

SHORT-TERM OVERNIGHT STUDY WITH SELENIUM ANTIBACTERIAL SILICONE HYDROGEL CONTACT LENSES

INTRODUCTION

Selenium [Se] is a trace mineral essential for cellular function. Dietary selenium comes from nuts, cereal, meat, fish and eggs.

Bacterial contamination of lenses during continuous wear is associated with inflammation and infection.

Selenium covalently attached to a surface is a catalytically biocidal agent which can arrest local cellular growth by creating transient, localized, free radicals.¹

PURPOSE

Study aims were to evaluate the antibacterial efficacy of Se-coated silicone hydrogel lenses *in vitro* and *ex vivo*, and assess cytotoxicity and clinical safety of Se-coated lenses.

MATERIALS AND METHODS

Se-coated balafilcon A lenses were challenged with *Staphylococcus aureus* 31 or *Pseudomonas aeruginosa* 6294.

After 24 hours incubation, bacterial colonization numbers on lens surfaces were enumerated.

Biofilm formation on selenium and control lenses were also examined under microscope after stained with fluorescence by using the LIVE/DEAD BacLight Bacterial Viability Kit.

Cytotoxicity of Se lenses was examined by using standard cell growth inhibition assay.

To detect difference of 0.5 ± 0.5 in bulbar/limbal redness and 10 ± 15 in comfort rating at 80% power, 20 subjects were required.

20 subjects completed a double masked, contralateral, randomised, controlled clinical trial by wearing Se-coated lens on one eye and standard balafilcon A lens on alternate eye for 24 hours.

Clinical assessments were performed during the course of the trial (BL, 6 hours, Prior to sleep and On waking). Grading scale for clinical variables was from "0" (Absent) to "4" (Severe) in 0.1 steps

Lenses were collected aseptically at trial conclusion and assessed for *ex vivo* antimicrobial activity.

RESULTS

Adhesion Testing

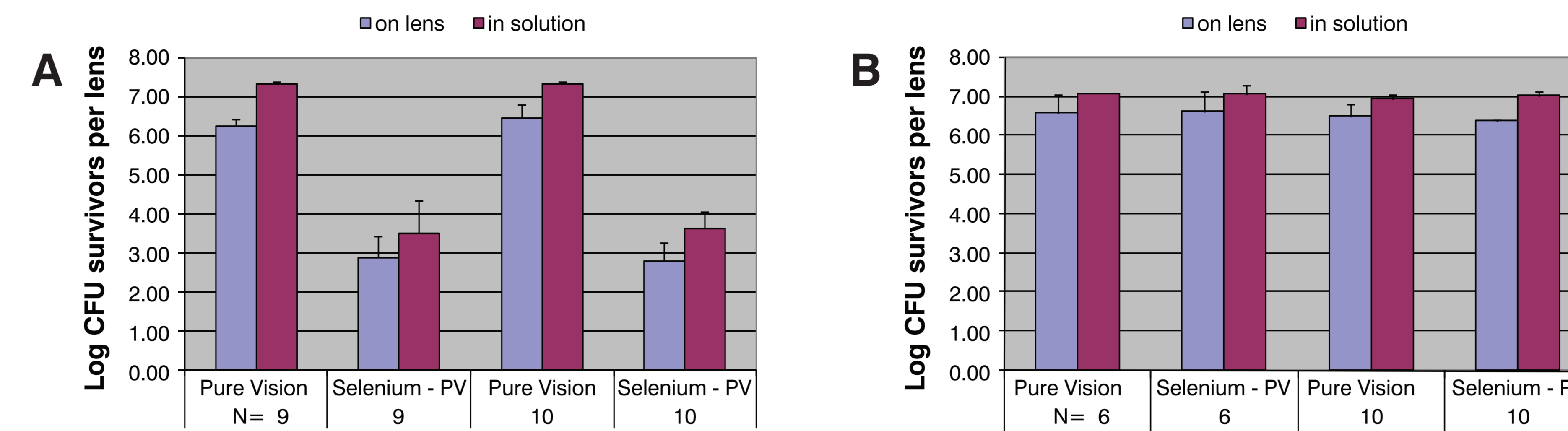


Fig 1: Activity of Selenium lenses against (A) *S. aureus* 31 and, (B) *P. aeruginosa* 6294, *in vitro* and *ex vivo*

Fluorescent Staining

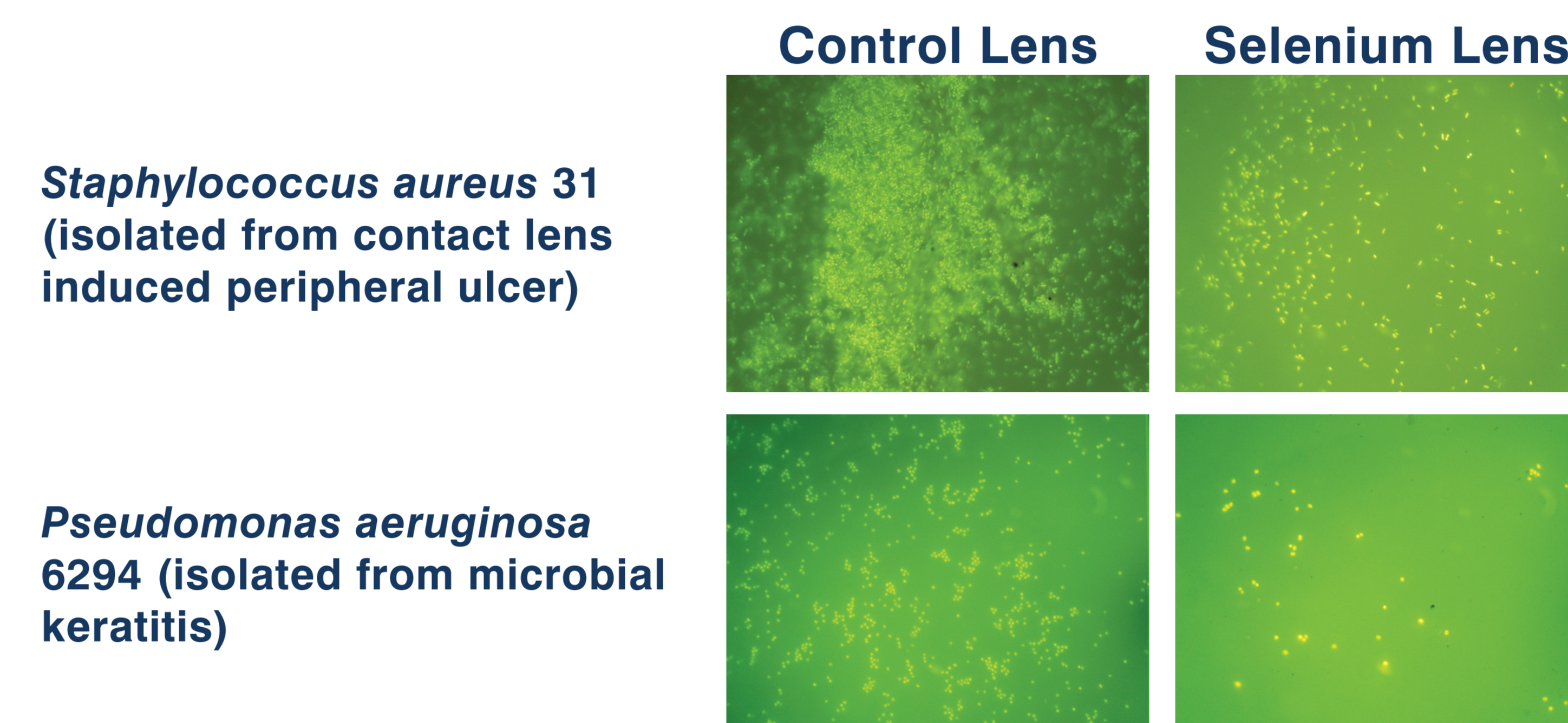


Fig 2: Fluorescent staining of control and test lenses.

Challenging bacterial cells were cultured with control or test lenses for 24h. After washing to remove loosely attached bacterial cells from lenses, the attached bacterial cells were stained with fluorescence by using the LIVE/DEAD BacLight Bacterial Viability Kit, in which live cells are stained by SYTO 9 to green color and dead cells stained by propidium iodide to orange red.

Staining

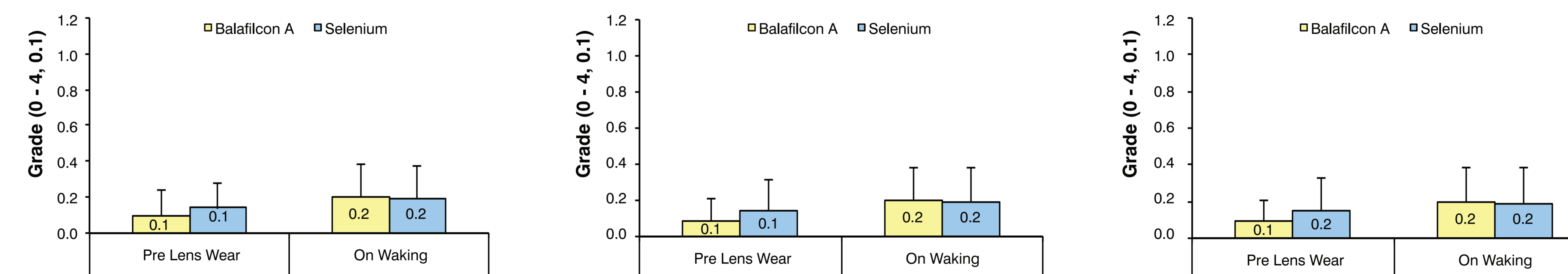


Fig 3: Grading of corneal staining at various time points

Redness

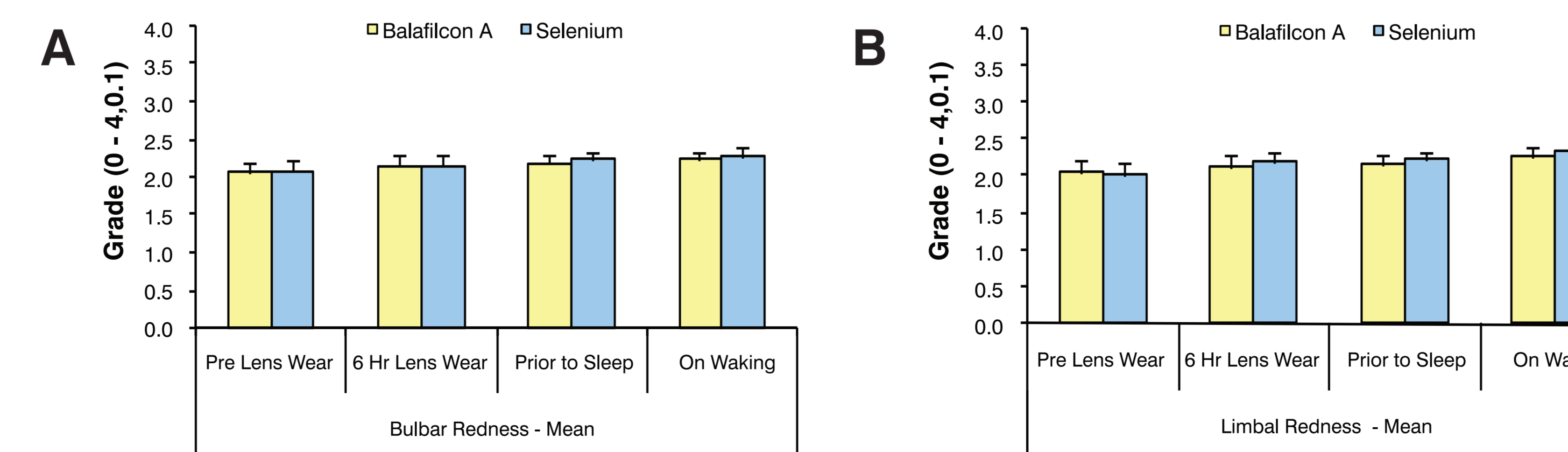


Fig 4: Grading of ocular redness at various time points

RESULTS

No differences were observed for corneal (Fig 3) and conjunctival staining between both lenses.

Biofilms formed by test strains on Se-lenses were markedly less than on control lens surfaces (Fig 2).

Se-lenses showed significant antimicrobial activity against *S. aureus* 31 *in vitro*, reducing colonization of *S. aureus* 31 by more than 3-log units (Fig 1A).

Se-lenses inhibited biofilm formation by *P. aeruginosa* 6294 (Fig 2).

Se-lenses showed no significant cytotoxicity/cell growth inhibition.

Se-lenses behaved similarly to control lenses for bulbar (Figure 4A) and limbal redness (Figure 4B).

Subjective responses and fitting performance between test and control lenses were similar.

CONCLUSION

The results of the study suggest that Se-coated lenses are able to inhibit bacterial colonization.

The overall clinical performance of the Se-lenses was comparable to the commercially available lens, and the efficacy of Se-lenses is maintained after 24 hours CW.

A larger scale, continuous wear, dispensing trial is required to further assess safety and efficacy of selenium lenses.

REFERENCES

- Mathews SM, Spallholz JE, Grimson MJ, Dubielzig RR, Gray T, Reid T. Prevention of Bacterial Colonization of Contact Lenses with Covalently Attached Selenium and Effects on the Rabbit Cornea. *Cornea* 2006;25(7):806-814

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