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The effect of previous soft contact lens wear on corneal refractive surgery outcomes☆

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ABSTRACT

Purpose: To examine the influence of previous soft contact lens (SCL) wear on corneal refractive surgery (CRS) outcomes when SCL wear is ceased for two weeks versus twenty-four hours, and also when compared to no wear, prior to CRS.

Methods: A retrospective examination of CRS patient records was carried out for two groups of patients- who ceased SCL wear for two weeks (n = 45) and for twenty-four hours (n = 49) prior to CRS and compared to a non-contact lens (NCL) control group (n = 45 and n = 49, respectively). CRS outcomes (efficacy, predictability, visual acuity and refractive error) were compared pre-operatively and one and six months post-operatively.

Results: One month post-operative results found unaided distance visual acuity (UDVA) was significantly better for LASEK/PRK patients who had ceased SCL wear for two weeks prior to CRS (-0.05 ± 0.09), compared with the NCL group (0.02 ± 0.09; $p = 0.04$). Furthermore, six month post-operative results found UDVA was significantly better for both LASIK and LASEK/PRK patients who had ceased SCL wear for two weeks prior to CRS, and for LASEK/PRK patients who had ceased SCL wear for twenty-four hours prior to CRS compared with the NCL group.

Conclusions: Given the current setup and methods followed, it was concluded that previous SCL wear had no negative impact on visual outcomes following CRS compared with a NCL control group, regardless of previous SCL cessation time prior to CRS.

1. Introduction

Corneal refractive surgery (CRS) involves ablation of stromal tissue to change corneal curvature and thickness, thereby correcting refractive error of the eye [1,2]. Patient satisfaction with the post-operative outcomes is dependent on the ability of the procedure to achieve emmetropia and maintain levels of unaided distance visual acuity (UDVA), which are similar to preoperative levels of best-corrected spectacle visual acuity (BCSVA) [3]. The outcomes of CRS are dependent on the accuracy of the pre-operative topographic and pachymetry measurements which aid to determine the appropriateness of the CRS procedure chosen. SCL wear has been found to result in significant changes to mean keratometry, corneal astigmatism and corneal eccentricity [4]. SCL- induced corneal oedema results in increased corneal thickness in response to hypoxia, and over long periods of time, SCL wear can result in chronic changes to corneal metabolism such as endothelial polymegathism and corneal thinning [5,6] Therefore, these pre-operative measurements may be negatively affected by soft contact lens (SCL) wear [7,8]. Thus, resulting in increased light scatter, less light transmission and may affect corneal healing [9,10].

The time required for resolution of corneal changes can vary according to the SCL material, in particular oxygen transmissibility, modality and length of previous SCL wear and can be longer than two weeks [11–14]. Despite these variations in effects relating to the properties of the SCL materials worn, prior to CRS, recommended cessation times can vary according to the regulatory body. While no specific guidelines are given in relation to SCL type, modality or wearing time, the United States Food and Drug Administration guidelines recommend that SCLs be left out for at least two weeks prior to initial consultation [15]. Whereas, the Royal College of Ophthalmologists in the United Kingdom recommend removing SCL for one day before consultation, but does not specify how long to cease SCL wear prior to the CRS procedure [16].

A review of the literature, revealed no known links between previous SCL wear and complications or risks associated with CRS. Furthermore, no previous study had investigated the influence of SCL

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Table 1
Preoperative demographic, VA and refraction parameters.

	LASIK			LASEK/PRK		
2 weeks SCL cessation group						
	SCL (n = 23)	NCL (n = 23)	Sig	SCL (n = 22)	NCL (n = 22)	Sig
LogMAR VA	−0.13 ± 0.06	−0.13 ± 0.04	0.19	−0.13 ± 0.05	−0.10 ± 0.07	0.25
Sphere, D	−3.72 ± 1.84	−2.43 ± 1.65	**0.01**	−3.75 ± 1.50	−2.68 ± 1.30	**0.01**
(range, median)	(−1.25 to −7.25, −3.75)	(−1.00 to −9.00, −2.00)		(−1.00 to −5.75, −3.75)	(−1.25 to −6.75, −2.38)	
Cylinder, D	−0.61 ± 0.25	−0.66 ± 0.36	0.80	−0.55 ± 0.25	−0.60 ± 0.32	0.68
(range, median)	(-0.25 to −1.00, −0.50)	(−0.25 to −1.50, −0.50)		(−0.25 to −1.25, −0.50)	(−0.25 to −1.25, −0.63)	
MSE, D	−3.97 ± 1.84	−2.75 ± 1.66	0.01	−3.98 ± 1.43	−2.95 ± 1.33	0.02
(range, median)	(−1.25 to −7.50, −4.00)	(−1.13 to −9.25, −2.50)		(−1.38 to −6.13, −3.81)	(−1.63 to −7.00, −2.63)	
Age (years)	32.6 ± 7.5	36 ± 9.6	0.16	31.4 ± 8	37.2 ± 11	0.22
(range)	(21 to 49)	(23 to 57)		(21 to 49)	(23 to 58)	
Sex (%) Males: Females	48: 52	52: 48		54.5: 45.5	77: 23	
24 h SCL cessation group						
	SCL group (n = 33)	NCL group (n = 39)	Sig	SCL group (n = 16)	NCL group (n = 10)	Sig
LogMAR VA	−0.11 ± 0.02	−0.10 ± 0.03	0.14	−0.10 ± 0.03	−0.10 ± 0.01	0.74
Sphere, D	−3.52 ± 1.47	−2.24 ± 1.47	**< 0.00**	−3.42 ± 1.68	−3.05 ± 1.35	0.56
(range, median)	(−0.75 to −7.00, −3.50)	(−0.50 to −6.25, −1.75)		(−1.00 to −6.75, −3.25)	(−1.00 to −5.50, −2.88)	
Cylinder, D	−0.52 ± 0.35	−0.67 ± 0.36	0.08	−0.61 ± 0.40	−0.48 ± 0.30	0.37
(range, median)	(0 to −1.50, −0.50)	(−0.25 to −1.50, −0.50)		(−0.25 to −1.50, −0.50)	(0 to −1.00, −0.50)	
MSE, D	−3.78 ± 1.46	−2.57 ± 1.46	**< 0.00**	−3.73 ± 1.78	−3.29 ± 1.38	0.51
(range, median)	(−1.13 to −7.38, −3.63)	(-0.88 to −6.38, −2.00)		(-1.25 to −7.13, −3.50)	(−1.38 to −5.75, −2.94)	
Age, years	30.2 ± 8.3	34.8 ± 8.9	0.03	28.0 ± 5.2	30.9 ± 8.1	0.27
(range)	(20 to 55)	(20 to 58)		(21 to 44)	(19 to 48)	
Sex, % Males: Females	30.3: 69.7	61.5: 38.5		60.0: 40.0	56.3: 43.8	

Mean ± SD, range and median of pre-operative demographic and refractive parameters. Mann-Whitney *U*-test (2 weeks cessation group) and two-way ANOVA test (24 h cessation group), significant differences ($p < 0.05$) are shown in bold text.

wear on outcomes of CRS procedures. The appropriate choice of CRS ablation profiles are based on precise pre-operative corneal topography measurements. If these measurements are inaccurate, due to instability associated with SCL wear, CRS outcomes may be negatively affected. To test this hypothesis, the influence of SCL wear on the outcomes of CRS was explored following two SCL cessation times (two weeks and twenty-four hours) and compared to a non-contact lens (NCL) control group.

2. Methods

This was a retrospective, non-masked analysis on data from a group of patients (n = 188), who underwent Laser in-situ Keratomileusis (LASIK) or Laser epithelial keratomileusis (LASEK)/Photorefractive keratectomy (PRK). Stability of the patient's refractive status was assessed by comparing the manifest refraction pre-operatively to the patient's prescription from two years previously. Less than 0.50D change (< 0.25D for those aged 21 years and younger) over the previous two years was termed stable [17–19]. PRK involved complete removal of the corneal epithelium [20–22]. During LASEK, an alcohol solution was used to loosen the epithelial layer, which was then removed as a single flap of tissue and replaced following stromal ablation [23,24]. During LASIK, a corneal flap of predetermined thickness was resected using a femtosecond LASER [22]. Ablation was performed on the exposed stroma using an Excimer Laser which ablated the sub-basal nerves, Bowman's layer and a variable amount of stromal tissue depending on the change in prescription being attempted [25]. Informed consent was obtained from patients to allow their data to be used anonymously for the purpose of research. This study was approved by the Ethics Committee of the Dublin Institute of Technology, and it adhered to the tenets of the Declaration of Helsinki [26].

CRS outcomes were compared between two groups of patients-those who ceased SCL wear for two weeks (n = 45) and those who ceased SCL wear for twenty-four hours (n = 49) prior to CRS and compared to respective NCL control groups (n = 45 and n = 49). Two control groups were separately compared to each test group in order to ensure the test conditions were matched and to satisfy the criteria for two-way ANOVA statistical testing [27]. The inclusion criteria for this study involved myopic patients (range of myopia: two weeks cessation group SCL −1.00 to −7.25D, NCL −1.00 to −9.00D, twenty-four hours cessation group SCL −0.75 to −7.00D NCL −0.50 to −6.25D) with low astigmatism (< 2.00DC) who wore spherical SCLs only, were free from systemic and ocular disease and had no history of ocular surgery. Dominant eyes only were analysed in order to account for the correlation between eyes, thus avoiding overstatement of the validity of statistical analyses [28]. Ocular dominancy was tested using the Dolman method, asking the patient to look towards a distant target through a hole in a piece of card held by both hands at arm's length, the eyes were covered in turn to determine which eye could still see the target [29]. Full-time SCL wearers were included (those wearing SCLs at least five days per week for at least one year prior to enrolment) and the control group had no history of previous contact lens (CL) wear.

This study focused on visual acuity (unaided distance visual acuity [UDVA] and best-corrected spectacle visual acuity [BCSVA]) and refractive error measurements taken pre-operatively and one and six months post-operatively. Quantitative comparison of the variations between the expected and actual changes in vision and refractive results was carried out between the groups in terms of efficacy and predictability. Efficacy was determined by assessing UDVA and manifest refraction values. The efficacy index was calculated as the ratio of the

post-operative UDVA to the pre-operative BCSVA [19,30]. Predictability was depicted by the number of eyes within ± 0.25D and ± 0.50D of the desired refractive outcome post-operatively [19]. Safety was evaluated by examining the number of intra- and post-operative complications associated with the CRS procedure [22].

Statistical analysis was carried out using the software package SPSS 22 (SPSS Inc., Chicago, Illinois, USA). The statistical programme G*Power 3.1.2 was used to ascertain which sample size was sufficient to ensure statistical power [26]. A total sample size of n = 82 was found to be sufficient for the power (1-β) of 0.95, effect size 0.37, actual power 0.95, critical value 1.99, and delta value of 3.66. Normality for continuous data were assessed using Shapiro-Wilks method (normal distribution when $p > 0.05$) [27]. Data that were found to have normal distribution were analysed using a two-way ANOVA. Data that did not show a normal distribution were assessed using Kruskal-Wallis or Mann-Whitney testing. An alpha value of $p < 0.05$ was considered significant.

3. Results

Demographic data are outlined in Table 1. Both hydrogel and silicone-hydrogel (SiHy) SCL wearers were included. In the two weeks cessation group 75.6% wore hydrogel SCLs and 13.3% wore SiHy. In the 24 h cessation group 71% wore hydrogel SCLs and 29% wore SiHy. As this was a retrospective study, it was not possible to determine the type of SCL material which some patients had worn since it had not been recorded at the initial pre-operative consultation. Results of Mann-Whitney and two-way ANOVA testing indicate that there were significantly lower pre-operative sphere and mean spherical equivalent (MSE) values found for the NCL group compared with both SCL groups who underwent LASIK and with those SCL wearers who ceased SCL wear for two weeks prior to LASEK/PRK ($p < 0.05$).

3.1. Post-operative results

Follow-up compliance for the study is outlined in Table 2. In the course of the follow-up some patients did not attend the clinic as they received follow-up care in clinics closer to their place of residence or work or abroad, hence the attrition rate.

3.2. One month post-operative results

The one month efficacy and predictability outcomes following CRS were compared between the SCL and NCL groups. UDVA was significantly better for LASEK/PRK patients who had ceased SCL wear for two weeks prior to CRS (−0.05 ± 0.09), compared with the NCL group (0.02 ± 0.09; $p = 0.04$) (Table 3, Figs. 1 and 2). These findings may be related to the significantly lower residual cylinder following CRS which was recorded at one month post-LASEK/PRK in the SCL group (−0.50 ± 0.40) compared with the NCL group (−0.76 ± 0.40; $p = 0.02$).

3.3. Six month post-operative results

One month following CRS, UDVA was significantly better for both LASIK and LASEK/PRK patients who had ceased SCL wear for two weeks prior to CRS and LASEK/PRK patients who had ceased SCL wear for twenty-four hours prior to CRS (see Table 4, Figs. 3 and 4). The residual cylinder was significantly higher in the NCL group compared with the SCL group who ceased SCL wear for twenty-four hours prior to LASIK (SCL −0.18 ± 0.12 D, NCL −0.29 ± 0.25D, $p = 0.01$). However, the residual sphere was lower in the NCL group so there was no significant difference in the residual MSE between the SCL and NCL groups.

The efficacy results of this study compare favourably with those reported by previous authors (see Table 5) [31–34]. The National Institute for Health and Clinical Excellence (NICE) undertook a systematic review of safety and efficacy of LASIK between the years 2000 and 2006 (n = 293,278) [35]. UDVA results greater than 6/6 were found in 64% of LASIK subjects, results of 6/12 or better were found in 94% of LASIK subjects. The superior results found in this study, compared with those reported by NICE (2005), may be due to the inclusion of lower myopia and the use of the femtosecond laser in LASIK flap creation [36].

Table 2
Post-operative following up compliance.

SCL cessation time	LASIK	LASEK/PRK	LASIK	LASEK/PRK
2 weeks	1 month 96%	100%	6 months 76%	82%
24 h	99%	100%	51%	50%

The percentage shows the patient who attended post-operative appointments.

3.4. Safety

In this study, there were no serious intra- or post-operative complications in any group. There were two cases of grade two diffuse lamellar keratitis. Both occurred in the NCL group, which were treated successfully with topical steroids. As there is higher risk of regression and increasing myopia following diffuse lamellar keratitis [3], these cases were excluded from the post-operative analysis.

3.5. Myopia

As there was a significant difference in the post-operative efficacy between the SCL and NCL control groups, the effect of the level of pre-operative myopic error myopia (low 0 to −3.00D, medium −3.00 to −6.00D or high > 6.00D myopia) on the efficacy of the CRS outcomes was explored. Results of two-way ANOVA testing on the one month CRS outcomes showed a significant effect of myopic group on efficacy for those who ceased SCL wear for two weeks prior to LASIK (Table 6). Post hoc comparisons using Bonferroni testing indicated that the mean UDVA measured one-month post operatively was significantly lower in the high myopia NCL group compared with both the low and medium groups. As there was only one patient in the high myopia NCL group who had LASIK carried out, it was not possible to draw any conclusions from this finding. There were no statistically significant differences found between the low and medium myopic groups who had LASIK, nor for any groups who had LASEK/PRK procedures. Furthermore, there were no significant differences between the groups at the six month post-operative visit. No statistically significant differences in CRS outcomes were found when the influence of myopia was explored between those who ceased SCL wear for 24 h and a NCL control group one month post-operatively. However, at the six month post-operative visit, significantly lower UDVA was found between the high myopic NCL group and the low and medium groups who had LASIK carried out (Table 7). As there was only one patient in the high myopic NCL group who had LASIK carried out, it was not possible to draw any conclusions from this finding.

3.6. Age

The influence of the patients' age groups (18–29, 30–39, 40–49 and 50–59 years) on the outcomes of CRS was explored. No statistically significant differences were found between the groups at either post-operative visit for those who ceased SCL wear two weeks prior to CRS and the NCL control group. Results of two-way ANOVA testing on the one month outcomes showed a significant effect of age on the efficacy of LASIK outcomes for those who ceased SCL wear for 24 h prior to CRS (Table 8). While no significant differences were found between the age groups following LASIK at the six month post-operative visit,

Table 3
Comparison of one month post-operative outcomes.

Two weeks cessation group						
	LASIK			LASEK/PRK		
	SCL (n = 23)	NCL (n = 23)	Sig	SCL (n = 22)	NCL (n = 22)	Sig
LogMAR UDVA	−0.04 ± 0.13	−0.08 ± 0.07	0.53	−0.05 ± 0.09	0.02 ± 0.09	**0.04**
Efficacy index	95%	92.5%		95%	94%	
LogMAR, Snellen						
> 0.3, < 6/12 n (%)	0	0	0.58	0	0	0.17
< 0.3, > 6/12 n (%)	23 (100)	21 (91)		21 (96)	22 (100)	
< 0.0, > 6/6 n (%)	19 (83)	18 (78)		15 (68)	11 (50)	
< -0.1, > 6/5 n (%)	15 (65)	12 (52)		12 (55)	6 (27)	
Did not attend n(%)	0	1 (4)		1 (4.5)	0	
Predictability						
Sphere (D)	+0.24 ± 0.38	−0.02 ± 0.52	0.16	+0.11 ± 0.46	+0.34 ± 0.67	0.16
Cylinder (D)	−0.44 ± 0.20	−0.42 ± 0.34	0.31	−0.50 ± 0.40	−0.76 ± 0.40	**0.02**
MSE (D)	+0.06 ± 0.35	−0.21 ± 0.63	0.15	−0.10 ± 0.50	−0.03 ± 0.70	0.46
Within ± 0.25D	15 (65)	13 (57)	0.94	12 (55)	10 (46)	0.66
Within ± 0.50D	20 (87)	15 (65)		13 (59)	12 (55)	
> ± 0.50D	3 (13)	6 (26)		7 (32)	8 (36)	

Twenty-four hours cessation group						
	LASIK			LASEK/PRK		
	SCL (n = 33)	NCL (n = 37)	Sig	SCL (n = 16)	NCL (n = 10)	Sig
LogMAR UDVA	−0.05 ± 0.10	−0.07 ± 0.09	0.44	0.00 ± 0.09	−0.01 ± 0.07	0.77
Efficacy index	97%	99%		95%	96%	
LogMAR, Snellen						
> 0.3, < 6/12 n (%)	0	0 (0)	0.47	0	0	0.42
< 0.3, > 6/12 n (%)	33 (100)	37 (97.4)		16 (100)	10 (100)	
< 0.0, > 6/6 n (%)	25 (75.7)	33(84.6)		8 (50)	7(70)	
< -0.1, > 6/5 n (%)	21 (63.6)	26 (66.7)		4 (25)	2 (20)	
Did not attend n(%)	0	1 (2.6)		0	0	
Predictability						
Sphere (D)	−0.07 ± 0.38	0.07 ± 0.36	0.13	0.22 ± 0.48	0.33 ± 0.39	0.56
Cylinder (D)	−0.29 ± 0.39	−0.27 ± 0.20	0.80	−0.50 ± 0.38	−0.50 ± 0.39	1.00
MSE (D)	−0.21 ± 0.34	−0.07 ± 0.38	0.10	−0.03 ± 0.46	0.08 ± 0.37	0.55
Within ± 0.25D	22 (66.7)	24 (61.5)	0.59	9 (56.3)	6 (60)	0.59
Within ± 0.50D	8 (24.2)	7 (17.9)		3 (18.8)	3 (30)	
> ± 0.50D	3 (9.1)	7 (17.9)		4 (25)	1 (10)	

Mean ± SD, two-way ANOVA test results of 1 month post-operative CRS outcomes, significant differences ($p < 0.05$) are shown in bold text.

significantly lower UDVA was found in the NCL group aged 30–39 years following LASEK/PRK (Table 9). Although significance values were < 0.05 following multiple comparison two way ANOVA testing, the post hoc Scheffe test values were greater than 0.05 in all cases. Thus indicating the limited nature of these statistical tests due to the small numbers within these sub-groups.

3.7. Sex

The results of this study found no significant differences between

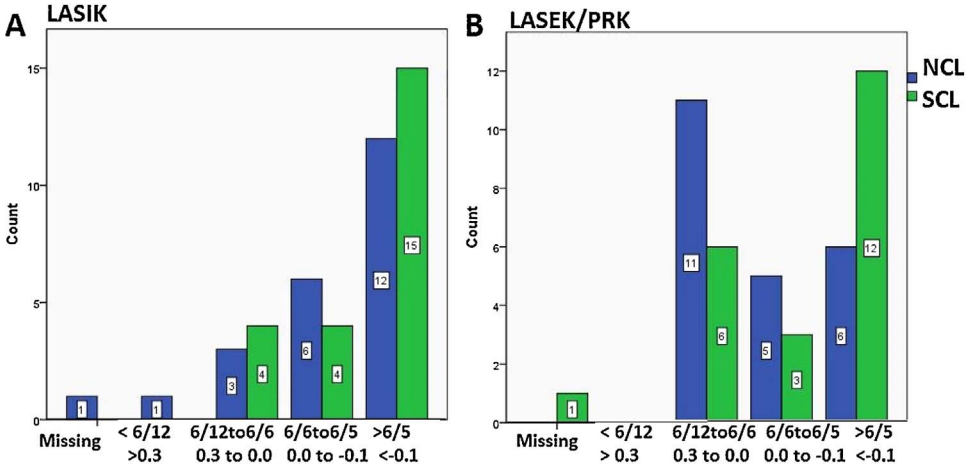

Fig. 1. Unaided distance visual acuity values at one month.
UDVA achieved at 1 month. SCL wearers (green) had a greater tendency to achieve VA of −0.1 or better when compared with the NCL wearers (blue), for both LASIK (A) and LASEK/PRK (B) procedures. Missing data refers to patients who did not show for their1 month follow-up visit.

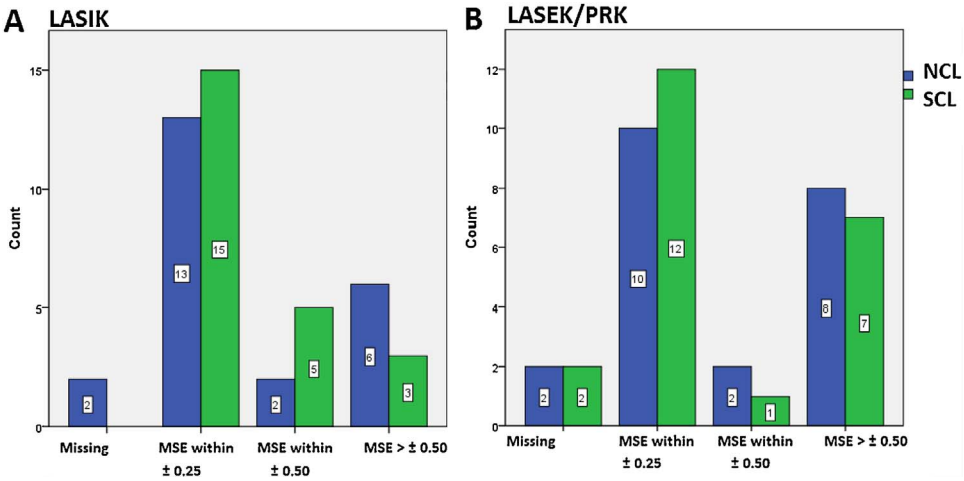

Fig. 2. Refractive accuracy of one month post-operative mean spherical equivalent refraction.
Number of eyes achieving mean spherical acuity (MSE) values within ± 0.25 and ± 0.50 dioptres of the target change at one month, SCL group in green, NCL control group in blue.

male and female patients who ceased SCL wear for either two weeks or 24 h prior to CRS at either 1 or 6 months following CRS compared with NCL control groups.

4. Discussion

The cornea is a living tissue and its biomechanical and physical properties are affected by SCL wear and CRS [37]. If CL-induced corneal warpage is present and sufficient time is not provided for the complete stabilisation of corneal changes, the biophysical response of the cornea will be compromised. Thus the efficacy of CRS may be influenced by SCL wear, since CL-induced corneal warpage can result in a transient increase in myopia, which can lead to over-correction following CRS [38].

Results of this study indicated that the efficacy of both LASIK and LASEK/PRK procedures were higher in the SCL group when compared with a NCL group regardless of SCL cessation times (two weeks versus twenty-four hours) between one and six months following CRS. These findings may be explained by the adaption of these SCL wearing patients to the diminished image quality which occurs due to light scatter, corneal surface alterations and reduced CSF following hypoxia and oedema with overwear of SCLs [39–42]. It is also likely that some patients may have adapted to small amounts of cylindrical refractive error which was not corrected by their spherical SCLs. It is estimated that up to a third of SCL wearers required astigmatic correction of between −0.50 to −2.00D [43]. However, only 13% of patients worldwide wear toric CLs [44] and in this study no toric SCL wearing patients were included. Therefore SCL wearing patients are likely to have previously adapted to under-correction of refractive cylinder, and be more tolerant of post-operative residual cylindrical refractive error.

Furthermore, SCL wear can result in increased corneal surface irregularities, which may negatively impact upon VA [42]. SCL wear can reduce tear break up time, which can result in reduced image quality [45]. Following myopic CRS, the cornea becomes more oblate. This shape results in increased spherical aberrations with excessive refraction of light rays incident on the periphery of the cornea [46]. It is therefore possible that previous SCL wearers, with experience of increased corneal surface irregularities, adapted better to induced spherical aberration and possible residual refractive error following CRS. Thus, allowing them to maintain better levels of UDVA when compared with NCL wearers. However, while these results were statistically significant for UDVA, one cannot conclude that they are clinically significant due to the small number of letters gained in the SCL group compared with the NCL (LASIK: SCL group had two more letters than the NCL; LASEK/PRK: SCL group had 3 more letters than the NCL), as standard uncertainty for VA is approximately two letters (four letters for a 95% confidence interval) [47].

Definitive reporting on the impact of previous CL wear on the outcomes of CRS in the literature is lacking. Gimbel and Sun (1993) found there was no significant difference in refractive or epithelial healing between NCL, SCL and RGP patients following PRK at one week, two weeks, four months and six month visits (n = 130) [48]. This study was conducted before the advent of LASIK or SiHy lens materials. LASEK was performed for low to high myopia (−1.25 to −14.38D) with astigmatism (up to 4.50D) in previous SCL wearers (n = 146 eyes) [49]. Daily SCL wearers ceased SCL wear one week and toric SCL wearers ceased lens wear for three weeks prior to examination. Recent studies examining the effect of pre-operative SCL wear on CRS outcomes is lacking.

The influence of age on VA and CRS outcomes must be considered. The SCL group who ceased SCL wear for 24 h prior to CRS were younger (29.49 ± 7.42 years) than their NCL control counterparts (34.00 ± 8.76 years, p = 0.01). The precision of corneal measurements used for planning CRS treatment profiles were not expected to have been affected by the difference in age between the groups as no link has been established between age and corneal curvature or thickness measurements [50,51]. However, there is disagreement in the literature as to the effect of age on the outcomes of CRS. Younger patients have been reported to require greater number of retreatments following CRS. This is attributed to an increased corneal healing response [52]. In contrast to this, younger patients have been reported to achieve better visual outcomes following CRS due to the increased levels of accommodation, which may provide the ability to accommodate over low levels of hyperopic residual refraction [53]. Perlman and Reinert found significantly higher retreatment rates following LASIK in patients aged over 45 years [54]. Advancing age has also been reported to result in a trend towards poorer efficacy outcomes following CRS. Ghanem et al. (2007) reported worse BCSVA, increased myopic residual refractions and higher retreatment rates following LASIK in older patients (p > 0.05). However, these authors performed a retrospective chart analysis and did not report whether the refractive outcome was intended to be plano, or a slight myopic refraction which would benefit these presbyopic patients with near work. Greater risk of loss of lines of BCSVA after CRS was not reported with advancing age [53]. While other patient demographics such as sex are known to have an effect on the outcomes of intra-ocular and cataract surgery [55,56], their impact on the outcomes of LASIK and LASEK/PRK has not been fully explored in the literature, no significant differences on CRS outcomes in terms of sex were found in this study.

5. Limitations

It is well agreed in the literature that the outcomes of CRS are dependent on the pre-operative level of myopia, with lower myopic

Table 4
Comparison of six month post-operative outcomes.

Two weeks cessation group						
	LASIK			LASEK/PRK		
	SCL (n = 19)	NCL (n = 16)	Sig	SCL (n = 18)	NCL (n = 18)	Sig
Efficacy						
UDVA (LogMAR)	−0.10 ± 0.10	−0.06 ± 0.07	**0.03**	−0.10 ± 0.08	−0.04 ± 0.08	**0.03**
Efficacy index	97%	98%		98%	97%	
LogMAR, Snellen						
> 0.3, < 6/12 n (%)	0	0	0.13	0	0	0.10
< 0.3, > 6/12 n (%)	19 (83)	16 (70)		18 (82)	18 (82)	
< 0.0, > 6/6 n (%)	17 (74)	12 (52)		16 (73)	15 (68)	
< −0.1, > 6/5 n (%)	14 (61)	9 (39)		14 (64)	6 (27)	
Did not attend n(%)	4 (17)	7 (30)		4 (18)	4 (18)	
Predictability						
Sphere (D)	+0.08 ± 0.31	−0.08 ± 0.45	0.36	+0.06 ± 0.55	+0.20 ± 0.56	0.69
Cylinder (D)	−0.42 ± 0.22	−0.44 ± 0.19	0.81	−0.37 ± 0.23	−0.28 ± 0.13	0.29
MSE (D)	−0.08 ± 0.31	−0.24 ± 0.45	0.30	−0.08 ± 0.60	+0.07 ± 0.52	0.80
Within ± 0.25D (%)	14 (61)	9 (39)	0.92	8 (36)	7 (32)	0.71
Within ± 0.50D (%)	18 (78)	13 (56.5)		10 (45.5)	11 (50)	
> ± 0.50D (%)	1 (4)	3 (13)		6 (27)	4 (18)	
Comparison of pre-operative BCSVA and post-operative UDVA						
Loss 1 line VA (%)	4 (21)	6 (37.5)	0.11	3 (17)	9 (50)	0.25
Loss ≥2 lines VA (%)	4 (21)	6 (37.5)		2 (11)	0 (0)	
Twenty-four hours cessation group						
	LASIK			LASEK/PRK		
	SCL (n = 17)	NCL (n = 20)	Sig	SCL (n = 7)	NCL (n = 6)	Sig
Efficacy						
UDVA	−0.06 ± 0.09	−0.04 ± 0.10	0.53	−0.11 ± 0.03	−0.04 ± 0.07	**0.03**
Efficacy index	98%	97%		100%	97%	
LogMAR, Snellen						
> 0.3, < 6/12 n (%)	0	0	0.74	0	0	0.14
< 0.3, > 6/12 n (%)	17 (51.5)	20 (51.3)		0	6 (60)	
< 0.0, > 6/6 n (%)	14 (35.9)	16 (48.5)		0	4 (40)	
< −0.1, > 6/5 n (%)	12 (30.8)	11 (33.3)		7 (43.7)	3 (30)	
Did not attend n(%)	16 (48.5)	19 (48.7)		9 (56.3)	4 (40)	
Predictability						
Sphere (D)	−0.13 ± 0.37	0.01 ± 0.31	0.20	0.18 ± 0.31	−0.13 ± 0.26	0.09
Cylinder (D)	−0.18 ± 0.12	−0.29 ± 0.25	**0.01**	−0.25 ± 0.14	−0.21 ± 0.19	0.66
MSE (D)	−0.22 ± 0.37	−0.13 ± 0.29	0.42	0.05 ± 0.31	−0.23 ± 0.31	0.13
Within ± 0.25D	10 (30.3%)	17 (43.6%)	0.23	5 (31.3%)	3 (30%)	0.69
Within ± 0.50D	2 (6.1%)	2 (5.1%)		1 (6.3%)	2 (20%)	
> ± 0.50D	5 (15.2%)	1 (2.6%)		1 (6.3%)	1 (10%)	
Comparison of pre-operative BCSVA and post-operative UDVA						
Loss 1 line VA	4 (12.1%)	4 (10.3%)	0.76	0	3 (30%)	0.17
Loss ≥2 lines VA	2 (6.1%)	2 (5.1%)		0	0	

Significant differences with Kruskal-Wallis testing ($p < 0.05$) are shown in bold text, in the two weeks cessation group ($p < 0.05$). Two-way ANOVA results showed no significant differences between the 24 h cessation group and NCL group ($p < 0.05$).

corrections achieving better and more stable visual outcomes [22,31,57–60]. The low sample size in the high myopia groups means that these findings lack statistical validity, therefore, the impact of the level of pre-operative myopic refractive error on CRS outcomes following SCL cessation should be addressed in future studies.

Mean myopic refractive error can be influenced by SCL material worn [61–63]. Fonn et al. (2002) found a significant increase in myopia with low DK/t SCL wear compared with high DK/t SCL wear- these differences between the groups were proposed to be due to hypoxia and mechanical moulding [63]. The mechanism of slowing of myopic progression was reportedly associated with the stiffer modulus of SiHy SCL materials [61,62]. As this study was retrospective in nature, and the generation of SiHy SCL material patients wore prior to CRS was not recorded at the time of data collection, it was not possible to explore the impact of SCL modulus on the outcomes of CRS. Furthermore, it must be considered that there were fewer surface LASEK/PRK patients compared with LASIK which may have impacted on the statistical validity of these results. It would be beneficial if these limitations were addressed in future studies.

6. Conclusion

Given the current setup and methods followed, the results of this study contradicted the hypothesis that prior SCL wear would have a negative impact on CRS outcomes. Following two weeks of SCL cessation, at the six month post-operative visit, the SCL wearers had statistically significantly better outcomes in terms of visual efficacy compared to the NCL control group. Patients who ceased SCL wear twenty-four hours prior to LASEK/PRK also had significantly better visual efficacy compared with the NCL group. While those patients who ceased SCL wear twenty-four hours prior to LASIK also experienced, on average, better UDVA compared to the NCL group, these results were

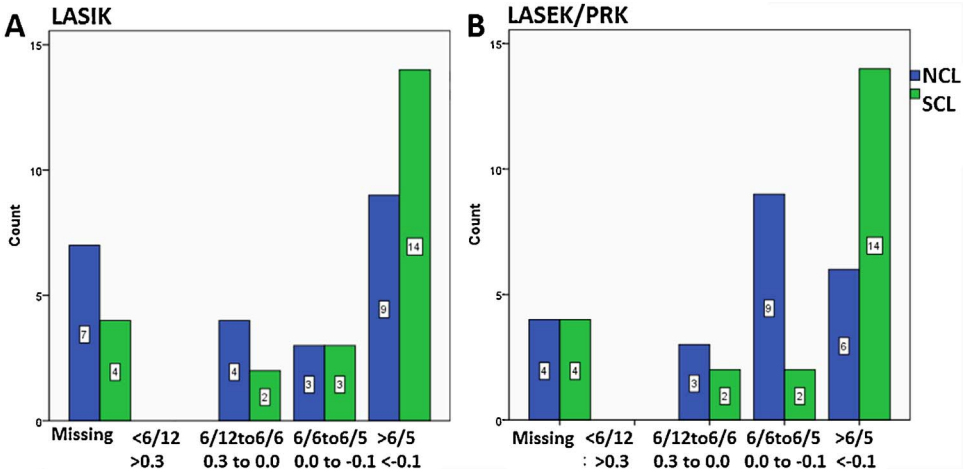

Fig. 3. Efficacy index at six months.
Results showed that the SCL group (in green) tended to achieve superior levels of UDVA compared with the NCL control group (in blue) for both LASIK (A) and LASEK/PRK (B) procedures. Both Snellen and LogMAR VA values are displayed.

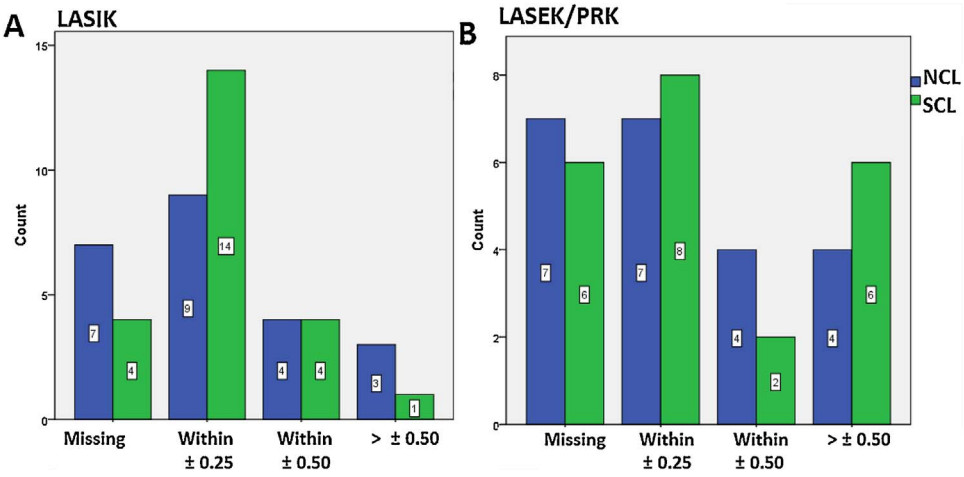

Fig. 4. MSE predictability at six months.
Refractive accuracy of mean spherical equivalent at 6 months post-operative showed a greater tendency for the SCL group (shown in green) to be within 0.25D than the NCL control group (shown in blue), for both LASIK (A) and LASEK/PRK procedures (B).

Table 5
Efficacy results of myopic CRS.

Study	N	Level of myopia	CRS	% eye achieved ≥ 6/6	% eye achieved ≥ 6/12	Post-op efficacy
Two weeks' SCL cessation	19	−1.13 to −9.25D	LASIK	SCL 74 NCL 52	SCL 83 NCL 70	SCL 79 NCL 62.5
24 h' SCL cessation	17	−0.88 to −7.38D	LASIK	SCL 82 NCL 80	SCL 100 NCL 100	SCL 100 NCL 100
Ghadhfan et al., 2007	464	0 to −6.00 D	LASIK	55.1	98.4%	96.6%
Ghadhfan et al., 2007	464	−6.00 to −11.25D	LASIK	28.4	85.1%	80.1%
O'Doherty et al. 2006	49	−1.50 to −13.00D	LASIK	53	88%	93%
Yuen et al., 2010	37932	0 to > −10.00D	LASIK	72.8%		
Two weeks' SCL cessation	18	−1.38 to −6.13D	LASEK/ PRK	SCL 73% NCL 68%	SCL 82% NCL 82%	SCL 89 NCL 100
24 h' SCL cessation	7	−1.25 to −7.13 D	LASEK/ PRK	SCL 100 NCL 67	SCL 100 NCL 100	SCL 100 NCL 100
Ghadhfan et al., 2007	104	0 to −6.00	LASEK PRK	47.8% 73.5%		
Ghadhfan et al., 2007	104	−6.00 to −11.25	LASEK PRK	29.7% 25.0%		
Taneri et al., 2004	171	−0.38 to −7.75D	LASEK		96%	
NICE Review Murray et al., 2005	15 785		LASEK PRK	64% 70%	92% 92%	

Blank cells indicate where these parameters were not reported within the studies.

Table 6
Efficacy outcomes at 1 month for SCL and myopic groups.

	LASIK			PRK/LASEK		
	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig
2 weeks SCL cessation						
Low Myopes	−0.05 ± 0.14 (n = 6)	−0.10 ± 0.05 (n = 13)	**0.00**	−0.11 ± 0.01 (n = 4)	0.02 ± 0.10 (n = 12)	0.07
Medium Myopes	−0.06 ± 0.09 (n = 10)	−0.04 ± 0.09 (n = 5)		−0.05 ± 0.09 (n = 12)	0.00 ± 0.08 (n = 6)	
High Myopes	0.07 ± 0.21 (n = 3)	0.70 (n = 1)		0.10 (n = 1)	0.12 (n = 1)	
24 h SCL cessation						
Low Myopes	−0.09 ± 0.09 (n = 8)	−0.07 ± 0.09 (n = 26)	0.64	−0.04 ± 0.12 (n = 6)	−0.04 ± 0.12 (n = 6)	0.80
Medium Myopes	−0.04 ± 0.11 (n = 22)	−0.06 ± 0.09 (n = 11)		0.02 ± 0.06 (n = 8)	0.04 ± 0.06 (n = 4)	
High Myopes	−0.02 ± 0.14 (n = 3)	−0.10 ± 0 (n = 1)		0.04 ± 0.00 (n = 2)	(n = 0)	

Mean ± SD of efficacy 1 month post-operatively for SCL and myopic groups, low myopia (0 to −3.00D), medium myopia (−3.25 to −6.00D) and high myopia (> −6.00D). The results of two-way ANOVA are shown with statistically significant results shown in bold text, ($p < 0.05$).

Table 7
Efficacy outcomes at 6 months for SCL and myopic groups.

Myopic group	LASIK			LASEK/PRK		
	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig
2 weeks SCL cessation						
Low	−0.15 ± 0.06 (n = 4)	−0.06 ± 0.07 (n = 10)	0.39	−0.10 ± 0.10 (n = 3)	−0.05 ± 0.08 (n = 10)	0.26
Medium	−0.09 ± 0.12 (n = 9)	−0.08 ± 0.05 (n = 5)		−0.11 ± 0.08 (n = 9)	−0.01 ± 0.08 (n = 4)	
High	−0.07 ± 0.06 (n = 2)	(n = 0)		−0.10 (n = 1)	(n = 0)	
24 h SCL cessation						
Low Myopes	−0.10 ± 0.00 (n = 3)	−0.06 ± 0.07 (n = 14)	**0.02**	−0.14 ± 0.06 (n = 2)	−0.05 ± 0.08 (n = 3)	0.92
Medium Myopes	−0.04 ± 0.11 (n = 12)	−0.03 ± 0.07 (n = 5)		−0.10 ± 0.00 (n = 5)	−0.02 ± 0.07 (n = 3)	
High Myopes	−0.10 ± 0.00 (n = 2)	0.24 (n = 1)		(n = 0)	(n = 0)	

Mean ± SD of efficacy 6 months post-operatively for SCL and myopic groups, low myopia (0 to −3.00D), medium myopia (−3.25 to −6.00D) and high myopia (> −6.00D). The results of two-way ANOVA are shown with statistically significant results shown in bold text, ($p < 0.05$).

Table 8
Efficacy outcomes at 1 month for SCL and age groups.

Age group (years)	LASIK			PRK/LASEK		
	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig
24 h SCL cessation						
18–29	−0.06 ± 0.09 (n = 19)	−0.10 ± 0.08 (n = 11)	**0.04**	0.01 ± 0.09 (n = 12)	−0.06 ± 0.05 (n = 4)	0.07
30–39	−0.09 ± 0.09 (n = 11)	−0.06 ± 0.10 (n = 19)		−0.01 ± 0.09 (n = 3)	0.00 ± 0.05 (n = 5)	
40–49	0.14 (n = 1)	−0.08 ± 0.05 (n = 4)		−0.10 (n = 1)	0.12 (n = 1)	
50–59	0.14 ± 0.06 (n = 2)	−0.03 ± 0.12 (n = 4)		(n = 0)	(n = 0)	

Mean ± SD of efficacy 1 month post-operatively for SCL and age groups. The results of two-way ANOVA are shown with statistically significant results shown in bold text, ($p < 0.05$).

not statistically significant. The visual efficacy in the two weeks' SCL cessation group and 24 h' SCL cessation group, prior to LASEK/PRK, were superior in terms of statistical significance. However, they may not be deemed clinically significant due to the small number of letters difference between the groups, considering standard uncertainty for VA (of 0.04 LogMAR) [47].

It is important to place these findings into context, with regards to the current literature and clinical practice relating to SCL wear and CRS. It is well agreed in the literature that SCL wear impacts on all corneal layers, resulting in changes to corneal shape and thickness, this

Table 9
Efficacy outcomes at 6 months for SCL and age groups.

Age group (years)	LASIK			PRK/LASEK		
	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig	SCL group Mean LogMAR ± SD	NCL group Mean LogMAR ± SD	Sig
24 h SCL cessation						
18–29	−0.07 ± 0.09 (n = 11)	−0.01 ± 0.13 (n = 6)	0.20	−0.11 ± 0.03 (n = 6)	−0.10 ± 0.00 (n = 3)	**0.01**
30–39	−0.04 ± 0.11 (n = 6)	−0.07 ± 0.07 (n = 7)		−0.10 (n = 1)	0.03 ± 0.02 (n = 3)	
40–49	(n = 0)	0.00 ± 0.10 (n = 4)		(n = 0)		
50–59	(n = 0)	−0.07 ± 0.06 (n = 3)		(n = 0)		

Mean ± SD of efficacy 6 months post-operatively for SCL and age groups. The results of two-way ANOVA are shown with statistically significant results shown in bold text, ($p < 0.05$).

is particularly evident with hypoxia, often related to over-wear of low DK/t SCLs [14,64–66]. The study population analysed in this work was comprised of normal, myopic patients, the majority of whom wore SCLs following a daily wear modality. They had been previously deemed suitable for CRS and so did not demonstrate significant signs of hypoxia or corneal warpage. This, in addition to modern SCL prescribing techniques (the lack of hydrogel SCLs for extended wear and use of SiHy for daily wear) suggests that these corneas were healthy and not compromised by SCL wear. When screening CRS candidates, it is essential that one considers recent studies by Moezzi et al. (2014) and Lira et al. (2015) who investigated the impact of various myopic and hyperopic prescriptions on manufacturers' published oxygen transmissibility figures [67,68]. Both sets of authors agree that even the highest oxygen transmissibility SiHy lenses, when used for extended wear, fail to meet the well-agreed critical oxygen transmission levels for the avoidance of corneal anoxia, in moderate and high hyperopia [69,70]. More worryingly still, hydrogel lenses (> + 3.00D) do not, even, achieve the oxygen transmissibility criteria required for daily wear. In light of these reports, it is likely that problems with hypoxia are still evident in hyperopic patients; therefore a study similar to this would be beneficial to assess the impact of hyperopic SCL wear on CRS outcomes. In the absence of this, these patients must be thoroughly screened and stability must be documented carefully prior to CRS. This is especially important for hyperopic CRS ablation, where the central cornea is made steeper. In these patients longer SCL cessation times would be advisable prior to CRS in order to maintain satisfactory CRS outcomes.

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