



## Original research

# Efficacy of corneal cooling on postoperative pain management after photorefractive keratectomy: A contralateral eye randomized clinical trial

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## Abstract

**Purpose:** To compare chilled and room temperature balanced salt solution (BSS) and bandage Contact Lens (BCL) on post photorefractive keratectomy (PRK) pain.

**Methods:** In a prospective, single-masked, controlled eye study, one hundred eyes of fifty patients were divided into two groups which received room temperature or chilled BSS and BCL in each eye, and compared for post-PRK pain. Three different pain evaluation systems were used to evaluate pain between the groups at 1 and 6 h and days 1, 2, 3, 5, and 7, postoperatively.

**Results:** 15 subjects were male (30%), and 35 were female (70%). The mean age was  $29 \pm 5$  (20–40) y/o. The mean spherical equivalent (SE) of preoperative refractive error in both groups was not statistically significantly different ( $-4.18 \pm 1.5$  in chilled and  $-4.19 \pm 1.7$  in room-temperature groups, respectively;  $P = 0.94$ ). The mean time of epithelial healing was  $6.16 \pm 1.7$  (3–13) days in the chilled and  $6.10 \pm 1.59$  (3–12) in the room temperature group ( $P = 0.32$ ). Best corrected visual acuity (BCVA) at 1 month was  $0.013 \pm 0.03$  (0–0.22) logMAR in the chilled group and  $0.014 \pm 0.04$  (0–0.22) logMAR in the room temperature group, postoperatively ( $P = 0.84$ ). No statistically significant difference was found between the two groups by any of the three pain scoring systems. No clinically important corneal haziness was found in the groups during follow-up.

**Conclusion:** Chilled BSS and BCL do not seem to be superior to room temperature in reducing post-PRK pain.

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**Keywords:** Photorefractive keratectomy; PRK; Balanced salt solution; Bandage contact lens; Cooling; Pain

## Introduction

For more than two decades, excimer lasers have been used for change of the corneal shape. In 1985 in Berlin, Theo Seilor treated corneal astigmatism in the first case of human eye with linear incisions which were created by an excimer laser. The first photorefractive keratectomy (PRK) was performed by Marguerite McDonald in 1988.<sup>1</sup> Surface ablation technique is one of the most common procedures for refractive error correction by excimer laser, especially in the range of mild to moderate myopia. Although photo refractive keratectomy (PRK) is the oldest of the surface ablation technique, with

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advances in laser technology, its results have improved, so that it is still a strong arm for refractive surgeon for ametropia correction. The advantage of PRK to LASIK is that there is no need for a flap creation and subsequent complication of flap, but pain that is the main limitation of PRK still exists.

The main cause of pain after PRK is baring of the corneal nerve after epithelial debridement, and it remains until epithelial repair occurs. For decreasing pain after PRK, various medical and surgical methods were suggested including: using bandage contact lens (BCL), dilute-tetracaine eye drops,<sup>1</sup> non-steroidal anti-inflammatory drugs (NSAIDs),<sup>2,3</sup> homatropine eye drops,<sup>4</sup> topical morphine,<sup>5</sup> trans-epithelial all surface laser ablation,<sup>6</sup> flap-off EPI-LASIK,<sup>7</sup> and LASEK.<sup>8</sup>

It is suggested that irrigation of the corneal surface with chilled solution diminishes pain by decreasing the thermal effect of the excimer laser. This effect of cooling may be due to decreasing prostaglandins and other inflammatory mediators. Furthermore, it has been shown that irrigation of the ocular surface with chilled solution after PRK for high myopia may diminish corneal haziness and regression of myopia.<sup>9</sup> However, these early studies were performed using older generation excimer lasers and postoperative regimen. Now, new excimer machines and effective pain medications are available. By using small flying laser spot, the temperature does not increase significantly during the ablation; therefore, inflammatory mediators might be released less in comparison with older laser machines. In this study, we evaluated the effect of chilled and room temperature balanced salt solution (BSS) and BCL on postoperative pain.

## Methods

Patients with myopia and myopic astigmatism who presented to our Eye Hospital for refractive surgery were enrolled in this study. Inclusion criteria were age between 20 and 40 years, spherical equivalent (SE) refraction between  $-1.00$  and  $-8.00$  diopters (D) with 3.00 D or less astigmatic error, stable refraction for at least 1 year, and preoperative best corrected visual acuity (BCVA) of 10/10 or better.

Exclusion criteria for this study included the presence of any ocular pathologic condition impairing visual function, any corneal dystrophies or abnormalities, keratoconus or keratoconus suspect, any previous ocular surgery, glaucoma or glaucoma suspect, diabetes mellitus, auto-immune diseases, pregnancy, breast feeding, and moderate-to-severe dry eye. All patients discontinued contact lens wear at least one month before refraction, topography, and aberrometric evaluation. We also excluded patients with a minimum corneal thickness less than 450  $\mu\text{m}$ , calculated residual thickness less than 400  $\mu\text{m}$ , and high-order wavefront root mean square (RMS) more than 0.50  $\mu\text{m}$  in a 6 mm optical zone.

The study followed the tenets of the Declaration of Helsinki. All patients were appropriately informed before their participation in this study, and after a complete ophthalmic examination and a thorough discussion of the risks and benefits of the surgery, all participants gave written informed

consent. We obtained full approval from the ethics committee of Mashhad University of Medical Sciences.

Before surgery, a detailed ocular examination was performed, including uncorrected visual acuity (UCVA), BCVA, slit-lamp examination, applanation Goldman tonometry, indirect funduscopy, manifest refraction, cycloplegic refraction, keratometry (Topcon KR8800Auto-kerato-refractometer, Tokyo, Japan), TMS-4 Topography (Tomey, USA), scanning slit corneal tomography (Orbscan IIz – Bausch & Lomb, Irvine, CA). Snellen acuity charts were used to measure UCVA and BCVA. The visual acuities were converted to logMAR for analysis.

One surgeon performed all surgeries using a flying-spot 193-nm excimer laser (Technolas217z, Bausch & Lomb, Irvine, CA) with a fixed pulse repetition rate of 100 Hz and a spot diameter of 1–2 mm. After sterile draping, the cornea was anesthetized with tetracaine 1% eye drops, and an eyelid speculum was placed. Ethyl alcohol 20% was then applied in a 9 mm well for 20 s, and the epithelium was removed with a hockey stick spatula.

Multidimensional rotational eye tracking was used during the ablation. The minimum optical zone was 6 mm, and equal optical zone was selected for both eyes of each patient. In all patients, a sponge soaked with mitomycin C 0.02% was applied over the ablated area for 5 s per each diopter of treatment. A BCL was placed following copious BSS irrigation of the ocular surface. The patients were randomly divided into two groups: one consisted of twenty-four and other was 26 patients. In the first group, BSS and BCL at room temperature (usually 21–23 °C) was applied to the right eye and chilled BSS and BCL (2–5 °C) to the left eye. In the other group, treatment was applied vice versa. Surgeons were unaware of the randomization. Then the ocular surface was irrigated with 30 cc BSS (chilled or room temperature). Finally, a drop of ciprofloxacin and a BCL (chilled or room temperature) were applied to the cornea, and speculum was removed.

Postoperatively, the patients were given Levofloxacin (Oftequix, Santen Pharmaceutical, Japan) for ten days and betamethasone 0.1% (Betasonate, Sina Daru, Iran) eye drops every 6 h. After complete re-epithelialization (usually on the fifth day), the BCL was removed. Betamethasone was used for one month and then fluorometholone 0.1% eye drop was started every 6 h and gradually tapered over 2 months. Preservative-free artificial tears were prescribed frequently in the first month and then tapered based on the ocular surface condition.

Three pain assessment systems were completed for each patient, including:

1. Visual Analogue Scale (VAS), consisting of a horizontal line, 10 cm in length, with a number from 0 to 10 in which, 0 is the lack of pain and 10 the most severe pain the patient experienced. The patient is asked to place a mark on the line that corresponds to the intensity of the pain he or she is experiencing.

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