BIOCOMPATIBILITY AND RETENTION OF ACTIVITY OF MELIMINE ANTIMICROBIAL CONTACT LENSES IN A HUMAN CLINICAL TRIAL

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INTRODUCTION

Micronidal contamination of contact lenses during wear is closely associated with ocular inflammation such as contact lens-induced red eye (CLARE),1 contact lens peripheral ulcer (CLPU) and infiltrative keratitis (IIK).2 Although rare, micronidal keratitis (MK) is a sight-threatening contact lens-related infection.3-4 A contact lens with high antimicrobial activity may inhibit microbial adhesion and consequently reduce these contact lens-related adverse events. Melimine, prepared by combining active regions of protamine and melittin, is a broad spectrum antimicrobial peptide (AMP).5-6 Covalently bound melimine on contact lenses has demonstrated high activity against a range of microorganisms including fungi, Acanthamoeba and various strains of multi-drug resistant bacteria.7� When worn by rabbit, these lenses did not produce any signs or symptoms that may indicate ocular toxicity.

The aim of this study was to investigate the performance of melimine-coated contact lenses in a human clinical trial.

METHODS

• Melimine (T-L-S-W-K-K-R-K-R-G-R-H-R-G-R-G-G-R-R-G-G-R-R-R-R-R-R-G-G-R-R-R-R) was covalently attached on contact lens surface that has been detailed by Dutta et al.8
• The study was approved by Human Research Ethics Committee (HREC) of the University of New South Wales, Sydney and followed the tenets of the Declarations of Helsinki. It was registered in the Australian and New Zealand Clinical (Trial Registry (ACTRN1261200062870).9
• Seventeen participants were enrolled in the prospective, randomised, double masked, controlled clinical trial. Their ages were 30.9 ± 9.4 years.

RESULTS

Clinical Signs and Symptoms:

• There were 10 females and 7 males in this study and mean (±SD) age of the participants was 30.9 ± 9.4 years.
• Following lens wear, follow-up visits were conducted after 1 and 4 weeks to evaluate participants' comfort, dryness and lens awareness with lenses and corneal health. Seventeen participants were enrolled in the prospective, randomised, double masked, controlled clinical trial. Their ages were 30.9 ± 9.4 years.
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Distribution of comfort scores during melimine-coated and control contact lens wear is presented in Figure 3 along box plots.

Figure 1. Diffuse corneal staining after melimine-coated contact lens wear

Figure 2. Fluorescein staining scores (median; mean ± SD) in melimine-coated and control contact lens areas.

Retention of Antimicrobial Activity:

• Worn melimine lenses showed 0.5 ± 0.3 log (p = 0.05) and 0.8 ± 0.5 (p > 0.05) log higher P. aeruginosa 6294 and S. aureus 31 adhesion to contact lenses collected from each of the 17 participants is presented in Figure 5.
• Worn melimine-coated contact lenses showed significantly lower adhesion (p < 0.05) when compared to worn control lenses, resulting in 1.5 ± 0.3 log and 1.5 ± 0.4 log inhibition in adhesion respectively.
• Worn melimine lenses showed 0.5 ± 0.3 log (p = 0.05) and 0.8 ± 0.5 (p = 0.05) log higher P. aeruginosa 6294 and S. aureus 31 adhesion than unworn melimine lenses (Figure 4).
• P. aeruginosa 6294 and S. aureus 31 adhesion to contact lenses collected from each of the 17 participants is presented in Figure 5.

Bacterial adhesion to melimine-coated and control contact lenses. The asterisk (*) represents significantly reduced adhesion to worn or unworn melimine-coated lenses compared to worn or unworn uncoated lenses, whereas # represents significantly higher adhesion to worn melimine lenses compared to unworn melimine lenses.

CONCLUSION

This study for the first time showed that antimicrobial peptide-coated contact lenses can be safely worn by humans. Melimine-coated lenses wear was uneventful except that it was associated with higher bacterial adhesion, similar in presentation to solution-induced corneal staining. The melimine-coated lenses retained high antibacterial activity after wear.

REFERENCES

9. Melimine (T-L-S-W-K-K-R-K-R-G-R-H-R-G-R-G-G-R-R-G-G-R-R-R-R-R-R-G-G-R-R-R-R) was covalently attached on contact lens surface that has been detailed by Dutta et al.8

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