



# SOLUTION-INDUCED-CORNEAL-STAINING (SICS): SYMPTOMS AND STAINING PATTERNS

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## Introduction

There has been considerable debate regarding the mechanism and clinical relevance of solution-induced staining (SICS).<sup>1,2,3</sup> SICS has previously been defined as diffuse punctate staining, grade 1 or more, in  $\geq 4$  corneal zones.<sup>4</sup> SICS often presents as a peripheral corneal annulus of diffuse staining<sup>1,4,6</sup> although an alternate presentation of diffuse pan-corneal staining has also been reported.<sup>5</sup> To date it is unclear which pattern is most common. Generally SICS is reported as a symptom-free phenomenon.<sup>1,3,5,6</sup> However, there have been a few publications and anecdotal reports that some wearers experience very specific symptoms when SICS is present.<sup>2,7</sup>

## Purpose

To report the symptoms and pattern of staining observed in a pilot study, which was conducted to investigate various aspects of the SICS response.

## Methods

- In an attempt to induce SICS,<sup>2,4</sup> 20 healthy subjects bilaterally wore -0.25D balafilcon A lenses (PureVision™) that had been soaked overnight in a PHMB preserved lens-care solution (renu® fresh™).
- Subjects wore the lenses for 2 hours,<sup>8</sup> after which lenses were removed and corneal staining was graded. Corneal staining was observed with sodium fluorescein using blue light and a yellow filter. The percentage area of the cornea affected by diffuse punctate stain was graded from 0-100, across 5 zones.
- Symptom data were collected immediately before and after lens insertion, and also after 2 hours of lens wear, immediately before and after lens removal. On each occasion, subjects were asked to provide a rating of ocular comfort (0-100 scale) and answer yes or no to whether they experienced any burning, stinging or itching; each eye was assessed separately.
- In this pilot study, one lens was saline-rinsed before insertion (randomized and masked), therefore only data from the eyes that wore the non-rinsed lenses are presented.

## Results

- All 20 subjects exhibited SICS (as previously defined).
- Only ID2, exhibited an annular-type staining pattern: low % staining centrally (20%) compared to peripherally ( $\geq 60\%$ ), Figures 1A & B.
- The other 19 exhibited pan-corneal staining: similar areas of staining across all five zones. Figure 1C is a typical example.
- As a group, mean total corneal staining was 92% (SD 13%), mean central zone staining was 94% (SD 18%).

## Results (cont'd)

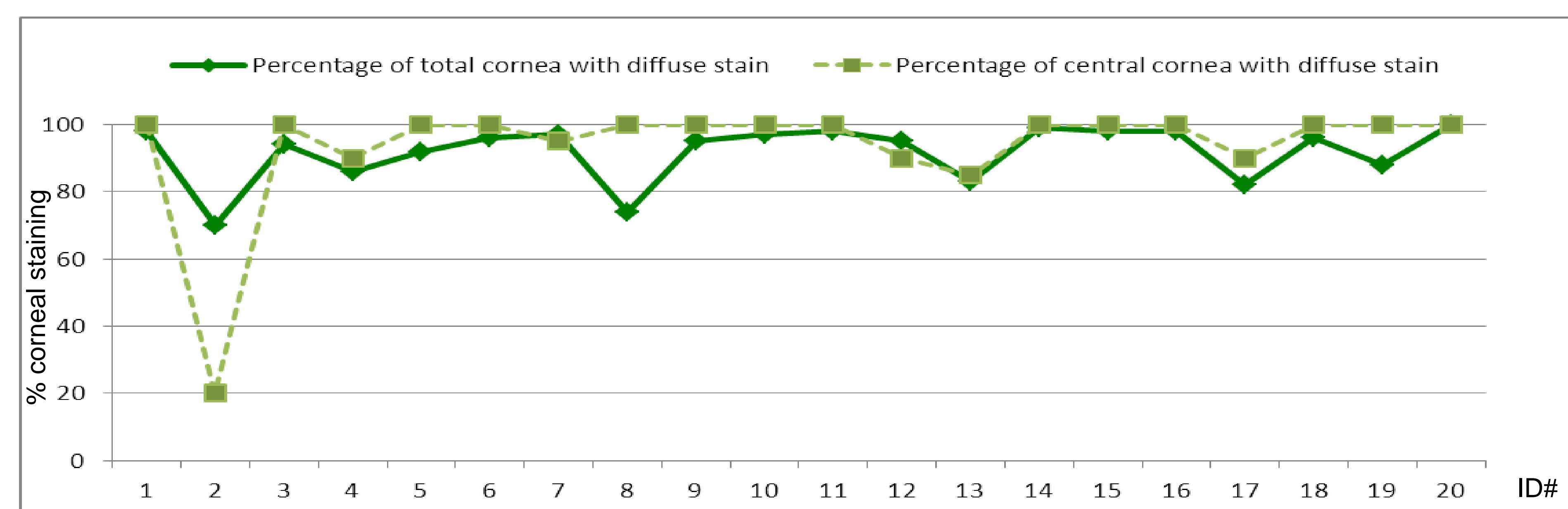


Figure 1A: Distribution of total % corneal staining & central % corneal staining for each subject

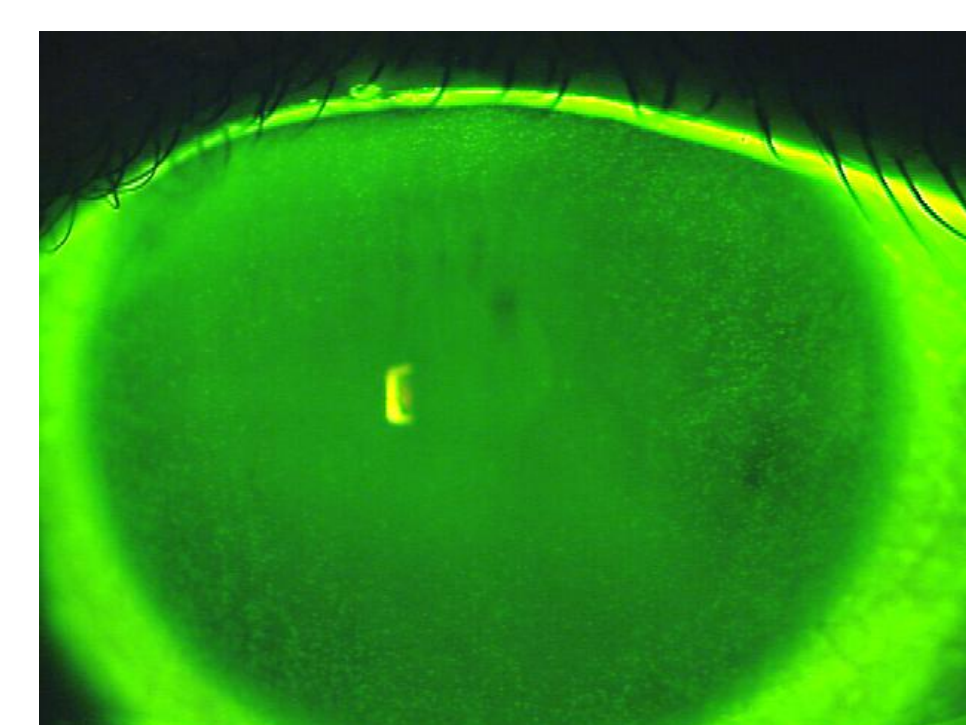


Figure 1B (left): Total corneal staining: 71% Central zone staining: 20%

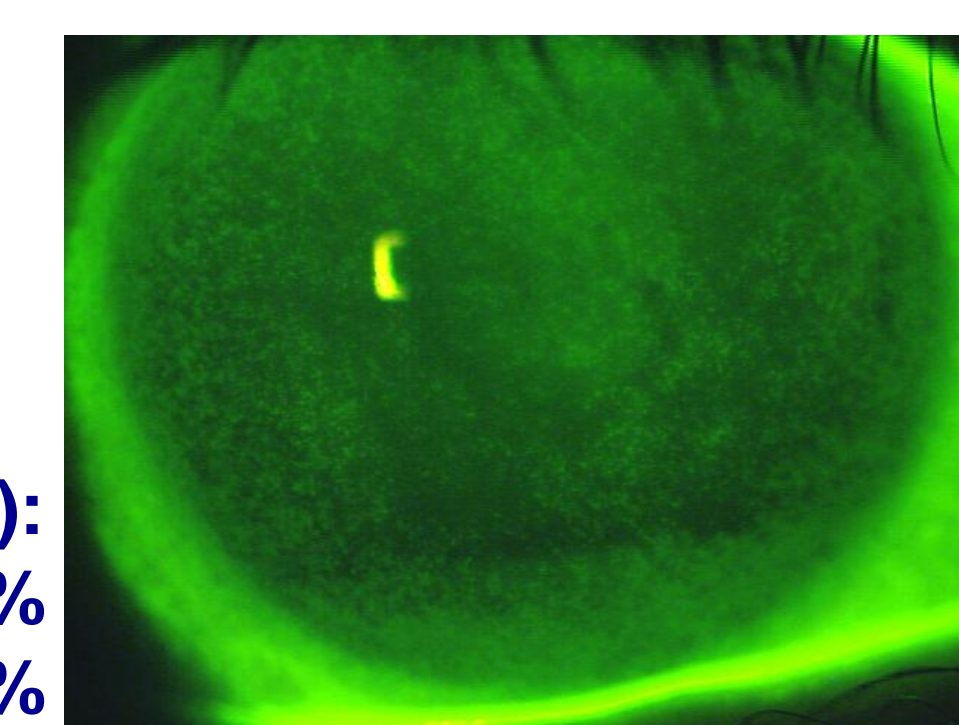


Figure 1C (right): Total corneal staining: 92% Central zone staining: 90%

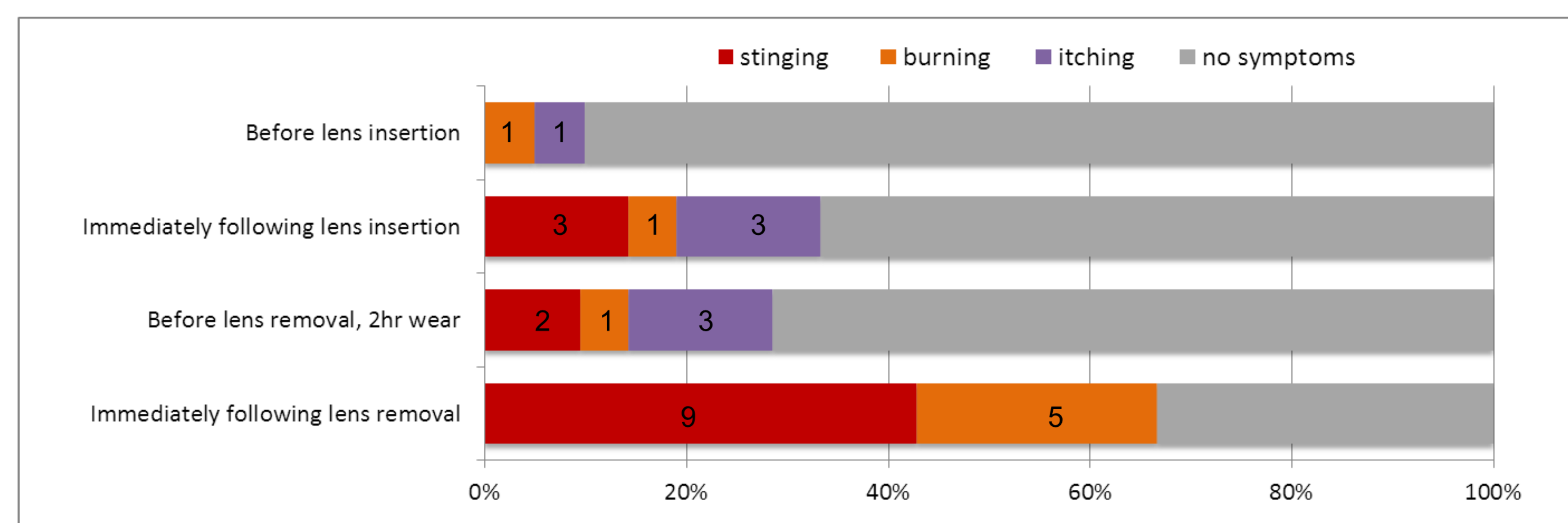


Figure 2: Frequency of stinging, burning & itching symptoms at each time-point

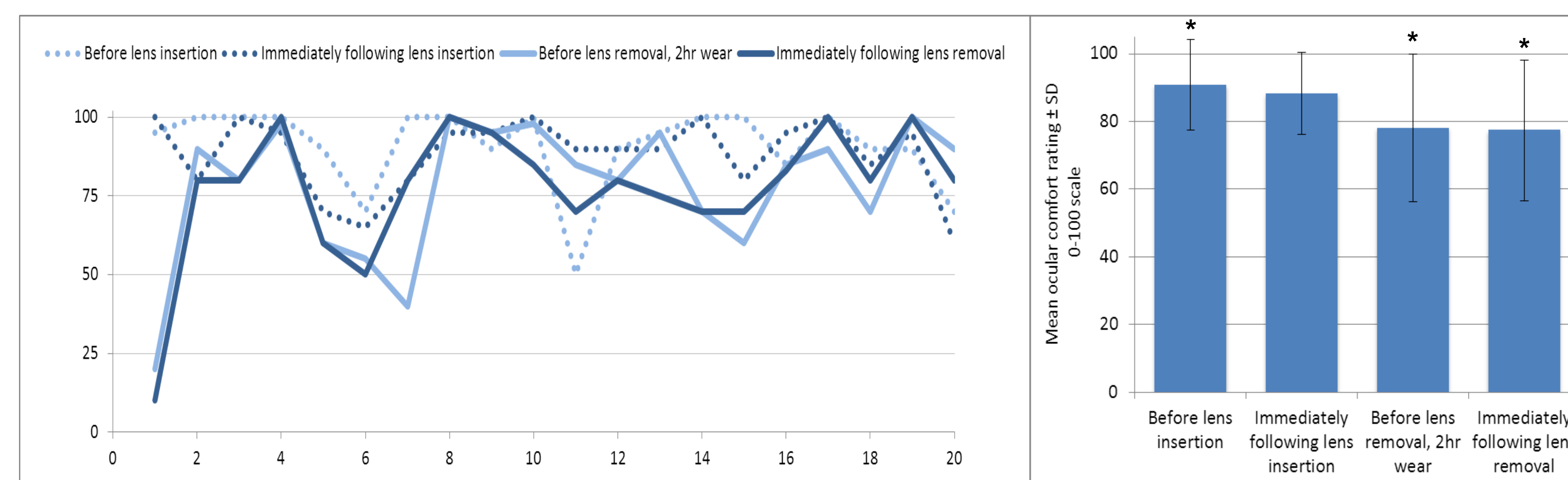


Figure 3: Ocular comfort ratings (0-100) at each time-point: for each subject (left); mean  $\pm$  SD (right)

## Results (cont'd)

- Sixteen subjects reported the specific symptoms during the study.
- Four were free of the specific symptoms at all 4 time points; these subjects did not present with the lowest levels of staining.
- The subject with the annular pattern of staining reported 'burning' symptoms immediately before and after lens removal.
- As shown in Figure 2, most symptoms were reported following lens removal; 'stinging' was the most common one, followed by 'burning'; 1 subject reported having both.
- The variability of comfort ratings was greatest at 2hrs and the drop in comfort from 'before lens insertion' (91) to 'before lens removal' and 'following lens removal' (78, 77) was significant, Tukey post-hoc  $p=0.032$  &  $0.024$ , respectively (Figure 3).

## Discussion

- It was more common to see pan-corneal staining than peripheral annular staining. It is possible that this group of subjects may not be representative of the contact lens wearing population, given that 100% of subjects demonstrated a SICS response, a higher rate than has been previously reported in the literature.<sup>1,5,6</sup> A much larger incidence study would provide more conclusive evidence of the distribution of these patterns among SICS responders. Clinical trials of repeated exposures on the same participants should provide evidence of whether the pattern of staining is repeatable, whether it is subject dependent and whether the patterns interchange with observation time.
- Stinging and burning were reported most frequently at the 2hr wear time, after lens removal.
- The total corneal staining area was fairly consistent across subjects, but the data show that certain individuals experienced reduced comfort while others did not.
- Absence of symptoms has been used to support the theory that SICS is a harmless phenomenon of simple molecular binding to the surface cells of the corneal epithelium.<sup>3</sup> But this trial shows that some subjects experience reduced comfort and specific symptoms with SICS. The exact mechanism of corneal staining in general, including SICS, remains unclear and requires more investigation.<sup>8</sup>

## References

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