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Pain, wound healing and refractive comparison of mechanical and transepithelial debridement in photorefractive keratectomy for myopia: Results of 1 year follow-up

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ABSTRACT

Purpose: To compare the efficacy, safety and postoperative pain of mechanical versus transepithelial photorefractive keratectomy (PRK) techniques.
Setting: Cornea and refractive surgery subspecialty.
Design: Prospective clinical trial.
Methods: This prospective comparative study included 84 eyes of 42 patients with myopia who received mechanical PRK (m-PRK) in 1 eye and transepithelial PRK (t-PRK) in the contralateral eye. The mean patient age was 28.5 ± 6.3 years (range 20–46 years). Postoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refractions, postoperative epithelial healing time, surgical time, postoperative pain rating and corneal haze were recorded.
Results: At week 1, statistically the UDVA was significantly better in the t-PRK eyes; however, at 3 months, similar refractive stability was achieved in both groups. The mean spherical equivalent (SE) decreased from −2.44 ± 1.00 D (m-PRK eyes) and −2.88 ± 1.24 D (t-PRK eyes) at baseline to −0.19 ± 0.38 D and −0.30 ± 0.40 D, respectively, after 1 year. Surgical time was 98.6 ± 9.8 s in m-PRK eyes and 58.0 ± 6.4 s in t-PRK eyes. On postoperative days 1 and 3, using the global assessment rating, 81% of mPRK eyes that had pain, reported more pain than that reported for the tPRK eyes. In addition, m-PRK treated eyes demonstrated higher mean pain scores based on the 11-point numerical rating scale and Visual Analogue Scale (VAS). The mean time to complete epithelial healing was 2.19 ± 0.39 days (t-PRK) and 3.76 ± 0.43 days (m-PRK).
Conclusion: t-PRK for mild-to-moderate myopia was more comfortable than conventional m-PRK; patients had less pain, and faster healing time.

1. Introduction

The advents of excimer LASER refractive surgery heralded a new era in ophthalmic practice [1,2]. Evolution of both LASERs and surgical techniques has resulted in millions of patients having undergone LASER-based procedures [3]. Although LASER in situ keratomileusis (LASIK) is the most commonly performed LASER refractive corneal surgery in the world, surface ablation with photorefractive keratectomy (PRK) may be a safer option [4–11]. Flap complications and a higher risk of iatrogenic keratectasia in association with LASIK have driven the increased popularity of PRK [12–22]. In PRK, refractive surgical ablation is performed on the corneal surface after epithelial debridement. Postoperative pain and the potentially higher grade of corneal haze after PRK limits its usefulness and acceptance [23]. Several techniques of epithelial debridement have been attempted with PRK surgery, including mechanical debridement, LASER transepithelial ablation, a rotating brush and alcohol debridement [23]. Previous studies document that all of the epithelial debridement methods with PRK are effective procedures for the surgical correction of myopia [24–26]. In transepithelial PRK, the excimer LASER is used to ablate the epithelium, followed by ablating the underlying stroma [27]. For this purpose, several excimer LASER devices provide surgeons with the option of performing both surface ablation and LASER treatment in eyes.

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In this study we evaluated and compared the efficacy, safety and postoperative pain evaluation of mechanical and LASER-assisted epithelial debridement techniques of PRK for low-to-moderate myopia.

2. Materials and methods

This prospective comparative study included 84 eyes of 42 patients with myopia who had mechanical PRK (m-PRK) in 1 eye and transepithelial PRK (t-PRK) in the contralateral eye performed by two surgeons (OFY, AD). One eye in each patient was randomly chosen to have m-PRK, and the other eye had t-PRK. Patients were told that each eye would have a different epithelial debridement procedure but did not know which eye had m-PRK and which had t-PRK. Written informed consent was obtained from all patients prior to their participation in this study. Patients were informed in writing of the objectives, methods, benefits, and risks of the operations and they understood that they were participating in the study of their own free will. The research was approved by the hospital ethics committee. Patients in the study were treated from January to August 2010 and were followed-up for 12 months. All eyes were treated consecutively on the same day.

Inclusion criteria were: primary low-to-moderate myopia (−1.00 to −6.00 D), emmetropia as the targeted correction, absence of refractive media opacifications, and stable refraction for 1 year before the procedure. Patients with connective tissue diseases, serious medical conditions, dry eye, active ocular disease, suspected corneal ectasia and keratoconus, corneal dystrophy or degeneration, retinal disease, previous ocular surgery, glaucoma and diabetes were not considered candidates for surgery. Pregnant and lactating women were also excluded.

All patients had the same preoperative examinations: uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), cycloplegic and manifest refractions, biomicroscopy, tonometry, keratometry, corneal topography and dilated fundus examination by binocular ophthalmoscopy. Patients were instructed to discontinue wearing soft contact lenses 3 weeks before examination.

Preoperative medications consisted of Vigamox© drop (0.5% moxifloxacin, Alcon Co. Inc. Canada) and Alcaine® drop (proparacaine HCL, Alcon Co., Inc., Canada) every 5 min, 3 times. On the operating table, the eyelids were prepared with Betadine® solution (10% povidone-iodine).

At the start of m-PRK, the cornea was marked with a 9.0 mm trephine centred on the point at which the visual axis intersected the anterior corneal surface; mechanical epithelial removal was performed with a blunt spatula. In the Amaris excimer LASER (Schwind eye-tech-solutions GmbH & Co. KG, Mainparkstrasse, Kleinostheim, Germany), the LASER energy calculation was based on 2 ablation values per pulse; the first was for the epithelium (in which the LASER ablates more tissue per pulse) and the other for the stroma [32]. At the start of t-PRK, transepithelial removal was performed using the ORK-CAM software module mode of the excimer LASER with a diameter of 7.0–9.0 mm. All procedures were performed using the Amaris excimer LASER with a 6.68 ± 0.31 mm (6.0–7.56 mm) ablation zone and a 0.85 ± 0.33 mm (0.09–2.09 mm) transition zone for all patients. The LASER works at a true repetition rate of 500 Hz and produces a beam size of 0.54 mm full-width at half-maximum with super Gaussian spot profile [28]. High-speed eye tracking (pupil and limbus tracker with cyclotorsional tracking) with a 1050 Hz acquisition rate is completed within a latency time of 3 ms [29,30]. Immediately after the LASER ablation, the cornea was flooded with chilled balanced solution for 30 s in all procedures. Mitomycin C, which is frequently used to prevent postoperative haze, was not available in our national pharmacy departments at the date that the study was performed. Because of this reason Mitomycin C was not used in our study.

At the end of each procedure, a bandage contact lens was applied to the surface-treated eye and was kept in place until re-epithelialisation was complete. A drop of Vigamox© (0.5% moxifloxacin, Alcon Co., Inc., Canada) was administered to the treated eye. All patients were seen daily until the epithelial defect was completely closed and were instructed to apply 1 drop of both Vigamox© (5 times a day) and Voltaren© (0.1% diclofenac sodium, Novartis, AG Hettlingen, Switzerland) (3 times a day) and artificial tears every 2 h until the epithelium was healed. After the therapeutic contact lens was removed, Pred forte© (Prednisolone acetate 1% Allergan Inc., Irvine, USA) eye drops were administered 5 times daily in the first postoperative week, 4 times daily in the second week, 3 times daily in the third week, twice daily in the fourth week, and once a day in the fifth week. Oral pain medication was also prescribed in the first postoperative day (Acetaminophen, every 6 h).

The patients were examined every day until the epithelial defect had healed. Full refractive and visual assessment was performed at the end of the first week followed by 1, 3, 6, and 12 month intervals. Complete epithelialisation time was recorded. Subepithelial corneal haze levels were graded on a scale of 0–4 by slit lamp examination based on the system described by Epstein et al. [31].

Postoperative pain questionnaires were completed on day 1 and 3. The questionnaires were implemented by a physician who was masked to the eye-specific treatment method. The questionnaires were administered to each patient before their ophthalmic examinations. First, sensory pain in each eye was measured by a global subjective rating and then with 2 questionnaires of 1-dimensional scale: the VAS and the 11-point numeric scale of pain. In global subjective rating, patients were asked to state which eye hurt more and the response was recorded by the physician. The VAS of pain consisted of a 100 mm horizontal line with the words “no pain” anchored at the left end of the line and “worst possible pain” at the right end. These words were read to each patient and was specifically pointed out by the physician. All patients were then presented the 11-point numeric scale of pain, and were asked to state their pain intensity in each eye on a scale of 0–10. The questioning physician first explained to the patient that 0 represents no pain at all and 10 would be the worst pain imaginable. The physician then marked the responses given by the patient for the right and left eyes [23].

The safety was assessed by analysing the loss of CDVA and assessing the grade of corneal haze. Efficacy assessment was based on UDVA outcome. The change in mean cycloplegic spherical equivalance (SE) was plotted over time to determine long-term stability. The main outcome measures were transformed LogMAR values of CDVA and UDVA.

Data from all patients were entered into SPSS 15.0 to create a database and perform statistical analysis of the 2 groups. Paired samples t test was used to compare the UDVA, CDVA, and mean refractive SE, and the Mann–Whitney test was used to compare postoperative pain, corneal haze scores and epithelial healing time in the m-PRK and t-PRK eyes. A p value less than 0.05 was considered statistically significant.

3. Results

The mean age of the 24 men and 18 women was 28.5 ± 6.2 years (range 20–46 years). The preoperative mean SE was −2.44 ± 1.00 D (range −1.00 to −6.00 D) for m-PRK and −2.88 ± 1.24 D (range −1.00 to −6.00 D) for t-PRK. All eyes had refractive astigmatism less than −1.00 D. The mean refractive cylindrical value was −0.43 ± 0.34 D for the m-PRK and −0.33 ± 0.35 D for the t-PRK.