

## Original Article

# Comparing the Rate of Regression after Conductive Keratoplasty with or without Prior Laser-Assisted *in situ* Keratomileusis or Photorefractive Keratectomy

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### ABSTRACT

**Purpose:** To assess the regression rate of conductive keratoplasty (CK) in patients with or without previous laser-assisted *in situ* keratomileusis (LASIK) or photorefractive keratectomy (PRK).

**Setting:** University of Utah, Medical School, John A. Moran Eye Center, Salt Lake City, Utah.

**Materials and Methods:** A retrospective, age-matched chart review identified records of 6 patients who underwent CK after refractive surgery and 12 patients who underwent CK without prior refractive surgery. The main outcome measures were postoperative uncorrected and corrected visual acuities and refraction changes over time.

**Results:** Preoperatively, the mean manifest refraction spherical equivalent (MRSE) of the 15 eyes (12 patients) that underwent CK without refractive surgery was 0.83 diopters (D) and the 7 eyes (6 patients) that underwent CK after refractive surgery had an average MRSE of 0.27 D. Postoperatively, the mean MRSE of the refractive surgery patients was -0.86 D at 6 months, regressing to -0.67 D at 12 months. The postoperative MRSE in the eyes without refractive surgery was -0.58 D at 6 months, regressing to -0.38 D at 12 months. The rate of regression was linear in both groups, calculated at 0.033 D per month in all patients.

**Conclusions:** Patients with previous LASIK or PRK showed a greater treatment response to CK but regressed at a similar rate as those eyes without prior LASIK or PRK. Overall CK is a safe procedure that inevitably regresses.

**Key words:** Conductive Keratoplasty, Laser-assisted *in situ* Keratomileusis, Overcorrection, Photorefractive Keratectomy, Regression

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### INTRODUCTION

Conductive keratoplasty (CK) utilizes radiofrequency energy delivered at 8–24 locations based on a patient's refraction to cause localized collagen shrinkage. This steepens the central cornea to correct hyperopic refractive errors up to 3.25 D of hyperopia.<sup>1</sup> CK is also a popular option to treat presbyopic patients by correcting the dominant eye for distance vision and the non-dominant eye for near or intermediate vision.<sup>2</sup> After the US Food and Drug Administration approval for hyperopia in 2002, it was hoped that CK would become the standard

treatment for both presbyopia and hyperopia. However, it became apparent that CK was similar to other methods of hyperopic correction in that regression to pretreatment manifest refraction was observed.<sup>1</sup>

CK is also effective in correcting refractive surgery-induced hyperopia, especially when a thin residual stromal bed precludes further corneal ablation treatment. Interestingly, CK after refractive surgery requires a reduced number of treatment spots compared to eyes without previous refractive surgery.<sup>3,4</sup> In this study, we compare the refractive outcomes and rates of regression in patients that

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underwent CK after laser-assisted *in situ* keratomileusis (LASIK) or photorefractive keratectomy (PRK) and a control group of eyes that underwent CK without prior refractive surgery.

## MATERIALS AND METHODS

### Study design

In a retrospective, single-center study, a chart review was conducted of 52 patients who underwent CK at the John Moran Eye, Department of Ophthalmology and Visual Sciences, University of Utah, between 2004 and 2011. Eligibility requirements for CK to treat hyperopia were patients with +0.75 to +3.25 D of refractive error, with no more than 1.0 D of astigmatism. Patients were eligible for CK treatment of presbyopia if the desired correction was between 1 and 2.25 D to achieve a myopic endpoint of -1.25 to -1.75 D in their nondominant eye.

Of the 52 patients, 6 patients (7 eyes) had CK after LASIK or PRK. All patients underwent LASIK for myopic correction except one patient who had LASIK to correct hyperopia [Table 1]. The average time since LASIK surgery was 31 months with a range of 6–90 months. Of the 46 patients who underwent CK without prior refractive surgery, only 12 age-matched controls (15 eyes) had adequate clinic data for analysis [Tables 2 and 3]. Of the refractive surgery patients, four eyes underwent CK to treat hyperopic overcorrection with an emmetropic target and three eyes for monovision correction. Of the patients without refractive surgery, 13 eyes underwent monovision correction and 2 eyes for hyperopia correction with an emmetropia target.

The main outcome measures were postoperative-uncorrected and -corrected Snellen visual acuities and refraction changes

over time. Complications were recorded from follow-up visit notes.

### Surgical procedure

Two surgeons (MM and MDM) performed all CK procedures using a ViewPoint CK system (Refractec, Inc.) and standard parameters (0.6 W, 0.6-s exposure time per spot). The target refraction was myopia or emmetropia. A standardized nomogram was used to determine the number and placement of treatment spots on the cornea, using a light touch technique.<sup>2</sup> The light touch technique is a modification of the number of spots, the diameter of the spot placement, and the amount of pressure used by the surgeon.

**Table 1: Patient demographics and preoperative refraction of both groups**

	Controls	CK after LASIK/PRK	P values
Patient-level variables			
	[n = 12 patients]	[n = 6 patients]	
Female, n (%)	7 (58)	5 (83)	0.60 <sup>a</sup>
Age (years), mean ± SD	54 ± 7	56 ± 5	0.63 <sup>b</sup>
Follow-up time, (months)	17 ± 14	24 ± 17	
Mean ± SD (min-max)	7–47	6–46	0.36 <sup>b</sup>
Eye-level variables			
	(n = 15 eyes)	(n = 7 eyes)	
Preoperative sphere (D), mean ± SD	0.64 ± 0.82	0.00 ± 1.04	0.22 <sup>c</sup>
Preoperative cylinder (D), mean ± SD	0.38 ± 0.19	0.54 ± 0.47	0.27 <sup>c</sup>
Preoperative spherical refractive equivalent (D), mean ± SD	0.83 ± 0.80	0.27 ± 1.08	0.36 <sup>c</sup>

<sup>a</sup>Fisher's exact test, <sup>b</sup>independent sample t-test, <sup>c</sup>mixed effects linear regression with eyes nested within patient

**Table 2: Preoperative and postoperative UDVA, CDVA, and manifest refraction of CK patients without prior refractive surgery**

Patient/eye	Preop UDVA	Preop CDVA	Preop Refraction (D)	Total follow-up (months)	Postop UDVA	Postop CDVA	Final refraction (D)	No. of spots	Optical zone (mm)
1/L	20/30	20/20	-0.75 + 0.5 × 155	46	20/40	20/25	-1 + 0.5 × 168	8	8
2/R	20/30	20/15	0.5 + 0.5 × 121	7	20/25	20/20	0 + 1 × 133	8	8
3/Both	20/70	20/20	1.5 + 0.25 × 45	44	20/30	20/20	-1.5 + 1 × 41	16	7,8
	20/70	20/20	1.5 + 0.25 × 45	44	20/30	20/20	-0.25 + 0.8 × 19	8	7
4/R	20/20	20/20	-0.25 + 0.5 × 4	17	20/100	20/20	-2.5 + 1.5 × 3	16	7,8
5/L	20/30	20/20	0 + 0.5 × 3	10	20/30	20/20	-0.25 + 1.25 × 7	8	6
6/Both	20/100	20/20	1.5 + 0.25 × 40	7	20/25	20/25	-1.5 + 1.25 × 165	14	7,8
	20/100	20/20	1.75 sphere	7	20/25	20/20	-0.25 + 1.25 × 170	8	6
7/R	20/20	20/15	-0.25 0.25 × 152	16	20/70	20/15	-1.75 sphere	24	6,7,8
8/R	NR	NR	NR	12	20/80	20/20	-1.75 + 0.5 × 143	16	7,8
9/L	20/15	20/15	-0.25 + 0.25 × 13	17	20/70	20/20	-1.75 + 1 × 6	16	6,7
10/Both	20/60	20/15	0.75 + 0.25 × 178	7	20/50	20/20	-1+0.5 × 150	16	7,8
	20/30	20/15	0.75 + 0.5 × 45	7	20/50	20/20	0+0.25 × 16	8	6
11/R*	20/40	20/20	1+0.5 × 161	7	20/25	20/15	0+0.75 × 146	8	7
12/R*	20/25	20/20	1.25 + 0.75 × 133	10	20/20	20/15	-0.25 sphere	8	7

R: right, L: left, NR: not recorded, \*All patients underwent monovision correction except for 11 and 12 who were treated for hyperopia with emmetropia target

The postoperative target refraction determined the number of CK treatment spots (8 or 16) and optical zone used (6, 7, or 8 mm). Because the effect of CK is exaggerated in patients who have had previous PRK or LASIK, the intended CK correction was reduced by 30–50% in the post-LASIK/PRK eyes.<sup>3,5</sup>

**Statistical analysis**

All statistical comparisons were performed using Stata version 12 statistical software (College Station, TX; StateCorp LP). All reported *P* values are from a two-sided comparison.

**RESULTS**

The average age of the patients with LASIK/PRK induced hyperopia was 56 years and the average age of control patients was 54 years. The gender distribution was 5 males and 7 females in the controls and 1 male and 5 females in the refractive surgery group [Table 1]. Prior to refractive surgery, the mean manifest refraction spherical equivalent (MRSE) in the seven eyes with refractive surgery was -3.73 D (range -7.5 to 0.625 D, SD 2.7 D). Prior to CK, the average MRSE of these eyes (post-LASIK or PRK/pre-ck) was 0.27 D (range -1 to 2 D, SD 1.08 D). The 15 control eyes had a preoperative MRSE of 0.83D (range -2.625 to 1 D, SD 0.80D) [Tables 1–3].

Safety was measured by a loss of more than two lines of best spectacle-corrected visual acuity (BSCVA) in treated eyes. We found that no eye had lost two or more Snellen lines at 6 months follow-up and all eyes had a BSCVA of 20/25 or better [Figure 1]. Complaints after CK surgery included minor pain (three patients), foreign body sensation (one patient), tearing (one patient), and burning sensation (two patients). All complaints resolved by 4 weeks postoperatively.

**Regression of conductive keratoplasty**

The mean follow-up was 18.6 months (range 5–47 months) in patients with prior refractive surgery and 16.7 months (range 7–46 months) in the control eyes.

Postoperatively, the mean MRSE of patients with previous LASIK/PRK surgery was -0.86 D at 6 months, regressing to -0.66 D at 12 months [Figure 2]. The postoperative MRSE in the control patients was -0.57D at 6 months regressing to -0.38 D at 12 months [Figure 2].

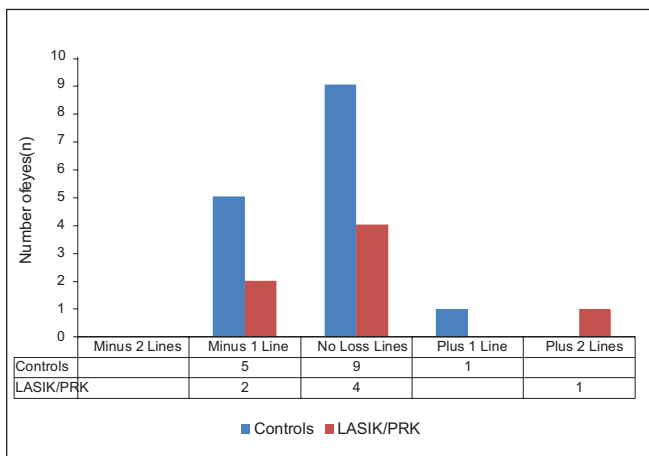
**Conductive keratoplasty treatment effect**

The mean number of CK treatment spots used for eyes with refractive surgery was  $9.6 \pm 3.0$  with a pre- to postoperative MRSE change of 1.43 D at 1 month [Table 4]. The average number of CK treatment spots used for the controls was  $12.1 \pm 5.0$  with

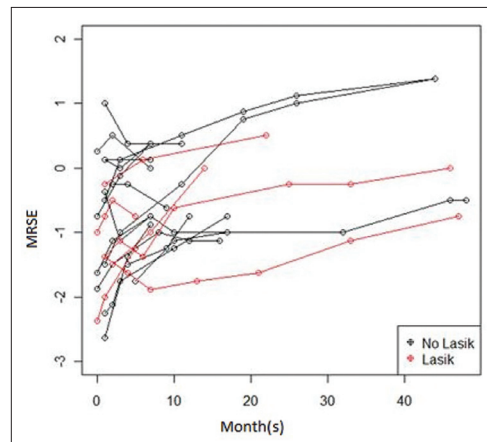
**Table 3: Preoperative and postoperative UDVA, CDVA, and manifest refraction of CK patients with prior refractive surgery**

Patient/eye	Preop UDVA	Preop CDVA	Preop Refraction (D)	Total months follow-up	Postop UDVA	Postop CDVA	Final refraction (D)	No. of Spots	Optical zone (mm)
1/L	20/20	20/20	-0.25 + 0.25 × 5	46	20/70	20/25	-1.75 + 0.75 × 180	8	8
2/R	20/40	20/30	-1.75 + 1 × 85	47	20/70	20/20	-2.25 + 0.75 × 94	8	6
3/R	20/50	20/20	-1 sphere	6	20/40	20/20	-0.75 sphere	8	7
4/ Both**	20/50	20/20	0.75 sphere	22	20/20	20/20	0 + 0.25 × 11	16	6,7
	20/50	20/20	0.5 + 0.5 × 105	22	20/20	20/20	0 + 0.25 × 156	11	6,8
5/R**	20/80	20/20	1 + 1 × 105	5	20/40	20/20	-1.25 sphere	8	6
6/L***	20/20	20/20	0 + 0.5 × 90	14	20/40	20/20	-1.25 + 0.5 × 165	8	NR

R: right, L: left, \*All patients underwent LASIK for correction of nearsightedness except patient 2 that had LASIK to correct farsightedness, \*\*All patients underwent monovision correction except for patients 4, 5, 6 who were treated for hyperopia with emmetropia target, \*\*\*All patients underwent LASIK correction except for patient number six who had PRK



**Figure 1:** Safety: change in BSCVA compared with preoperative BSCVA (*n* = 22 eyes)



**Figure 2:** MRSE regression in CK patients with and without prior LASIK/PRK at 50 months (*n* = 22 eyes)

a pre- to postoperative MRSE change of 1.73 D [Table 4]. Using mixed effects linear regression and controlling for the difference in number of treatment spots and preoperative refractive error, the prior refractive surgery patients showed a greater treatment effect of 0.42 D of MRSE at 1 month [Table 5].

### Regression analysis

Considering the follow-up visits could be nested within eyes, repeated measure analysis using a hierarchical model was performed. All preoperative and postoperative variables including demographics, pre- and postoperative refraction, the length of time from refractive surgery to CK, the number of CK treatment spots, and the optical zone(s) used for the CK treatment were analyzed. This regression indicates that time since surgery was the only variable found to be significantly related to MSRE when all data points were used up to 50 months ( $P = 0.000$ ). When controlling for whether or not an individual had refractive surgery, every 1 month increase in time since CK surgery led to an increase in MSRE of 0.033 D. These results suggest that both groups had equal, linear rates of regression at each month. In addition, on average at any given month the MRSE for eyes that have had LASIK/PRK is 0.38 D lower than non-LASIK/PRK eyes. This 0.38 D of difference is explained in part by a lower mean preoperative MRSE of 0.56 D in the LASIK/PRK group compared to the controls. Indeed, with a  $P$ -value of 0.274, there is insufficient evidence to conclude the difference is statistically significant. Analysis of data collected up to 6, 12, and 30 months also found no significance between refractive surgery and control patients.

## DISCUSSION

The purpose of this study was to examine the regression rate after CK in patients with or without prior refractive surgery. Regression rates after CK have a reported range of 0.02 D (1) to 0.04D (2) of MRSE per month. Our patients demonstrated

a similar rate of regression at 0.03 D per month ( $P = 0.00$ ).

By studying corneal histological changes after CK, Esquenazi *et al.* have demonstrated the regression of CK is due to a wound healing response.<sup>6</sup> Initially there is a rapid activation of myofibroblasts in the CK treatment areas. It is likely that these contractile cells contribute to the purse-string tightening and steepening of the cornea. However, over time as the numbers of myofibroblasts in the wound site diminish, so does the refractive correction of the procedure.<sup>6</sup>

Although the LASIK/PRK eyes regressed at a similar rate as the controls, there was a greater treatment effect in the LASIK/PRK eyes. After controlling for the number of spots and preoperative measurements, the LASIK/PRK eyes demonstrated a greater myopic shift of 0.42 D after 1 month. Tomita *et al.* reported similar findings despite setting the refractive target to 20–30% less than the standard nomogram.<sup>5</sup> This greater refractive outcome may be attributed to structural changes caused by flap creation or excimer ablation. As the central corneal thickness is more reduced than the peripheral regions, the corneal elasticity is decreased.<sup>4,6</sup> This induces a strong steepening effect, which results in an approximate doubling effect of CK when compared with eyes without a refractive surgery history.<sup>5</sup>

We found CK to be a safe procedure with no eye losing two or more Snellen lines at 6 months of follow-up and all eyes had a BSCVA of 20/25 or better. The most common complaints were blurry vision and minor pain which resolved by 4 weeks postoperatively without sequela.

Due to CK's safety profile, CK remains an appealing option for several patient populations. As LASIK has become the most popular choices for the correction of refractive error, we expect that the number of patients seeking treatment after LASIK will increase. In

**Table 4: Postoperative refraction changes at 1 month postoperatively of both groups**

	Control eyes ( $n = 15$ eyes)		CK after LASIK/PRK eyes ( $n = 7$ eyes)	
	Refraction	Pre- to postoperative change	Refraction	Pre- to postoperative change
Postoperative sphere (D), mean $\pm$ SE	-1.30 $\pm$ 0.31	1.94	-1.39 $\pm$ 0.34	1.39
Postoperative cylinder (D), mean $\pm$ SE	0.80 $\pm$ 0.15	0.42	0.46 $\pm$ 0.21	0.08
Postoperative MRSE (D) mean $\pm$ SE	-0.90 $\pm$ 0.27	1.73	-1.16 $\pm$ 0.28	1.43

**Table 5: Difference of CK treatment effect among the controls and refractive surgery patients**

Characteristic	Mean difference of pre- to postoperative change between groups*	$P$ value	Mean difference adjusted for preoperative measurements and number of treatment spots*	$P$ value
Postoperative sphere (D)	0.15 (-0.91, 1.21)	0.78	-0.40 (-1.68, 0.94)	0.58
Postoperative cylinder (D)	-0.36 (-0.99, 0.27)	0.27	-0.23 (-0.91, 0.44)	0.50
Postoperative MRSE (D)	-0.14 (-1.04, 0.77)	0.77	-0.42 (-1.29, 0.46)	0.35

\*The difference (refractive surgery group minus controls) and 95% confidence interval is the difference in the one-month postoperative means, adjusted for the preoperative refractive measurements and number of treatment spots, using a mixed effects linear regression with eyes nested within patient. This can be interpreted as the mean difference in amount of change from pre to post surgery (positive value is less change with refractive surgery, negative value is more change with refractive surgery)

patients with refractive surgery, CK avoids flap manipulation and further laser ablation. CK is especially useful in patients with thin corneas, thin flaps, multiple previous eye surgeries, or epithelial basement membrane dystrophy where further LASIK or PRK may expose the patient to unnecessary risk.<sup>7</sup>

CK may also be preferable to LASIK and PRK for low hyperopes who have very flat corneas or dry eyes. In addition, CK may be a reasonable bridge for low hyperopes with early cataracts with a refractive error too small to consider clear lens extraction. Finally, CK remains a viable option for presbyopic near-vision correction.

A major weakness of this study is the small sample size, which lacks the power required to demonstrate significant differences between the control and refractive surgery patients. Another weakness is the inclusion of both right and left eyes in three patients, which are not independent variables. The limited number of patients with different targets of emmetropia versus presbyopic targets made it difficult to match these characteristics between the two groups.

Despite these limitations, patients with previous LASIK or PRK showed a better response with similar regression after CK compared to those without refractive surgery. Overall, we found CK to be a safe procedure that inevitably regresses.

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