New Material, New Rules

In this second instalment of our series of articles, we present unique opportunities for speciality lens manufacture when using Definitive, our new latheable silicone hydrogel. It is widely accepted that silicone hydrogels offer significant advantages in terms of on-eye performance when compared to conventional hydrogels, and Definitive is no exception. Such performance improvements signify that these two material groups are quite different and each needs to be treated appropriately. Specific considerations for lens manufacture using Definitive are addressed, together with the behaviour of this material with different lens care systems - currently a very topical subject for silicone hydrogels.

Our recent article 'A New Silicone Hydrogel for Custom Lens Manufacture', introduced Definitive, the latheable silicone hydrogel material produced by Contamac Ltd. The benefits of a material that significantly exceeds the Holden and Mertz criteria for oxygen delivery to the cornea, even after long wear periods, were presented. The exceptional results for comfort, water retention and visual acuity in initial clinical studies were also highlighted. This material has created a significant impact on the market in a very short time.

The performance of Definitive clearly changes the rules of soft lens materials, with significant improvements in end of day comfort, when compared to conventional hydrophilic materials. The increased levels of oxygen transported, ensure corneal health is not compromised by the demands of the contact lens wearer. Long wear periods are possible thanks to the combination of excellent water retention and improved corneal health. However as a result of the unique polymer structure required for this improved performance, the material behaves differently to conventional soft materials and requires different treatment for the production of custom lenses.

LENS MANUFACTURE

Significant investigations have been undertaken to evaluate the key considerations that should be given to this material during each step of the lens manufacturing process. Where possible the use of specific blocking wax and solvents have been identified, and recommendations have been suggested in terms of key process steps. Silicone hydrogels have a lower glass transition temperature than conventional hydrogels and extremes of temperature should be avoided during both the blocking and de-blocking stages. Solvent selection for de-blocking is important and exposure to any solvent should be kept to a minimum, as it is possible that these could penetrate into the polymer, particularly at increased temperatures. The material is relatively hygroscopic and will readily absorb moisture from the environment. The material should be stored in sealed moisture resistant bags until ready for use and cut or polished base curves should not be stored in an open laboratory for longer than 20 minutes. Part-finished lenses should be stored in a re-sealable plastic container with desiccant.

Blocking

When blocking Definitive it is important to use as low a heat as possible. The use of Contamac C – 15 white blocking wax is recommended, as this has an operating temperature of 65°C or less. Particulate contamination that remains on the block or on the base curve will cause dimples on the lens after de-blocking and should be minimised.

Diamond Tooling

A tool with a 0.50mm radius or less is recommended and the use of a negative rake geometry diamond will reduce the level of wear. The diamond tooling should be replaced on a regular basis, particularly when the cut surface appears dull and no image is obtainable on a radiuscope before polishing.

Machining Recommendations

The swarf should appear ribbon like and be soft to the touch. If the cut surface of the lens has rings in the center after lathing, it is possible that the speed of the final cut is too slow. Vacuum suction should be used to remove swarf at the point of cutting, as accumulation around the tool tip will affect the surface quality of the lens.

Polishing

The recommended polish compound is Contapol 2, using a brushed cotton polishing cloth. Polishing times will depend on the surface quality attained during machining. Clean the surfaces after polishing using a clean soft tissue; care must be taken to avoid damaging the lens.

De-Blocking

The de-blocking of Definitive is best performed in an ultrasonic bath using Petroleum Ether, Isopar E or equivalent. It is best to keep exposure times to solvents to a minimum, as over exposure could cause permanent distortion of the lens. Solvents should be changed frequently and not be heated to more than 60°C. Once de-blocked ensure the lens is completely clear of all traces of wax and polish, using a soft tissue or jet of dry air. When using a hotplate to de-block, ensure the hotplate is thermostatically controlled to a maximum of 65°C.

Hydration

Prior to hydration ensure that the dry lenses are free from swarf, wax, polishing compounds and solvents. Hydration is best performed in a buffered saline, with a PH of 6.8–7.5. Experience has shown that performing the initial hydration at 2–5°C can aid the durability of the finished lens. Allow the lenses to hydrate for a minimum of 12 hours with at least one change of solution.

Sterilisation

Finished lenses can be sterilised via a typical autoclave cycle of 15 minutes at approximately 121°C.

LENS CARE

There are various types of cleaning systems available to lens wearers for the care of soft contact lenses and a combination of professional advice and personal preference, determines the system used. The interaction of such systems with conventional soft lens materials is well established, however their behaviour with silicone hydrogels are not so predictable. Silicone hydrogels are very different to conventional materials in terms of their polymer structure and

they are also very different to each other, therefore a broad statement of their interaction with care solutions is not possible. The behaviour of Definitive with various types of care system has been investigated and some initial results are presented below.

MULTI-PURPOSE SOLUTIONS

Multi-purpose solutions are the most common cleaning system for the care of hydrophilic contact lenses. The number of solutions on the market is staggering and it would be a significant task to investigate the compatibility of all these solutions with a single material. Hence the investigation into the compatibility of DEF01 with multipurpose solutions was targeted at a selection of some of the most popular, as shown in Table 1.

Solution	Manufacturer	Active Ingredients
Focus Aqua	Ciba Vision	PHMB
Optifree Express	Alcon	Polyquad & Aldox
Optifree Replenish	Alcon	Polyquad & Aldox
Renu Multipurpose	Bausch & Lomb	PHMB derivative
Complete Multipurpose	AMO	PHMB
Synergi	Sauflon	Preservative free
Menicare Soft	Menicon	PHMB

Table 1.

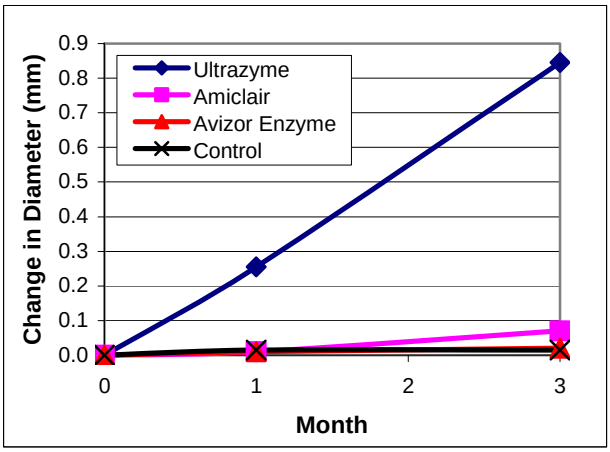
The investigation was designed to reveal material incompatibilities with selected soaking solutions and not to determine the efficacy or anti-microbial activity. Lenses were manufactured and sterilised by autoclave, then BC, diameter and water content were measured before and after soaking. None of the tested solutions were found to have any significant effect on lens parameters.

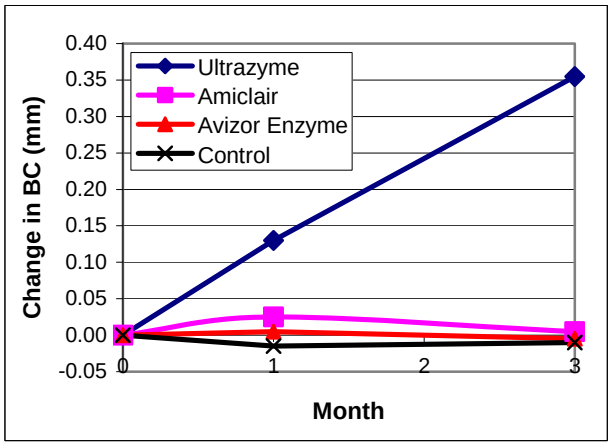
ENZYME CLEANERS

Custom manufactured lenses are often used for 3 months or more and protein removal with enzymatic cleaners can form an important part of their care regime. Unfortunately as the greatest proportion of lenses fitted are now monthly disposable or less, the commercial availability of enzyme cleaners is limited. In Europe Ultrazyme by AMO, Amiclair by Abatron and Enzyme by Avizor are readily available. Unizyme by Ciba Vision could not be sourced and although there are some smaller own brand labels, they are not widely available.

Again the study was designed to reveal material incompatibilities between Definitive and enzyme cleaners, and not to determine their efficacy. Enzymatic cleaning is usually performed on a weekly basis. Finished -10.00 lenses were put through repeated cleaning cycles following the manufacturers instructions and physiological saline was used as the soaking solution. Lenses were measured before cleaning, then after 4 and 12 cycles, simulating 1 and 3 months of cleaning. The diameter and BC were measured at 20°C using an Optimec, and power was measured using a standard focimeter.

The average change in parameters after a simulated 1 and 3 months of cleaning are shown in Figure 1.





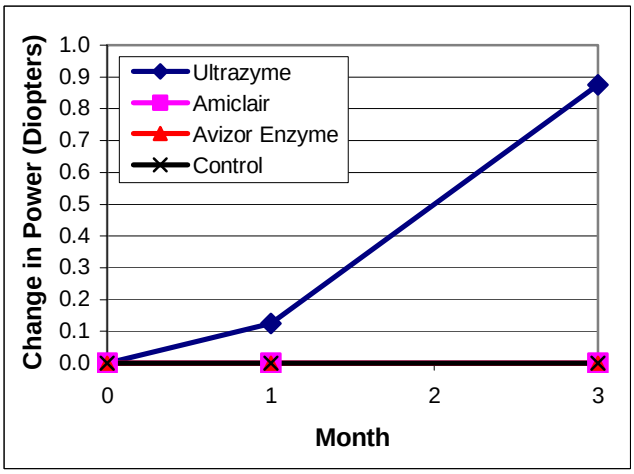


Figure 1.

Movement of Amiclair, the control, and Avizor Enzyme over the simulated 3 months, were within measurement error for all the parameters considered. Clearly Amiclair and Avizor Enzyme had no significant effect on the material.

However the Ultrazyme did have a significant affect on the material. After a simulated 3 months the average diameters increased 0.85, BC flattened by 0.36, power increased by 0.88 Diopters, and some distortion was observed. Therefore it must be concluded that Ultrazyme should not be used with Definitive contact lens material. Without knowing the full formulation for the enzyme tablets, it is not possible to determine why Ultrazyme affects the material in this manner.

PEROXIDE SOLUTIONS

Although multipurpose solutions are the most popular, there has recently been a resurgence of interest in peroxide based systems. Peroxide cleaning is typically performed on a daily basis, with the patient placing lenses in the solution at the end of the day and allowing neutralisation to occur overnight, so that the lenses are ready for use the following morning.

Table 3 shows some commonly available solutions that are being tested for use with Definitive.

Solution	Manufacturer	Active Ingredients	Neutralisation Method
AOSept	Ciba Vision	3% Peroxide	Pt insert
OxySept	AMO	3% Peroxide	Tablet
Everclean	Avizor	3% Peroxide	Tablet
Novoxy	Avizor	3% Peroxide	Solution
EasySept	Bausch & Lomb	3% Peroxide	Pt insert

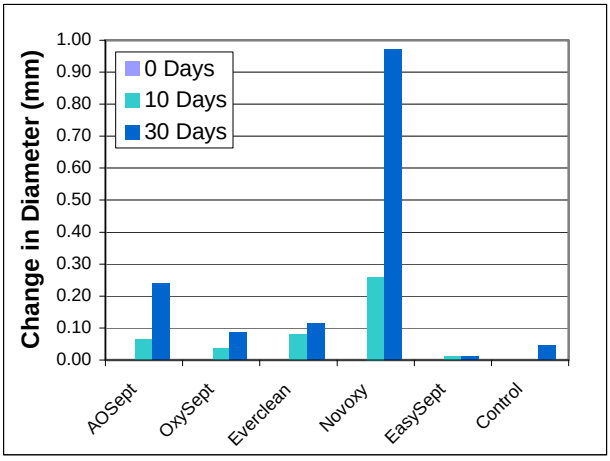
Table 3.

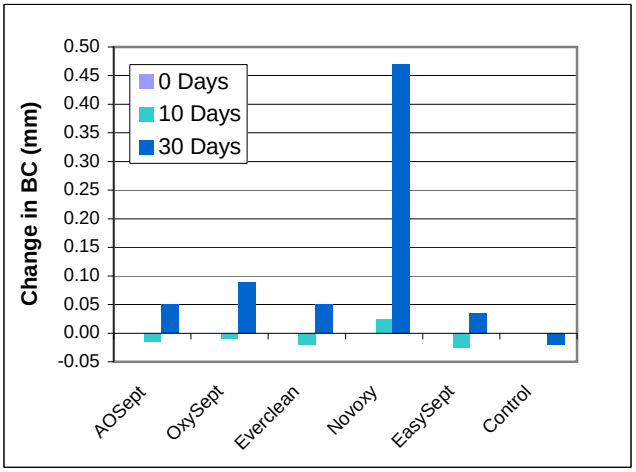
The majority of solutions use either tablet or Platinum (Pt) insert to neutralise the peroxide. The advantage of the Pt insert is that it is incorporated into the lens case and starts neutralisation as soon as the peroxide is added, reducing the possibility of the patient accidentally putting a lens containing active, un-neutralised peroxide into their eye.

Novoxy was the only system tested that uses a neutralising solution. The lens is placed into the peroxide solution for a minimum of 20 minutes. The lens case is emptied, a neutralising solution added and given a minimum of 15 minutes to take effect. It is therefore possible that the lens could be exposed to full strength peroxide for extended periods and feasible that the patient may leave the lens in the peroxide overnight, only adding the neutralising solution in the morning, prior to use.

To investigate the affects of these solutions on Definitive, finished lenses were repeatedly cycled through the cleaning regime given in the manufacturers instructions. Lenses were placed in the peroxide solutions at the end of each day, and where appropriate the neutralising tablet was added immediately. In the case of the Novoxy and as discussed above, the lenses were left to soak in peroxide overnight and neutralised the following morning.

The lenses were measured after a simulated 10 and 30 days of daily cleaning, and the average change in parameters are given in Figure 2.





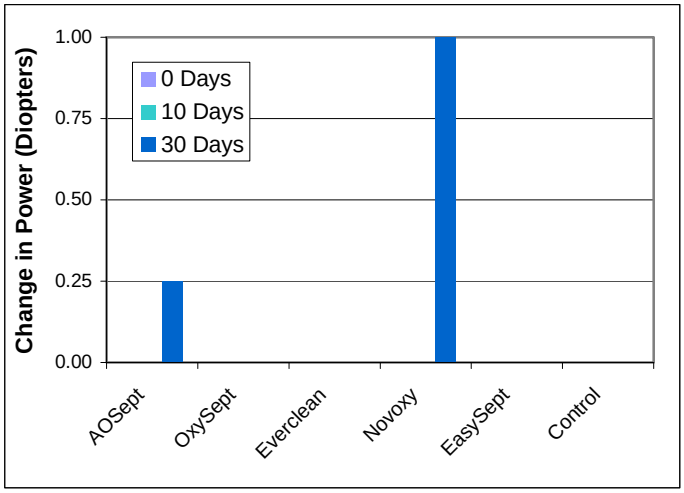


Figure 2.

After a simulated 30 days of daily cleaning, lenses soaked in OxySept, Everclean and EasySept showed little or no movement. The data suggests AOSept caused an increase in power of 0.25 Diopters, but BC moved less than some other solutions. Given the increased error associated with measuring the wet parameters of high water content materials, with the added challenge of incorporated silicone, results from these 4 solutions can be considered to be comparable. Similarly, no distinction could be made between tablet and Pt insert systems.

Novoxy, which uses a neutralising solution, had the greatest and most significant effect on the material, causing an average increase in power of 1 full Diopter, diameter of 1.0 mm and BC of 0.47 mm.

These results indicate that peroxide systems that allow the lens to remain in contact with the fully active, un-neutralised solution for extended periods, should be avoided. When using tablet systems, the tablet should be added at the same time as the solution. As always compliance is of paramount importance and lens cases should be changed at the intervals recommended by the manufacturer. Regular lens case changes will reduce the risk of contamination and ensure that Pt inserts are operating at optimal performance.

IN SUMMARY

Definitive offers clear benefits to the patient and has a unique polymer make-up that does not behave like a conventional soft hydrogel lens. This unique material therefore requires different handling to conventional hydrogels, and appropriate production conditions and lens care regimes must be employed. This article provides some clear recommendations, which should be useful to lens manufacturers and practitioners, for whom Definitive silicone hydrogel material will mean increased patient satisfaction.

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