Evaluation of a Cleaning and Disinfecting System and a Multi-Action Solution Against Compendial Challenge Organisms with Scleral and Conventional Rigid Gas Permeable Contact Lenses

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Introduction

Rigid gas permeable (RGP) contact lenses provide a wide range of benefits for patients. Conventional RGP contact lenses are manufactured using silicone acrylate or fluoro silicone acrylate lens materials. RGP contact lenses fit directly over the cornea and range in diameter from 9mm – 15mm. Recent advances in these designs include a variety of specialty scleral RGP lenses that are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject: 1. cannot be adequately corrected with spectacle lenses, 2. require a rigid gas permeable contact lens surface to improve vision, 3. are unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities. Use of scleral lenses has increased over the years and are more likely to be fitted to males and older patients.[1] Modern scleral lenses vary and include mini scleral lenses (16 mm in diameter) to a full scleral lens that may have a diameter of up to 24mm and a sagittal depth of 10mm. These scleral RGP lenses are unique to contact lens wearers (CLW) due to the placement of the lens on eye. The scleral lens vaults over the cornea and fits directly on the ocular corneo-scleral junction or may extend over the sclera surface. This offers the eye care practitioner a unique opportunity to successfully treat serious sight threatening conditions. Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).[1,2]

As with all CLW, the most significant risk factor to the patient is Microbial Keratitis (MK). Adequate care of all contact lenses, regardless of type, is critical to patient safety. A thorough assessment of contact lens care and patient compliance is essential when using conventional RGP and scleral RGP contact lenses.[3]

These studies sought to evaluate the cleaning and disinfection effectiveness of a 2-product system (DS-1) and a single-product multi-action solution (DS-2) with silicone acrylate (SA), fluoro silicone acrylate (FSA), and FSA scleral contact lenses.

Methods

Testing was performed in accordance with ISO 14729:2001/AMD. 1:2010 for Regimen disinfection efficacy.[4] Test SA contact lenses (<15mm in diameter) and FSA scleral lenses (≥14.5mm - ≤23.5mm diameter) were inoculated with $2.0x10^5$ to $2.0x10^6$ colony forming unit (CFU)/ml on the convex and concave surfaces of each lens with *S. aureus* (ATCC 6538), *P. aeruginosa* (ATCC 9027), *S. marcescens* (ATCC 13880), *C. albicans* (ATCC 10231), and *F. solani* (ATCC 36031) and prepared with 100% organic soil. After 5 minutes of adsorption, both sides of the lens were rubbed for 10 seconds with 2-4 drops of DS-1 cleaner, followed by a 5 second rinse with a sterile saline solution. Lenses were placed in a lens case filled with 3mls or a scleral lens case filled with 6mls of DS-1 (Table 1) conditioning solution containing the disinfectants chlorhexidine (CHG) and polyaminopropyl biguanide (PAPB) for 4 hours.

An additional set of test lenses were inoculated as described above and each lens placed in the respective lens case containing 3mls or 6mls of DS-2 (Table 1) multi-action solution and soaked for 4 hours.

Methods (Continued)

After soaking in DS-2, the lens was removed from the lens case and both sides of the lens were rubbed for 10 seconds with 2-4 drops of DS-2 and rinsed with the same solution for 5 seconds.

Membrane filtration was performed to evaluate each set of lenses and soak solutions to recover viable challenge organisms. Total colony forming units were enumerated for each test lens and associated soak solution.

Table 1: Composition of a Cleaning and Disinfecting System and a Multi Action Solution

DS-1 – Cleaning and Disinfecting Formulations
Cleaner: Sterile, concentrated, homogeneous surfactant solution containing alkyl ether sulfate, ethoxylated alkyl phenol, tri-quaternary cocoa-based phospholipid and silica gel as cleaning agents; with titanium dioxide. **Conditioner:** Sterile, aqueous, buffered, slightly hypertonic solution containing a cationic cellulose derivative polymer, a cellulosic viscosifier, polyvinyl alcohol and a derivatized polyethylene glycol as wetting and cushioning agents; preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%) and edetate disodium (0.05%)
DS-2 – Multi-Action Formulation
Sterile, aqueous, buffered solution that contains poloxamine, hydroxyalkyphosphonate, boric acid, sodium borate, sodium chloride, hydroxypylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%)

Results

Results demonstrated minimal or no recovery for each challenge organism when using DS-1 or DS-2 with silicone acrylate (SA), fluoro silicone acrylate (FSA), and FSA scleral contact lenses. All test solutions met the performance criteria of ≤ 10 CFU mean recovery for the lens/storage solution combination for each lens type evaluated as shown in Table 2 and Table 3. [5]

All test lens controls for each organism were within the range of $2.0x10^5$ to $2.0x10^6$ colony forming unit (CFU)/ml for each lens type.

Table 2: Mean Recovery (CFU) of DS-1

Lens Type	***S. aureus*** ATCC# 6538	***P. aeruginosa*** ATCC# 9027	***S. marcescens*** ATCC# 13880	***C. albicans*** ATCC# 10231	***F. solani*** ATCC# 36031
(14.5mm RGP Lens) fluoro silicone acrylate	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
(≤23.5mm Scleral Lens) fluoro silicone acrylate	**0.0**	**0.0**	**0.0**	**0.0**	**0.5**
(14.5mm RGP Lens) silicone acrylate	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Table 3: Mean Recovery (CFU) of DS-2

Lens Type	***S. aureus*** ATCC# 6538	***P. aeruginosa*** ATCC# 9027	***S. marcescens*** ATCC# 13880	***C. albicans*** ATCC# 10231	***F. solani*** ATCC# 36031
(14.5mm RGP Lens) fluoro silicone acrylate	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
(≤23.5mm Scleral Lens) fluoro silicone acrylate	**0.5**	**0.0**	**0.0**	**0.0**	**0.0**
(14.5mm RGP Lens) silicone acrylate	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

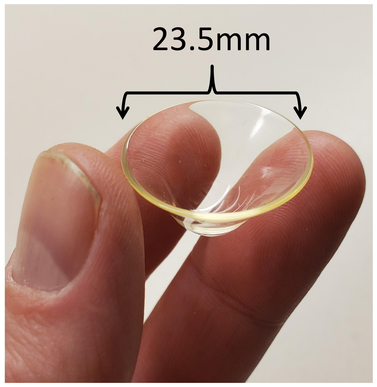

Figure 1 – Specialty Scleral RGP Contact Lens
≥14.5mm diameter and up to ≤23.5mm diameter / up to 10mm Sagittal Depth

Material:
Fluoro silicone acrylate

Figure 2 – RGP Contact Lens
9-15mm diameter

Material:
Fluoro silicone acrylate, silicone acrylate

Conclusion

Disinfection efficacy is important for successful RGP contact lens wear including, patients with corneal abnormalities and conditions that require the use of a specialty scleral contact lens. The results of this evaluation demonstrate that scleral and conventional RGP contact lenses are effectively cleaned and disinfected using either a 2-product cleaning and disinfecting system or a single-product multi-action solution.

References

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