

Achieving the Optimum



Contamac's R&D laboratory

THE INTRODUCTION by Contamac of the Optimum range of RGP materials came about as the result of a lengthy and extensive research and development programme.

This article outlines the various factors involved in such a programme. During this process the team drew upon the experience gained through previous work to develop the Hybrid FS (fluid surface technology) materials (see *OPTICIAN*, January 9, 2004).

The Hybrid FS project had confirmed the need in the RGP lens sector for new materials, combining the traditional wearer benefits of RGP stability and good optical performance with high wettability.

Wettability is also important, not only because a highly wettable lens surface is more comfortable (as good surface wettability of a lens promotes tear film maintenance), but because wettable surfaces have better deposit resistance.

Oxygen permeability is also vital for successful material performance. This is provided by the incorporation of molecules containing silicone and fluorine within the lens material. Oxygen permeability is represented as Dk , where D is the diffusion co-efficient of a gas, such as oxygen, through a polymer, and k is the solubility of the gas in the polymer.

For practical purposes, permeability of a contact lens is represented in terms of transmissibility Dk/L . Here the term L is

Following on from our series on the properties of contact lens materials, **Dr Richard Young** discusses the development of a new range of RGP lens materials

introduced, such that the transmissibility at a specific thickness can be expressed. This is important, as a highly permeable material may not allow good transmission of oxygen if it is very thick.

All contact lens materials necessarily represent a balance between different, to some extent opposing, desirable properties. In the case of RGP lenses, these are wettability, oxygen permeability and stability. Other important properties are the refractive index of the material (for its optical properties) and its specific gravity (weight per cubic gram of lens material is significant in terms of comfort, lens movement and overall performance).

At the outset of the Optimum project, past experience and industry feedback indicated that there was increasing demand in the market for a range of new materials of varying permeability, to allow for different lens prescribing, fitting and wearing requirements.

It was hoped that such a range would represent a significant contribution to the growth of the RGP lens sector throughout the world.

MEASURING OXYGEN PERMEABILITY

When developing contact lens materials one of the challenges is their evaluation by *in vitro* methods, since clinical evaluation of every potential contact lens material is not feasible.

In the development programme, the objective was that these materials should perform better than established products in several key areas. To achieve this goal, there was a need for appropriate methods to quantify performance in key characteristics that would be relevant to the clinical situation. These methods could be used to compare the performance of these developed materials with the market leaders within a particular Dk range.

Oxygen permeability is a property that is difficult to measure accurately and reproducibly. ISO 9913 describes a method for the measurement of this property, but there are opportunities for this method to yield differing Dk values. It is, therefore, important to consider the correction factors that must be applied to

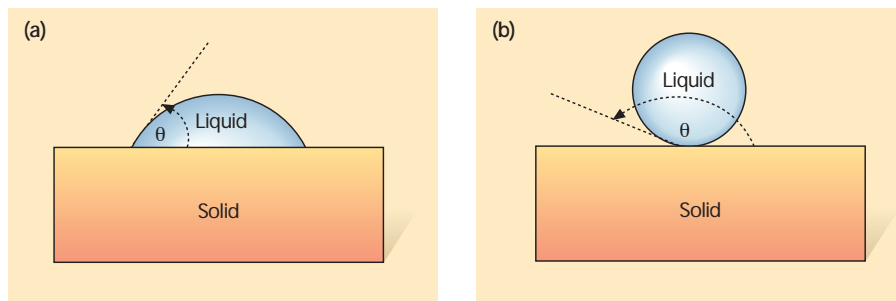


FIGURE 1. Schematic representation of the Sessile Drop Technique for a wettable surface (a) and a non-wettable surface (b)

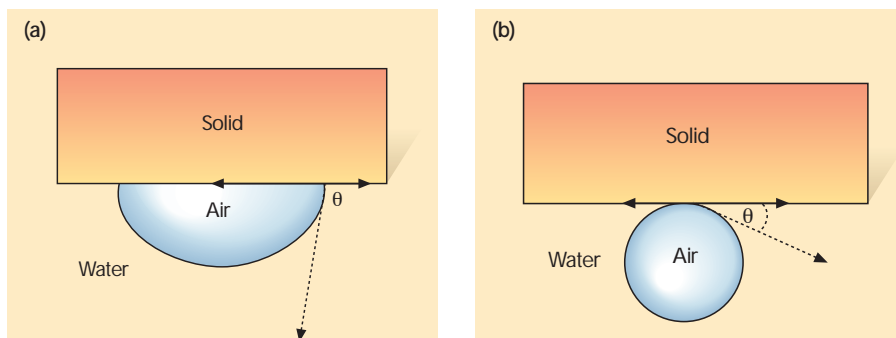


FIGURE 2. Schematic representation of the Captive Bubble Technique for a wettable surface (a) and a non-wettable surface (b)

this procedure, namely the boundary layer effect and the edge effect.

In order to obtain valid results, the apparatus used to measure the Dk was calibrated using samples where the Dk has been determined by the leading independent centre for this technique.

The School of Optometry at the University of Alabama holds the Permeability Reference Materials Repository, a collection of materials where the Dk values have been accurately determined.

Once calibrated, the equipment was used to determine the Dk of both the Boston and Paragon ranges of materials. These results were then compared to the values published by the manufacturers and those determined by the University of Alabama.

MEASURING WETTABILITY

Like oxygen permeability, wettability is a difficult property to characterise for a material in a specific application. This is particularly true for contact lens materials and the complex interactions that occur within the ocular environment. The wettability of a material is often determined by measuring the contact angle, made as a liquid wets a solid surface. This is the angle made by a tangent drawn to the droplet at its point of contact with the surface and its size is dictated by the resolution of forces at this three-phase interface. Traditionally, they are measured by direct optical determination of the formed angle at the interface.

A number of methods have been developed for measuring the contact angle of lens materials and these include the

Sessile Drop Technique (Figure 1) and the Captive Bubble Technique (Figure 2).

These different methods are based on different principles and yield different information. Yet, results using these methods are subject to user interpretation and can be influenced by several environmental and operational factors. Importantly, these methods rely on the high surface tension displayed by water being maintained.

However, this can be dramatically reduced with the introduction of any impurities during measurement. This, of course, is often accidental, although it can be deliberate. The addition of conditioning solutions can reduce surface tension and lead to misleading results.

THE WILHELMY PLATE TECHNIQUE

A relatively recent method for the measurement of contact angles is the Wilhelmy Plate Technique, which is also known as Dynamic Contact Angle Analysis (Figure 3).

This method has the advantage that it can be used to measure either the advancing angle, as a droplet of liquid advances across a dry surface, or the receding angle, as the droplet retreats from the wetted surface.

Crucially, the contact angle is calculated from the force acting on the solid sample as it is immersed and withdrawn from the test liquid. In this way the method does not rely on an optical determination and it is, therefore, free of the problem of user interpretation observed in traditional techniques.

The advancing contact angle is usually

quoted most often, as it is more reproducible. However, the receding angle is almost certainly more important in terms of clinical significance. This is as a result of the fact that the eyelid mechanically assists the establishment of the tear film that corresponds to the advancing contact angle situation.

The receding angle is more relevant to the *in vivo* situation, as it reflects the status of the tear film and whether it will break up on the surface of the eye.

Therefore, we concluded that the receding contact angle obtained using the Wilhelmy Plate Technique could be used as a measure of the wettability in the development of the new range of Contamac RGP materials.

COMPARATIVE TESTING

The team carried out comparative tests of these materials with other available products, measuring wettability as a function of soaking time in saline.

The surface tension was obtained before each measurement to ensure accuracy. The evaluation of potential RGP materials was complemented by practical examination in our technical services department to confirm stability, processibility and performance of the new lens materials. It was also vital that our internal research and development (R&D) project should be supported and completed by clinical trials of lenses made from these new materials. These were carried out by a nationally recognised specialist agency, using lenses made in our technical services department in line with the practitioner's specifications.

CLINICAL TRIAL

Properly conducted clinical trials are a vital and integral element in the process of contact lens development. Their purpose is to test, and if appropriate to validate, the safety and performance of new products.

As contact lenses are categorised in Europe as medical devices, clinical trials must be conducted in accordance with the protocols prescribed by the relevant committees in Britain and Europe. These in turn work in close co-ordination with the US Food and Drug Administration (FDA). The main objective of the Optimum trials was to evaluate this new range in support of an FDA 510(k) application. Protocols require clinical trials to be conducted over a sufficiently long period for evidence of any adverse eye reactions to emerge, and must encompass a sufficiently large wearer group to obtain relevant data.

The Optimum (Roflufocon) range includes four materials (Optimum Classic, Optimum Comfort, Optimum Extra, Optimum Extreme) all with similar

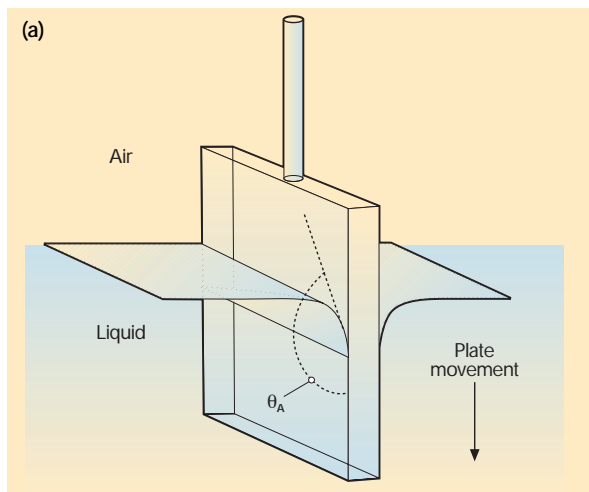
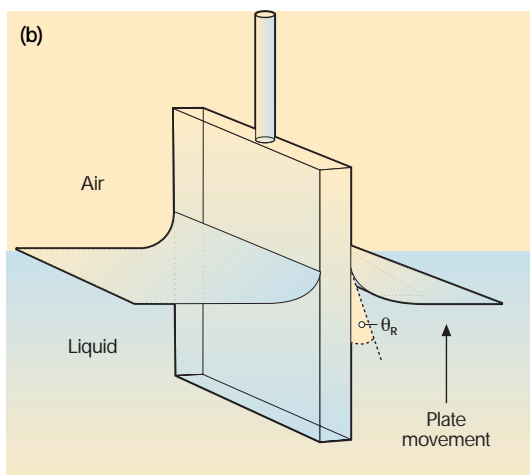


FIGURE 3
(a) Schematic representation of the Wilhelmy Balance Technique (advancing contact angle)

(b) Schematic representation of the Wilhelmy Balance Technique (receding contact angle)



polymeric constituents, but with different oxygen permeability (Dk values).

The clinical trial was constructed to compare the performance of two Contamac materials; Optimum Classic with a Dk of 26 (ISO Fatt, mm Hg) and Optimum Extreme, Dk 125 (ISO Fatt, mm Hg). The materials were given code names for trial purposes and compared with Boston ES Enflucon A (Dk 18) and Boston XO Hexafocon A (Dk 100).

METHOD

As prescribed by protocol, this was a three-month, subject-masked, bilateral randomised trial. Conducted at eight sites in the UK, by 10 appropriately experienced and registered optometrist investigators, the trial covered lenses used in daily wear mode.

The total number of subjects originally enrolled for the study was 136; including previous RGP lens wearers and non-contact lens wearers. The clinical inclusion criteria covered freedom from active ocular disease or eye-significant systemic disease, no clinically significant slit lamp findings, clear central corneas and no evidence of lid or conjunctival abnormality or infection. Subjects had vision correctible to 6/12 or better, with spherical refractive errors in the range +20.00D to -20.00DS, and cylindrical error no greater in either eye than 3.00 DC.

Patients who had undergone corneal refractive surgery were deemed ineligible for inclusion. One of the 136 subjects enrolled was disqualified as falling outside these criteria. Of the remaining 135, 44 were fitted with Optimum Classic lenses in both eyes, and 43 with Optimum Extreme, while 23 wore Boston ES and 23 Boston XO lenses. There were two subjects who, though enrolled, were not dispensed with lenses. The average number of subjects managed by each investigation site was 17.

Before the end of the 12-week trial there were 10 subjects who discontinued wear. Of these, six discontinued because of discomfort and three for non-contact lens related reasons. Only one subject was lost to follow-up.

The average age of subjects was 42.9 years and the age range was nine to 64 years. Subjects below the legal age of consent had received parental authorisation to take part. Overall, 94 of the 136 subjects were female (70 per cent) and 38 male (29 per cent). Average spectacle correction measured on entry to the trial was -4.09D Sph, -0.71D Cyl.

All patients were instructed to adopt a lens care regimen using Boston Advance cleaner, Boston Advance Comfort Formula conditioning solution and Boston rewetting drops, with the proviso that if eye reactions to Boston solutions occurred, alternatives would be prescribed individually.

CLINICAL DATA

Data was collected at the subject's initial visits and at follow-up visits, one week, one month and three months after lens dispensing. Those taking part were also asked to fill in questionnaires on completing the study, firstly regarding their experience with the lenses worn during the trial, and then regarding any previous experience with RGP lenses.

Lens specifications for the test and control lenses were based either on a subject's existing RGP lens prescription or on empirical fitting guidelines. Checks carried out at each follow-up visit included over-refraction, slit-lamp examination and keratometry. Slit-lamp findings were recorded using the Cornea and Contact Lens Research Unit (CCLRU) grading scales.

Overall, five adverse reactions/events (AE) were recorded during the study, three rated 'significant' and two 'non-significant'; none were 'serious'. Only two of the five were considered as directly attributable to contact lens wear.

In general, slit-lamp findings suggested that the physiological response of the eye to either Optimum Classic or Optimum Extreme lenses did not differ from responses to lenses made from Boston ES or XO material. However, people wearing lenses made from Boston XO tended to show more conjunctival staining than those wearing Optimum Extreme. Average daily wearing time for all lenses was 14 hours at the conclusion of the trial period.

PATIENT SATISFACTION

From questionnaires completed at the conclusion of the trial, it was noted that more subjects who had worn Optimum Extreme lenses reported vision 'good' to 'excellent' in bright light conditions than subjects who had worn Boston XO, with fewer reports of photophobia among Optimum Extreme wearers.

A slightly higher proportion of Optimum Extreme wearers than of Boston XO wearers reported overall quality of vision through the day as 'good' to 'excellent'. Both high proportions of Optimum Extreme and Boston XO wearers reported comfort on insertion and comfort at the end of the day as 'good' or 'excellent'. Similar results for both lenses were reported involving computer work.

CONCLUSION

Following evaluation of clinical trial results, the Optimum range of RGP contact lens materials was launched in January 2004. A number of trials by our contact lens manufacturer customers worldwide have already taken place, utilising processing advice provided by our technical services department.

The feedback received indicates that the Optimum materials are straightforward to process, yielding lenses of consistently high quality. The development of Optimum has been necessarily acquired on complex and painstaking investigation. It has, however, been well worthwhile.

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