Evaluation of a new lathable silicone hydrogel material

- with the ability to manufacture custom made contact lenses for specialty lens fits -

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Introduction

Contamac Ltd (Saffron Walden, Essex, UK) has developed a lathable, high water content/low modulus silicone hydrogel material (*Definitive*) that has a 74% water content and a Dk of 60. Custom made lenses (*HydroWave*) are manufactured from this material by UltraVision CLPL (Cambridge, UK).

The main aim of this study was to assess lens wearing comfort, lens performance and corneal/conjuctival physiology of the *HydroWave* (test) lens compared to a control lens worn on the fellow eye. The control lens material used in this study is the only commercially available alternative for the same indications (e.g. custom-made silicone hydrogel lens designs).

Methods

This three-month, single-blind, prospective study was carried out to independently evaluate comfort, vision, lens performance, and corneal/ conjunctival physiology of a new silicone hydrogel lens material compared to a control silicone hydrogel lens material. This was a multi-centre study, performed by large contact lens practices around the Netherlands using existing lens wearers, and it therefore resembles a true-life evaluation.

Included in this study were subjects with high myopia (-6.00D minimum). The aim was to evaluate higher ametropic corrections to maximally benefit from the theoretical advantages that this new material can offer.

All subjects were free from pathological eye conditions, and only existing contact lens wearers were included in this study (minimal lens wearing period prior to the study was six months). K-readings ranged between 7.20 and 8.30mm, and astigmatism was limited to 2D maximum (no toric lens designs were allowed in this study). All participants signed an informed consent (in Dutch) prior to the study.

• ***Lens fit***

Lenses were ordered based on central keratometry values, spherical cylindrical spectacle refraction (corrected for vertex distance), and horizontal visible iris diameter (HVID). A right or left lens was randomly assigned by the manufacturer and sent to the practitioner in a masked fashion. The control material used in this study was the CIBA Vision Air Optix Individual (32% water content, Dk 82, modulus 1.1Mpa). Lens material was traceable by a unique code only, not available to the participating subjects. But although the lenses were dispensed in neutral vials, practitioners could not be masked during slit lamp exam since the control lens was engraved with the company logo.

Methods (continued)

• ***Care system***

The care system used during the study was a one-step peroxide system (AOsept, CIBA Vision) for all lenses and all participants, and it was used as indicated by the solution manufacturer.

• ***Evaluation***

All lenses were worn for a minimum of one hour at the examination visits. Evaluation visits took place immediately after dispensing, two weeks following dispensing, eight weeks following dispensing and twelve weeks following dispensing (exit visit).

• ***Comfort***

Comfort was graded by completion of a visual analog scale (VAS) for ocular comfort (0= painful, 10=can't feel the lenses at all) for each eye separately at each consequent visit.

• ***Vision***

Overrefraction and best corrected visual acuity were registered, using a Snellen chart and digital notation system, at all follow up visits.

• ***Lens performance***

Lens movement and centration (in the horizontal and vertical direction) were registered as optimal (0), acceptable (suboptimal, 1), or non-acceptable (rejected, 2). Wettability of the lens surface was examined on a three point scale ranging from optimal (0) to suboptimal (1) to poor (2). Lens debris was rated as either absent (0), minimal (1), or severe (2), regardless of the type of deposition.

• ***Ocular health***

Evaluation of corneal and conjunctival health was assessed using the 0-4 CCLRU (Cornea and Contact Lens Research Unit, Sydney, Australia) grading scale. A baseline was taken at the dispensing visit for all variables. For corneal staining a fluorescein dye and a yellow barrier filter were used to grade type, depth, and extent of staining. Bulbar conjunctival redness, palpebral conjunctival redness, and roughness (contact lens induced papillary conjunctivitis, CLPC) were evaluated using this scale.

• ***Analysis***

Statistical analysis of the data was performed using Statistical Package for Social Sciences (SPSS) version 15.0. The t–test and chi-square test were used for statistical analysis. A critical p value of 0.05 was used to denote statistical significance for all analysis.

Results

With regard to the most important variable considered in this study, lens comfort, it was found that lens comfort was slightly higher in the test material than in the control material, but this was statistically significant only at dispensing (Fig 1). Mean comfort score at dispensing was 6.4 ± 2.2 in the test group and 5.0 ± 2.3 in the control group (p=0.01).

Results (continued)

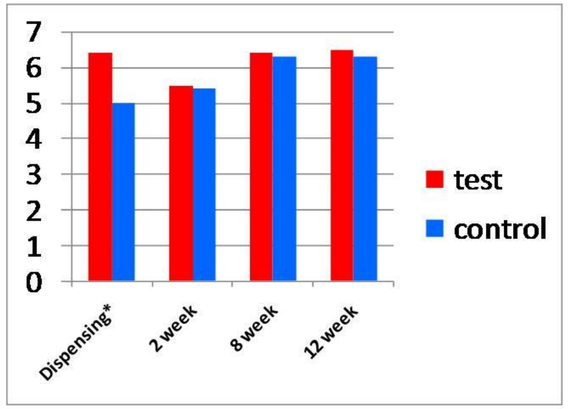

Fig 1.
Comfort scores on a VAS scale (0-10) at four visits for the test and control material
* indicates a statistically significant difference of p=0.01

No difference in visual acuity was found at any of the visits between the test and control group.

Lens performance was found to be the same with the test material as with the control material regarding centration: equal amount and type of decentration in the horizontal direction and in the vertical direction was found. A pattern was seen regarding lens movement, with more often minimal movement ratings seen in the test material versus more excessive movement in the control material. This reached only statistical significance at the two week visit (p=0.01).

For lens surface quality, slightly more lenses were rated as 'poor' wettability (grade 2) in the control material (18%) than in the test material (9%) at eight weeks, but this was not significantly different. At twelve weeks (Fig 2), slightly more lenses were rated as 'poor' in the control material (21%) than in the test material (11%) group, but this also was not significant.

For debris, no difference was found at eight weeks, but again more lenses were rated as having 'severe' debris (grade 2) in the control group (32%) at twelve weeks (Fig 3) than in the test material (16%) but without statistical significance.

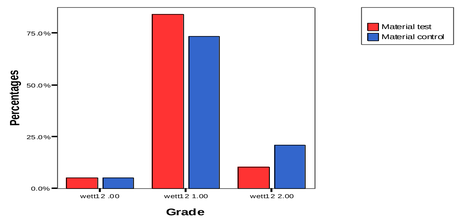

Fig 2.
Percentages of lenses rated as grade 0 (wett .00), grade 1 (wett 1.00) and grade 2 (wett 2.00) at eight weeks 12wk

Results (continued)

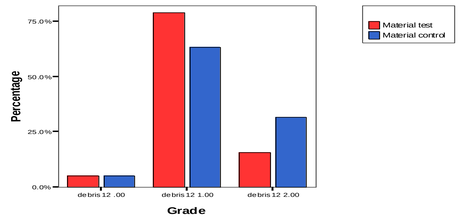

Fig 3.
Percentages of lenses rated as grade 0 (debris12 .00), grade 1 (debris12 1.00) and grade 2 (debris12 2.00) at 12wk

When looking at corneal physiology, there was no difference between the test material and control material concerning corneal staining (type, extent, or depth). Also, no difference in ocular redness was observed at any visit. A slight difference in CLPC was seen in favor of the test material group compared to the control group. At baseline, the CLPC grades were exactly the same (grade 0.9), at the two week visit a minimal difference was seen (0.1 grade difference) while at eight weeks and twelve weeks this difference was 0.2 grade (not statistically significant).

Discussion & Conclusions

The results of this randomized, single-blind, prospective study comparing two silicone hydrogel materials for high myopic spherical correction indicate that the test material performed equal to or slightly better than the control material.

Comfort of lens wear, the main objective of this study, was higher at dispensing in the test material group. Since the study was blind from the perspective of the lens wearer this information is of interest, but is open to speculation as to why lens comfort was different at dispensing and why this difference was not present at the follow up visits. Hypothetically, the reported smooth surface of the *Definitive* material could be responsible for the initial higher rating in comfort. This could also, again hypothetically, play a role in the more minimal movement ratings of the test material versus the more excessive movement ratings in the control material group. Lens surface quality (both wettability and debris) in combination with the incidence of CLPC are points of interest for future studies evaluating the material.

The lathable nature of the silicone hydrogel material has large potential for custom-made lens purposes for specialty lens fits. Currently more than 280,000 speciality silicone hydrogel lenses have been produced worldwide in the *Definitive* material. The material will become available in the US in 2010 through authorised manufacturers.

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