ABSTRACT

PURPOSE: A major disadvantage of photorefractive keratectomy (PRK) is pain and discomfort in the first three postoperative days. We tried to assess the efficacy and safety to the cornea of a limited amount of topical tetracaine given to patients for use when needed to manage severe pain.

METHODS: Sixty-nine eyes of 49 patients who underwent PRK between June 21, 1996 and June 15, 1998 by a single surgeon were prospectively included. Approximately 10 drops of commercial, non-preserved 0.5% tetracaine were given to patients to use when needed to control severe pain. A bandage soft contact lens was applied. Patients were examined at 1 and 3 days after surgery, at which time corneal re-epithelization was assessed and the number of tetracaine drops used was noted. No systemic analgesic or topical non-steroidal anti-inflammatory was prescribed.

RESULTS: All eyes healed within 3 days. The mean number of drops of tetracaine used was 2.3 drops over 3 days, although in 33 eyes (48%) the patient did not use any tetracaine. There was no correlation between the attempted correction in diopters and the number of drops used. No significant difference was found in the number of drops used in the second eye of patients who had both eyes treated.

CONCLUSIONS: Limited use of topical anesthetics is an effective and safe analgesic option after PRK. Use of tetracaine in this protocol did not prolong the time to re-epithelialization. Giving only a limited amount of tetracaine to patients prevents abuse and toxicity to the cornea while managing severe pain. [J Refract Surg 2000;16:444-447]

C ases of persistent epithelial defects or even keratitis due to local anesthetic abuse have been reported.1,2 The use of topical anesthetics after photorefractive keratectomy (PRK) has, therefore, been viewed with some skepticism. One case of keratitis secondary to local anesthetic abuse after PRK has been reported.3 On the other hand, prospective studies found topical anesthetics did not delay the rate of epithelial healing; most patients heal within 4 days4 whether they use local anesthetics or not.5

Many PRK surgeons manage pain with narcotics, but this decreases the ability of the patient to function during the epithelial healing period. Topical anesthetics, topical non-steroidal anti-inflammatory agents, and bandage soft contact lenses are all part of our armamentarium to manage pain after PRK. In a study by Cherry, the combination of all three was found to be the most effective.6 A combination of preoperative and postoperative ketorolac7, a non-steroidal, with a bandage soft contact lens has also been found to be effective. The same applies to topical proparacaine with a contact lens, which prolonged epithelial healing only from 3.15 to 3.48 days compared to placebo.8

With this study, we intended to determine whether a limited amount of topical tetracaine to be used when and if needed to control severe pain, in combination with a bandage soft contact lens, would provide adequate pain control without delaying epithelial healing. Tetracaine was selected because it was commercially available as a non-preserved solution in a unit dose container. We used the number of tetracaine drops taken by the patient as an indirect indication of pain.
PATIENTS AND METHODS

All eyes undergoing PRK from June 21, 1996 to June 15, 1998 were prospectively included. There were 69 eyes in 49 patients. All treatments were performed by a single surgeon (TAD), and all follow-up examinations were done by the surgeon. PRK was performed using a Summit Apex or Apex Plus laser (Summit Technologies, Waltham, MA).

The eye was anesthetized with two drops of tetracaine 0.5% (Alcon Surgical, Fort Worth, Tx) just prior to treatment. A blunt-edged spatula was used to create a central epithelial defect approximately 7 mm in diameter. Following the ablation, a drop of antibiotic, a drop of corticosteroid, and a drop of a non-steroidal anti-inflammatory was placed on the eye. A -0.50-diopter (D) contact lens (SofLens66, Bausch & Lomb, Inc, Rochester, NY) was opened, and two drops of tetracaine were placed in the contact lens solution. The lens was then removed from the solution and placed on the eye.

The patient was instructed to use the antibiotic and corticosteroid four times per day. No topical non-steroidal anti-inflammatory was given to the patient, nor was any systemic analgesic prescribed. Patients were told to take oral acetaminophen or ibuprofen if desired.

The tetracaine was given to the patient in the original dropper bottle. It was previously determined that if Alcon’s proprietary bottle (DROP-TAINER) is one-fourth filled, it will dispense 10 drops. Therefore, each bottle was depleted to a one-fourth fill so that the bottle would dispense approximately 10 drops. Each patient was given identical, specific instructions to use the tetracaine drops in the event of pain that was not tolerable, but not to overuse them because they slowed the healing of the epithelium.

Patients were examined at 1 and 3 days postoperatively. At each examination the patient was asked how many drops of tetracaine had been used, and the bottle was inspected. The epithelium was examined and a determination was made as to whether it was completely epithelialized. The eyes were followed until complete epithelialization was achieved. One patient was lost to follow-up during the epithelialization period.

Data was entered into an Excel spreadsheet (Microsoft Corporation, Redmond, Wa), which was also used for analysis.

RESULTS

The average spherical equivalent refraction in the 69 eyes before PRK was -4.40 D (range, -1.00 to -6.75 D); after PRK it was -0.042 (range, -0.75 to +2.50 D). Our patients used on average 2.3 tetracaine drops. Nearly half of the patients (33 patients; 48%) did not use any drops at all. Seven used the entire amount (Figure).

No patient had an epithelial defect when seen 3 days postoperatively. Five patients came in 1 day late (4 days postoperative), and seven 1 day early (2 days postoperatively); all had healed. One patient was lost to follow-up. None of the 36 patients who used tetracaine developed corneal toxicity.

In 20 patients who had both eyes operated, there appeared to be no difference between the pain experienced in the first eye done (2.15 ± 2.98 drops of tetracaine used) compared to the fellow eye that was operated at a later time (2.00 ± 3.64 drops). There was no statistically significant difference (P = .89), although the number of patients (n = 20) was small. Approximately one-third of these patients used more drops after their first PRK, one-third used more drops after their second PRK, and one-third used the same number of tetracaine drops after each operation.

We attempted to correlate the amount of refractive correction in diopeters (diopters after PRK minus diopters before PRK) to the amount of pain as shown by the number of tetracaine drops used, however, there was no statistically significant correlation (r = 0.154).

Another observation was the similarity of the pain threshold between men and women (2.0 ± 3.2 vs 2.6 ± 3.3 tetracaine drops used, P = .54).
DISCUSSION

It has been suggested that pain after PRK peaks within the first 24 hours postoperatively\textsuperscript{4,7}, then drops below the threshold of pain to the spectrum of discomfort for 2 more days.\textsuperscript{2,5} The epithelial defect, on the other hand, persists for approximately 3 days.\textsuperscript{5,6}

The side effects of topical anesthetics have been outlined by Rosenwasser and colleagues\textsuperscript{10}: anesthetics and their preservatives decrease the tear film stability and tear break-up time by disrupting the surface microvilli. To minimize this problem we used 0.5\% tetracaine in a preservative-free preparation. The reflex tearing mechanism is also blocked, adding to corneal desiccation. This might be the pathophysiology of punctate keratitis associated with local anesthetic use, although hypersensitivity mechanisms and intraepithelial protein precipitation have also been implicated.

The most disastrous potential complication from the use of a topical anesthetic is bacterial keratitis. One could argue that a patient with an anesthetic cornea would not notice a brewing infection as rapidly as with a sensate cornea. We followed these patients closely, examining them at 1 and 3 days after treatment and until the epithelium was completely healed. In addition, by giving the patient only 10 drops, we attempted to ensure that there would be insufficient tetracaine to last for more than a short period.

The patient with keratitis secondary to local anesthetic abuse after PRK\textsuperscript{3} had secretly abused topical proparacaine over a period of 6 months, and had a penetrating keratoplasty and recurrence of erosion on the graft before he was unmasked. Our patients seemed to use their drops responsibly. They often remarked that they would have used a drop, but knew that the pain was not sufficient to warrant slowing epithelial healing. This seems to emphasize the importance of fully explaining the rationale behind dispensing only a small number of drops.

Non-steroidal anti-inflammatory agents have also been proposed for pain control after PRK, with some controversy about whether they provide more relief than local anesthetics. In the study by Cherry\textsuperscript{6}, there did not appear to be a significant difference in pain control between the group that used tetracaine and the group that used diclofenac. We elected not to provide the patients with diclofenac to take home, both because of the cost and the fact that some cases of stromal infiltrates have been reported after non-steroidal use, estimated to occur in 1/250 to 1/300 to cases.\textsuperscript{9-11}

Our study suggests that adding a second drug, such as a topical non-steroidal, might not be necessary, since most of our patients did not use all 10 drops of the tetracaine that were available to them. Our patients were not given any narcotics, and were told to take oral acetaminophen or ibuprofen if desired. We avoided the use of narcotics, as many of our patients worked during the epithelial healing period, and narcotic usage might have impaired their ability to travel and work.

One conclusion we can draw is that around-the-clock administration of topical anesthetics might not be necessary, as half our patients (33 of 69) did not use any tetracaine drops. Determining their own need and time for analgesia also provides patients with the feeling of control over their pain. On the other hand, in seven cases the patient used all of the tetracaine provided, suggesting some patients have a lower pain threshold than most.

The use of a bandage soft contact lens after PRK has been shown to be safe and not to delay epithelial healing.\textsuperscript{5,9,12,13} It has been proposed that the contact lens might act as a sponge that absorbs, then slowly releases topical anesthetics.\textsuperscript{6} This is a way to avoid excessively high (toxic) or low levels of tetracaine, which would impel the patient to use more of it. In our practice, we apply the tetracaine on the contact lens before inserting it, rather than directly on the eye. This may have contributed to less pain during the first several hours after treatment.

Subepithelial infiltrates associated with the use of bandage contact lenses have been reported.\textsuperscript{13,14} Cases of keratitis attributed to bandage contact lens use after PRK also exist in the literature.\textsuperscript{15,16} In our study and in our practice we have not encountered such complications.

There were several disadvantages to this study. Although the data were collected in a prospective manner, cases were not randomized or masked to the patient or surgeon. Both eyes of some patients were considered, and it would not be expected that there would be an independent reaction to pain in the two eyes. The patients were not examined daily, and so the rate of epithelialization cannot be fully understood from these data. All that can be concluded is that the eyes became epithelialized in the expected time frame of untreated eyes. Finally, we
used the use of tetracaine drops as an indirect measurement of pain, but some patients did have pain that they chose not to treat.

The additive analgesic effect of tetracaine with a bandage soft contact lens has been addressed in studies with a scale-rated quantitative approach to pain. This was not the purpose of our study, but rather to provide evidence that a limited quantity of topical tetracaine combined with a bandage soft contact lens can safely be provided after PRK for use when needed rather than around the clock within the first 3 postoperative days. With proper counseling, a delay in epithelial healing is unlikely and patients benefit from adequate self-determined management of pain.

REFERENCES