Surface-Modified Silicone Contact Lenses from Interfacial Design to Clinical Evaluation

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Statement of Purpose: A water-coordinating modification was applied on silicone contact lenses with the goal of improving wettability and comfort. A betaine polymer, which provides lubricity and hydrophilicity, was covalently grafted on the lens surface. The research includes surface chemistry development, material analysis, hysteresis evaluation, contact lens performance evaluation and a clinical trial for safety evaluation.

Methods: Commercially available silicone hydrogel lenses (CIBA Air Optix Aqua, AOA) were surface-modified using a one-step controlled polymerization process. Control lenses were cleaned after removal of residual packaging solution components. Wettability was analyzed with dynamic contact angle (DCA) using an underwater captive bubble method. Further, hysteresis was assessed by comparing advancing and receding DCA. Coefficient of friction (COF) measurements in linear reciprocating mode using a nano-indentation instrument. The durability of the modification was evaluated following autoclaving after aggressive cleaning using a 3% hydrogen peroxide regimen for 30 cycles. The modified lenses were further evaluated after a 90-day shelf-life test. Optical, dimensional, mechanical, oxygen permeability, and biocompatibility properties of the contact lenses were evaluated following relevant ISO standards. A single-center, double-masked one day safety study was performed for safety. Ten adapted contact lens wearers with myopia and astigmatism (n= 10 subjects) were contralateral eye randomized into wearing modified contact lenses (n=10 eyes) and control contact lenses (n=10 eyes). Subjects were examined at the baseline/screening exam and at a final exam after 4 to 6 hours of wear. Subjects also completed a comfort questionnaire at baseline, 1 hour and at the final examination. The primary study endpoint was a comparison of objective findings, including slit lamp (biomicroscope) evaluations and adverse events, along with an evaluation of patient reported responses comparing the wear of modified to unmodified contact lenses. The trial lenses were evaluated for wettability and stability.

Results: Pre-clinical testing revealed that the surface wettability and lubricity of the AOA contact lenses were significantly improved after surface modification. The advancing DCA of modified lenses was reduced by 71% . The DCA hysteresis is substantially lower than the 16 degree hysteresis on the AOA lens. The COF of modified lenses was reduced by 62% relative to unmodified. The surface modification had no substantial effect on the bulk properties including water content, clarity, power, oxygen permeability, dimensions, and mechanical properties. The modification was stable to an aggressive cleaning regimen with mechanical and oxidative challenges. The lenses were within the acceptance criteria after autoclave sterilization or a 90-day aging, and there was no evident change in modification concentration and surface wettability. The randomized clinical study revealed no safety concerns after 4 to 6 hours of use by a population of adapted control contact lens wearers. Objective evaluations showed no corneal changes as viewed by slit lamp and demonstrated longer time to haze for the modified lens wearers. Patient reported symptoms were similar both the modified and the control lenses. The implantation did not change the wettability and presence of modification.

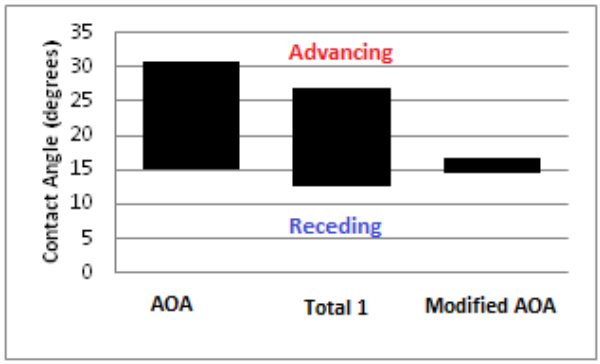

Figure 1. DCA hysteresis of control and modified lenes. Contact Lenses were rubbed 30 times for 30 seconds with 3% H_2O_2 prior to analysis by dynamic contact angle

Conclusions: Pre-clinical and human evaluations indicate that the betaine-modified lenses significantly improved surface performance such as lubricity and wettability without sacrificing dimensional, mechanical, physicaland optical properties of the underlying materials. The surface modification process is alsocompatible with required cleaning and sterilization processes. The clinical safety study also confirmed the safety and feasibility of the interfacial design. These modified lenses are likely to outperform currently used silicone contact lenses in terms of comfort, especially for patients requiring extended implantation and use

References:

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