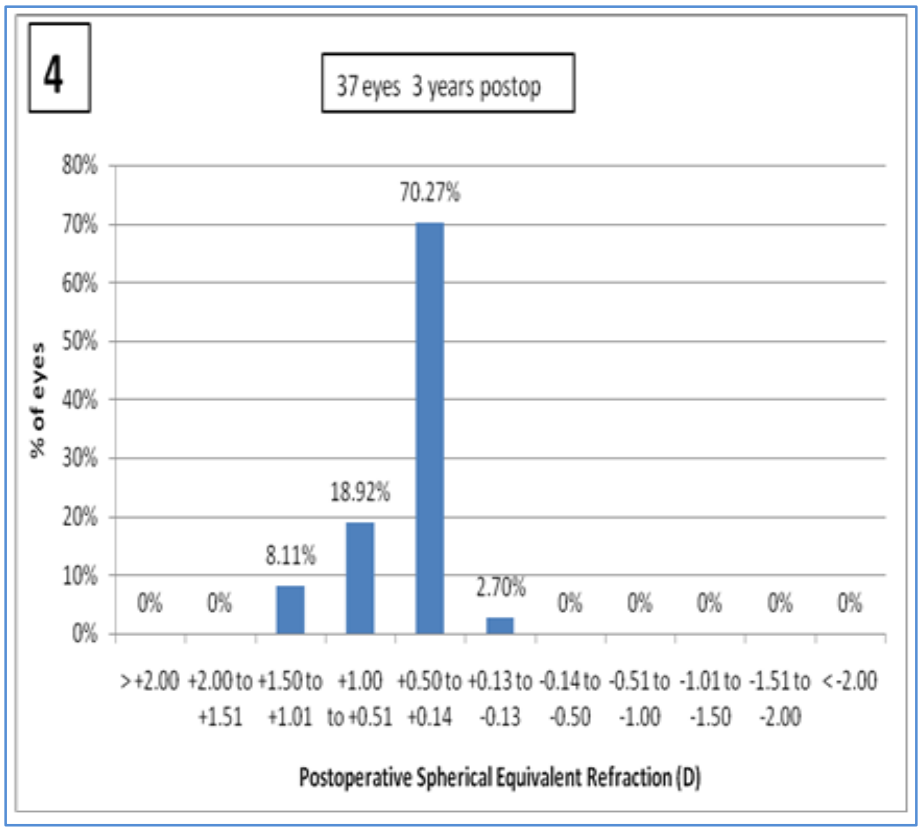

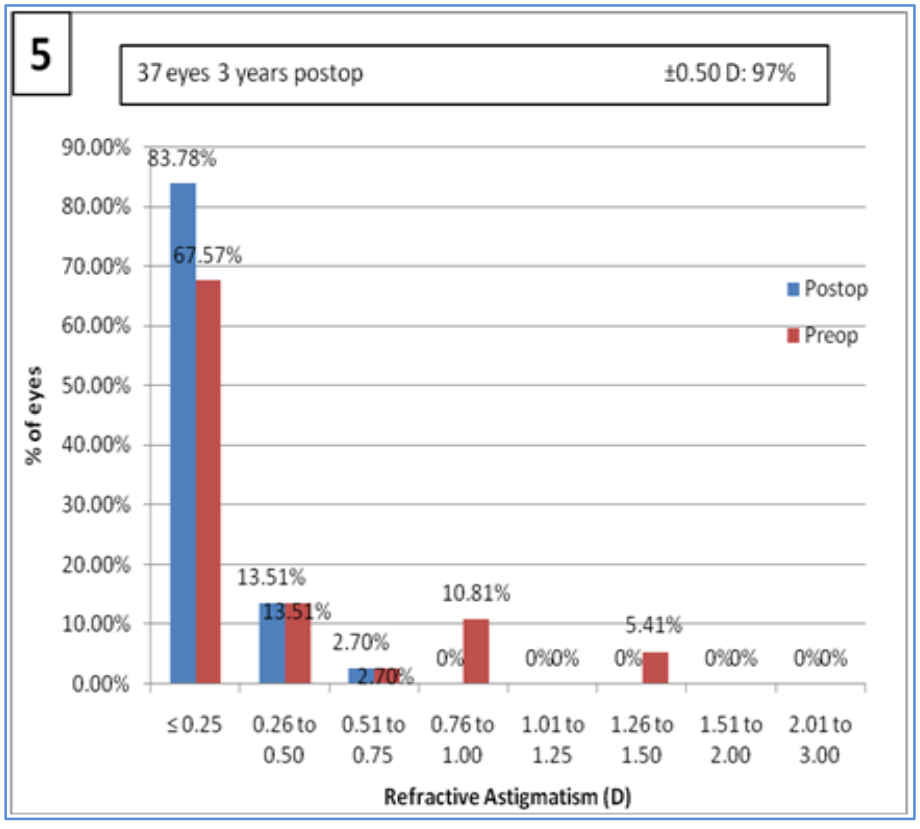

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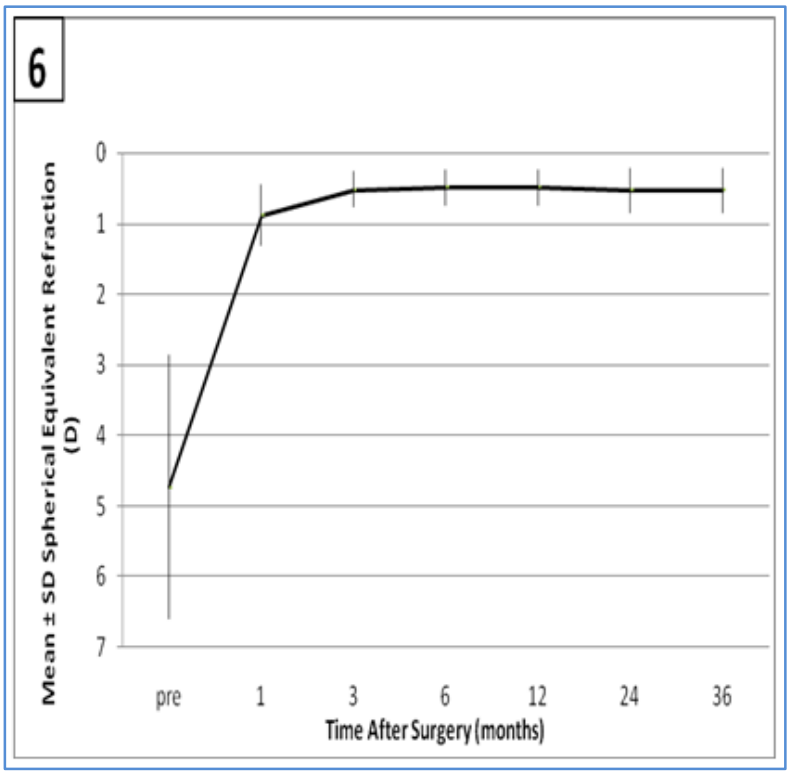

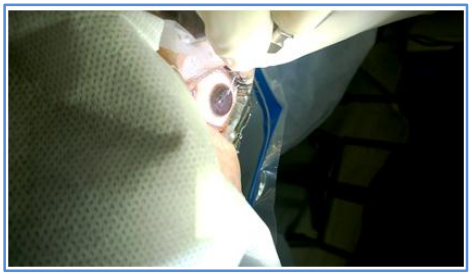

Figure 1

Figure 2

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