

Highlights of "An Ophthalmologists' Symposium on the Soft Lens"

Royal College of Surgeons, London, May 18, 1972

This symposium was sponsored by Hydron-Lens and convened by the Institute of Ophthalmology. The meeting was opened by Mr. Alex G. Cross, Dean of the Institute of Ophthalmology, who welcomed the speakers. The chairman of the meeting, Mr. Montague Ruben, said in his introduction that the approach to contact lens fitting had changed within a decade. The main reason was that modern lenses of the softer plastics required chemical engineering know-how and advanced optical engineering procedures not used in conventional hard contact lens practice.

The ophthalmologist's role is at the beginning and at the end of the process: firstly to suggest new ideas and lastly to conduct clinical trials. Objective evaluation of the end-product is necessary for progress and also to protect the public against faulty or injurious contact lenses. The liaison between industry and the profession is not new in medicine but in this instance where many thousands of individuals will use an optical appliance in contact with the eye the liaison must be ethical and the responsibility shared by both practitioner and manufacturer. The legislation that controls drugs and devices in the United Kingdom must consider the soft lens in one or in a combination of three roles—a therapeutic device, a drug dispenser, or an optical appliance—an extremely difficult task.

Dr. Shepherd of Hydron Laboratories discussed the chemistry of the polymer used in soft lens practice. The ability to absorb water was connected with the type of covalent linkages between the long molecule chains. He also noted the existence of ionic linkage materials, which so far have not been used in contact lens practice with any success. The polyHEMA material at this time offers a very stable material which, if polymerized correctly, can be lathe-cut to the exact specifications of the practitioner. While it is admitted that other materials exist, technological research tended to show that pure polyHEMA had a long life, inertia to enzyme systems, no foreign-body effect and, of greatest importance, could be subjected to sterilization by boiling. The last technique considerably reduced the life and therefore the use of higher water-content gels. It was important for the practitioner to note that several years of research had resulted in a method of preparing a hydrophilic plastic contact lens and that these methods, often requiring costly equipment and controls, formed the basis of future research and techniques.

Dr. Sammons then made some interesting comparisons between high water content plastics and the polyHEMA used in Hydron Lenses. When the rate of swelling of the material was measured at various temperatures, different pHs and tonicities, it was evident that the polyHEMA material first used by Wichterle and now by Hydron was constant in behaviour, whereas some high water-content materials behaved in such a way as to introduce stress within the materials and a change of form when made into contact lenses.

Dr. P. Halberg brought out some interesting points concerning the history of soft lenses. He reminded the audience that Dr. Fick in 1888 considered that gelatin would form a good lens and went on to describe the development by Wichterle and Lim of a material first described in the journal *Nature* in 1960, both as a biological tissue embedding agent and as a contact lens. He noted that because of rigid controls the Federal Drugs Administration in the U.S.A. had so far permitted only polyHEMA to be used as a contact lens and this was available in the U.S.A. in only one form and that was a spun-cast lens made by B & L. The same material used by Hydron and other manu-

facturers had been lathe-cut. At this time in the U.S.A. several materials were undergoing trials and many others awaited registration at different phases of development. Unfortunately the development of new soft materials was not academic but industrial, and the Wall Street Stock Exchange journals often made scientific observations to help investors, which were not in the interests of either patient or practitioner. The chairman added a note at the end of this paper that Fick was, in fact, advocating a reduced form of collagen, *i.e.* gelatin. The last paper to be given would outline a method of using collagen. He also drew attention to one point in the history that was of interest to British ophthalmologists. Wichterle had planned to use hydrophilic plastic to make an intraocular implant to replace the cataractous lens, and Harold Ridley's use of polymethyl methacrylates for this purpose had stimulated his thoughts in this direction. When animal experiments showed how difficult this would be, he designed the contact lens to achieve the same purpose. In 1963 Wichterle said that at least 10 years would be required to develop the material. This has so far proved to be true.

Dr. Miles Galin's interests were primarily with glaucoma and his work involved the perfusion of the surface of the human eye with solutions of pilocarpine over 24-hour periods and a comparison with a drop technique of administration. He showed that continuous perfusion resulted in a stabilized tension not obtained by periodic drops. When he heard that De Carle's soft lens of limbal size could be worn constantly, he applied this lens soaked in 4 per cent. pilocarpine to the human glaucomatous eye. The lens was removed every 24 hours and soaked in pilocarpine solution before re-insertion. Using scleral methods of tonography, he showed that this method maintained a stabilized tension as satisfactorily as perfusion. His present work is concerned with fitting this type of lens on several normal patients, especially aphakics, and following up the possible implications resulting from long-term wear.

Dr. E. Gruber had so far only had experience with spun-cast polyHEMA lenses. He described the technique of fitting, which in the case of spun-cast lenses had a limited choice of fittings. All lenses of a particular power have two or three fittings, and within the normal myopic physiological range there were available quarter diopter intervals of power. Using the knowledge that the more negative the power the steeper the back curve, it was possible within tolerances of acuity to obtain a variation in fittings. It was, however, necessary to have over seventy lenses in order to fit a patient by this technique. He pointed out that the method had its drawbacks but that this was the only soft lens available for the U.S.A. The technique for sterilization was boiling in saline in a special container similar to that used for Hydron lenses. He showed some examples of corneal staining from such fittings and also the limitations in acuity.

Dr. D. Highgate, a physicist and adviser to Contact Lens Manufacturing, explained how, with soft lenses of 'Sauflon' material, although of high water content, the surface physical chemistry, inherent elasticity, and water content were related in maintaining a surface curvature, that the behaviour of the material under extremes of physiological conditions must form a basis of statistics before manufacturing techniques, form, and thicknesses could be determined; and that there existed many materials that could be made to satisfy the criteria required by the eye. He stressed that it was essential to have a feed-back of information from clinicians before progress could occur.

Dr. T. Spring said that he now fitted 90 per cent. of his patients with lathe-cut polyHEMA lenses. To avoid complications he had simplified the technique to fitting a lens 13.50 mm. in overall size using only four or five back curves, with fittings flatter than the cornea. He was extremely happy with his results, and considered infection a much overstated problem. The patient used a very simple lens container placed in a saucepan of water, which was boiled. He considered that the Hydron material that he used was not infected by the patient since an individual's own bacterial flora were in no way harmful and daily use of a soft lens maintained it in perfect condition. He recognized the limitations of power using the type of lens he was at present cutting by the lathe. The curvatures used were not of the advanced design used by Hydron-Lens but nevertheless suited most of his patients. His experience with lathe-cut lenses would therefore appear to be happier than with those using spun-cast polyHEMA.

Dr. J. Hartstein has had a wide experience with Bionite lenses used in diseased eyes and, in his opinion, they are of greatest value in the treatment of bullous keratopathy and also keratoconus. In the latter condition he often used supplementary spectacles to correct any residual cylinder defect. Used as a protective they also had value, especially for continuous wear.

Dr. Herschell Boyd used a statistical approach to show his experiences with the spun-cast poly-HEMA lens. His results were disappointing. In his opinion, these lenses were only fully successful in a third of the patients fitted. He used the same criteria for success as are applied to hard corneal lenses. It had some success initially with patients who had failed to wear hard lenses. His success rate for hard lens wear was very high. It might be concluded that a well-fitted hard lens has a high success rating compared with a type of soft lens over which there is no control of the fitting.

Dr. Richard Hill, a researcher in physiological optics, discussed the effect upon epithelium, as shown by special glycogen stains, of various contact lenses. With an increase in impedance for oxygen, the epithelium became more oedematous and lost glycogen.

The Chairman reported the essence of the paper of Dr. Irving Fatt who was unable to attend. It was chiefly concerned with the idea that individuals have different levels of oxygen utilization. He considered the lens as a form of resistance to oxygen flow. The oxygen tension present at the epithelial surface enabling survival should not be less than 10 mm. Hg, but his present views were that for long-term survival a higher tension was necessary. No lens yet existed which would allow a satisfactory oxygen tension during sleep or complete closure of the lids. The Chairman inferred that most soft lenses constantly worn on normal eyes were, in fact, not as large as the cornea or else the epithelium had adapted to a lower oxygen utilization. Dr. Hill had clearly shown that materials varied considerably for oxygen flow, silicon rubber being by far the best. The Chairman indicated that where low gas flow materials were used, flat fittings were necessary if the lenses used were larger than the limbal diameter. This allowed oxygen flow *via* peripheral retro-lens tear flow.

Dr. J. Espy had the difficult task of acting as advocate for the United States Federal Drugs Administration. He clearly defined U.S. Federal law and its application to soft lens material, the form, and the sterilization techniques. The concern of the administration at all stages of material acceptance, and animal and human trials, was in depth. The soft material could inadvertently act as a carrier of toxins, bacteria, and drugs, even when used for cosmetic purposes; hence the control of its manufacture, distribution, and use.

Dr. Kim described a method of fixing human and animal corneae so that transparency would be maintained. The technique required stages in chemical fixation by formaldehyde vapour. The corneae were stretched upon spheres so as to form curved shells. When they were re-hydrated they behaved as inert clear contact lenses and have been used at the Scientific Research Centre of the Fondation Ophtalmologique A. de Rothschild as therapeutic devices. Her report upon their use inferred favourable results superior to soft lenses. She thought that the reason for greater success was that biological tissue was being used. The shells were made in corneal and scleral sizes.

Mr. K. Tattersall clearly showed that merely heating in physiological saline provided a satisfactory method of maintaining hygiene. This technique, a form of pasteurization, is capable of killing vegetative micro-organisms but not bacterial spores. However, by using an autoclaving technique, it was possible to sterilize a Hydron (polyHEMA) lens in a sealed container and keep the lens sterile indefinitely. All materials could not be sterilized by this technique; the problem of using solutions with germicides was that none satisfied all performance criteria. It was rare to have a non-toxic germicide at the concentration necessary to produce the same safety factor as boiling or pasteurization. The Hydron lenses were therefore treated in an automatic heater which brought the temperature to nearly 100°C. and kept the fluid at higher than pasteurization levels for over 20 minutes.

The meeting concluded with a paper from Mr. Montague Ruben. He reviewed his experience with spun-cast lenses of the Czech type, which had not been favourable because of the steep back curves. He compared the geometry of the spun-cast and lathe-cut lenses and showed that the larger back optic and thicker junctional zones must contribute to better acuity results. Furthermore, the

front surface of a lathe-cut lens was not under stress. He showed a Hydron lens fitted correctly on an eye with pseudo-pterygium and after 3 months' daily wear no neo-vascularization of the affected zone occurred. A hard lens would have caused problems. His experience with therapeutic lenses was mainly with Bionite. Although many patients had worn these for more than a year, the average life of a soft lens was 6 months in the diseased eye. Spoilation of the lens occurred for several reasons.

Dr. Tripathi showed an electron microscope section of a lens Mr. Ruben had removed from a patient who had spoilt his lens with a deodorant spray. The outside surface was intact, but the inside surface had broken up into lacunae and crevices, and zones of yeast-like organisms could be seen; mucin also was apparent and adherent to the lens. The role of bacteria or small living organisms in breaking up the plastic was only hinted at. This particular lens was of Bionite material and had been worn for 3 months on an eye grafted for keratoconus.

Mr. Ruben read out the analysis of infection occurring in the Moorfield's Contact Lens Department over a 2-year period (1970-72):

3,000 fitted with hard lenses; 500 fitted with soft lenses.
130 (3.70 per cent.) had clinical infection; 35 (1.00 per cent.) had proven pathogens.

Of the 130 with clinical infection occurring after contact lens wear, 110 had progressive eye disease likely to result in infection.

Of the soft-lens wearers 20 per cent. had clinical conjunctivitis and 6 per cent had proven pathogens. Of the hard lens wearers 0.3 per cent. had clinical conjunctivitis and 0.1 per cent. proven pathogens.

These figures, however, are of significance only when it is realized that, of the total number fitted with soft lenses, more than two-thirds would be considered to have progressive eye disease. Furthermore, such patients were wearing the soft lens continuously, which means almost twice the wearing time of hard lenses. Even so, this shows a high incidence of reaction after continuous wearing. The conclusion is that effective sterilization of a lens should be carried out weekly or at least monthly. It is possible to combine use of antibiotics with lens wear but this did not prevent infection. In the same period only one case of severe infection in a normal eye was reported, and there were several minor episodes which were no more frequent than these encountered with hard lenses. Statistics for normal eyes will take at least another year to obtain.

Nearly 2 hours were devoted to discussion with the speakers and questions from the delegates. The questions were concerned chiefly the selection of patients: for example, the treatment of young aphakics, vascularization in bullous keratopathy, the economics of contact lens practice, and the effect of the contraceptive pill.

Mr. A. Bron was asked to comment upon neovascularization in an eye with bullous keratopathy when wearing soft lenses. His angiofluoroscopy studies did not permit one to blame the soft lens as an aetiological factor since vascularization occurred in this condition when lenses were not worn. The Chairman remarked that, in his experience, the tight fitting and the type of material used were possibly the cause of an acceleration of neovascularization in some eyes.

Miss Chaston was asked to comment upon Dr. Halberg's statement that the power of a soft lens could be measured with a focimeter if it were placed in a water tank and the readings were multiplied by four. She agreed with the Chairman that this led to gross errors, since the lens form and thickness could make this factor vary from $\times 3$ to $\times 6$.

Dr. Hartstein showed some electron microscope slides to illustrate abnormal ovoid zones in the Bionite lens material.

Mr. Nicholas Brown was asked to comment on the visual acuity of patients wearing soft lenses in a clinical trial at present being carried out at Moorfields. At this stage he judged that the average acuity with soft lenses was more than 90 per cent. of the normal.

The concluding remarks of the speakers indicated that the soft lens had its place in contact lens practice, both as a visual cosmetic lens and a therapeutic device, but that development would be costly and time-consuming, unless another major advance occurred in the availability of materials. The Chairman thanked the Dean for convening this useful meeting and the sponsors (Hydron-Lens) for making it possible.