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The application of ultrasound in contact lens metrology

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Illustrations

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Declaration

Abstract

An original method of measuring the radius of curvature of soft lenses is described. It is based on the use of the sagitta principle and used ultrasound to measure the sagitta itself. The time taken for sound to travel from the transducer to the lens apex and back to the transducer (Round Trip Time [RTT]) was measured. The sagitta itself was calculated from the RTT and the velocity of sound at the specified temperature but it was found to be more accurate to use a series of rigid test pieces to calibrate the system. This enabled a RTT to be converted directly to a radius value. Whilst the methowas kept constant this was an indirect advantage as the dimensions of hydrogel lenses do vary with temperature. The method described has been acknowledged in an International Standard (ISO 10388; 1996) related to the measurement of contact lenses. The method remains the only one in general use to measure sagitta without any mechanical interference with the lens

The apparatus evolved to produce equipment that was compact and had integral temperature control of the saline. Measurement of the Back Optic Zone Radius and Front Optic Zone Radius was investigated in detail. The variance in a series of readings for a single lens on one day was very small (0.02mm [modal value]) but this variance increased to 0.12mm when mean values were compared on three different days. However, even this was still adequate when radius fitting steps are usually 0.3mm apart. Measurement repeatability was more dependent on material than lens dimensions.

It was possible to evaluate the change in radius with temperature especially in the band 20° to 30°C. The change in radius in this band was linear in relation to the water content of the lens. A 85% hydrogel changed 0.39mm for this 10°C change in temperature

Other uses of an ultrasound system are described viz determination of water content, measurement of centre thickness, estimation of lens power and evaluation of the surface topography of soft lenses.

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Abbreviations

B&L	Bausch and Lomb company
BOZD	back optic zone diameter
BOZR	back optic zone radius
BVP	back vertex power
CL, CLs	contact lens (es)
Dk	gas permeability
expt.	experiment
HEMA	hydroxyethylmethacrylate
F	Flatter
FOZR	Front Optic Zone Radius
PMMA	polymethylmethacrylate
N	number
Rm	radius valued measured
Rs	radius value specified
RTT	Round Trip Time
SCL, SCLs	soft contact lens(es)
S	steeper
SD	standard deviation
SE	standard error
TD	total diameter
USM	Ultrasound Microscope

Chapter 1   **INTRODUCTION**

1.1   The development of contact lenses

The first suggestion of visual correction by the use of contact lenses is probably attributable to Leonardo da Vinci in 1508 (Ferrero, 1952). He described the neutralisation of the corneal surface with a liquid and the provision of a new refracting surface in front of this liquid layer. Descartes in 1636 (Enoch, 1956) amplified Leonardo's ideas by suggesting a more compact form of correction where a sealed tube of liquid was placed against the eye rather than immersing the whole face in a liquid. This idea was taken up by Young (1801) who realised the potential of neutralising corneal power to correct ametropia and astigmatism and speculated on the inclusion of corrective elements in the system. Hershel in 1823 (Pascal, 1941) further suggested that the corneal lens could be used to correct corneal irregularities. He mooted the notion of moulding the cornea to obtain a suitable lens form and advocated the use of gelatin between the eye and lens.

Sixty four years elapsed until Müller in 1887 (Müller and Müller, 1910) started blowing glass shells for cosmetic, protective and corrective reasons. The lenses were worn well and in 1908 corrective lenses were designed and manufactured. Fick (1888) published work related to corneal sized lenses which could be manufactured by grinding or moulding glass to correct irregular astigmatism. He described the lens/cornea space as being filled with a liquid of the same refractive index as the cornea. However, in his work he moved towards the scleral type of lens which offered better support and weight distribution. August Müller (1889) described a scleral lens to correct myopia. His eye moulding was primitive and the lenses he made were not very successful. However, he made it clear that contact lenses should follow the ocular contours and that tightness of lenses on the ideal eye should be avoided if good tear circulation, and hence comfort, was to be maintained. Panas (1888) reported on the corneal type lenses pioneered by Kalt. His lenses were mainly used to correct keratoconus and Kalt found that vision could be improved by applying some pressure on the cone - a principle which still applies today. Pascal (1941) also reported the

early work of Sulzer in 1892. Sulzer fitted two of his patients with ground corneal lenses. Between the years 1888 - 1948 improvement took place in scleral lens design, Glass lenses were blown by Müller of Wiesbaden or ground by Carl Zeiss (Jena). Heine (1929) developed the Zeiss lenses so that a series of afocal lenses with different radii were used to correct ametropia.

Synthetic materials were utilised in scleral lenses (Feinbloom, 1936) but a glass optic portion was retained. A few years later the all plastics scleral lens was developed. This had the advantages that the lens was lighter, less brittle, easily worked and polished. Bier (1945) introduced a fenestration in the scleral lens and this in conjunction with minimal corneal clearance prolonged wearing times and reduced oedema. The same effect was achieved by channelling the haptic portion. (reduced frothing and bubbles) and Trodd (1971) described the use of a partial annular slot around the transition which is particularly effective with irregular eyes. Corneal lens development took a step forward in 1947 when Tuohy ceased producing glass lenses and manufactured lenses from plastics (Tuohy, 1963). The plastic lens was refined by Söhnges (cited by Dickinson,1954) who halved the lens weight by reducing the thickness and overall diameter of the lens. Other workers e.g. Dickinson (1954) and Bier (1957), worked along similar lines at the same period. However, the single curve 'microlens' had a short life as designs incorporating additional peripheral curves on the back surface were found to be more efficient (Bier, 1957; Hodd, 1958) .

Numerous developments took place in the next decade mainly in lens designs and fitting technique e.g. Bayshore (1963),Thomas (1967) who developed the Conicoid lens with a conical periphery and Steele (1969) - who advocated aspherical peripheries on the back surface lenses. Corneal lenses generally became thinner and smaller so that now lenses are in the region 8.5 - 10.0 mm diameter and can be 0.08 mm centre thickness with minus lenses. Improved manufacturing expertise has enabled laboratories to produce bifocal lenses of many designs, varifocal lenses, toric lenses, keratoconus lenses and lenses with lenticulations and fenestrations.

In the 1970s the main developments in the corneal lens field were in materials. Surface

treatments previously developed e.g. Erb (1961) , Gesser et al (1965) and Blue (1966) were superseded by the material changes. Copolymers of polymethyl-methacrlate (PMMA), silicone rubber and cellulose-acetate-butyrate (CAB) have proved most popular e.g. Menicon 02, Polycon, Boston, XL20.   The materials aimed to give better oxygen permeability and surface wetting compared with the conventional PMMA.   However, these new materials were not always dimensionally stable at high powers and the method of manufacture (moulding or lathing) affected lens characteristics.   The slightly softer surface of these copolymers tended to make the scratch resistance lower and surface contamination with deposits was often greater. Some materials needed a surface treatment to maintain a hydrophilic surface. Surface contamination with mucus and protein became more of a problem than with PMMA. However, despite some shortcomings these newer materials offered some patients increased comfort, tolerance and better corneal integrity compared with PMMA lenses.   Developments in the 1980s mainly revolved around the addition of fluorine to the silicone acrylate materials. This had two benefits viz increased gas permeability and strength.   As there is no water present in these materials, their use for extended wear has been possible (Port, 1985).   There is still a useful role for rigid lenses and the gas permeable hard lens is especially attractive in providing good vision whilst often giving less trouble to the wearer than the variety of soft lenses now available. Certainly the overall risk of infection is less than with hydrogel lenses (Brennan and Coles, 1997).   The disinfection regimes associated with rigid lenses are simpler than those used for soft lenses.

The biological use of soft hydrophilic polymers (hydrogels) (Wichterle & Lim, 1960) initiated a rapid development of soft lenses and there has been a gradual evolution of polymers for contact lens applications. The original Czechoslovakian material was poly-Hydroxy Ethyl Methyl Acrylate (poly HEMA) and this has been modified or copolymerised with other monomers to produce materials whose water content lies mainly in the 30 - 85% range. The materials need to have the necessary chemical and physical properties to make them viable for contact lens usage. The copolymers are varied by basically adding extra units (as monomers or polymers) to the HEMA structure and by

altering the cross linking. The extra units may be hydrophilic or hydrophobic. Thus the acrylic based polymers have enjoyed considerable success whilst others such as the polyelectrolytes have not been effective as contact lens materials. The manufacture of contact lens polymers has been described by Larke et al (1971) , Larke (1973) , Ruben (1974) .

Soft lenses, like the rigid corneal lenses, have tended to become thinner, The Bausch and Lomb Hyperthin O-series is some 0.04 mm thick at the centre (hydrated) for minus lenses; Hydron Europe also have a thin 0.06 mm lens (Zero 6) and both these lenses are polyHEMAs (water content about 40%). Most soft lenses have a total diameter of 13.5 to 14.5mm although values outside this range are used on occasions. Soft contact (SCLs) are now produced with prisms, truncations, near additions, cylinders, bifocal segments, lenticulations and multicurve surfaces etc. In fact, there is generally a soft lens to meet most situations if it is considered desirable. Tinted lenses, pupil lenses and lenses with hand-painted or machine-printed irides are also available. The care needed by patients is generally greater with soft lenses and the disinfection process is a very important step the soft lens wearer has to make time for. Research towards the safe wearing of soft lenses for extended wear continues. Ciba Vision now have a new low water content high Dk material which is currently undergoing trials for extended wear. The use of moulded lenses has increased over the last five years and Vistakon was the first multinational company to introduce a disposable soft lens for daily wear. Their technology of wet-moulding was based on that of a Danish patent which was first used to produce the Danalens.

Silicone rubber has been developed for contact lens use (Becker, 1966) especially by Titmus Eurocon, Wöhlk, and Dow Corning. Silicone is a very strong material which has to be produced by moulding (unlike the hydrogels which can be moulded or lathe cut) .The surface of silicone rubber is inherently hydrophobic and the surface has to be treated by chemicals and/or irradiation to convert it to a hydrophilic surface and it is the lack of permanence of this surface that has impeded development of this material. Failure of the

surface can result in deposits accumulating and poor vision. Lenses which are thick and have poor edges are naturally uncomfortable but the smaller, thinner lenses of Danker & Wohlk have gone a long way in improving these aspects. Besides the excellent durability of the material, it also has exceptional oxygen permeability compared to other contact lens materials (Hill, 1966). The material is useful for some types of therapeutic lens as it does not dry out and many of the hydrogel lens problems are due to this effect . Dimensional variations can also affect the hydrogel lens but are not seen in the water-free silicone lens.

A contact lens with a soft periphery and hard centre was described by Söhnges (1980) and a similar design is now marketed as 'Softperm' by Wesley Jessen.

1.2   Properties of soft contact lenses related to their measurement

Many properties of soft contact lenses (SCLs) are important in relation to the fitting of the lens, its behaviour on the eye, the effect on the ocular physiology and the visual performance.   Essentially these properties are:

Permeability and porosity

Hydrophilicity

Water content and hydration

Refractive index

Transparency

Specific gravity

Scratch resistance

Tensile strength

Wettability

Resistance to chemical agents

Adsorption and absorption of chemical agents

Surface hardness

Elastic recovery

In measuring SCL parameters some of the above are relevant and are dealt with below. In essence, the dynamic properties of the material are some of most relevant. During measurement, the lens is handled and positioned and this involves flexing of the lens. Naturally the ability of the material to maintain or return to its physical dimensions after these handling forces have been applied is very important.   In the same way as blinking will flex the material, handling will impose similar forces. Visual performance will suffer if the material does not recover quickly after a blink. If the lens does not recover its shape in a reasonable time during measurement it may be designated as inaccurate or it may give rise to spurious results during measurements or in a series of repeat measurements. Physical properties measured for soft contact lenses have included:

Specific Gravity (SG)

If a lens is supported for measurement in air or saline then the SG in relation to the surrounding medium is important. The SG in conjunction with other factors affecting the bending of the lens will determine the effect of gravity on the lens whilst it is supported.

e.g. SG   PMMA = 1. 19

              Hoya soft (35% water content at 20° C) = 1.13

Material strength.

The strength of a material is usually defined as the force per unit area required to cause failure when the material is subjected to a particular test procedure (eg tensile, shear, impact, tear). The modulus is defined as the true stress required to produce true unit strain in the direction of the force (Tighe, 1997).

Tensile Strength (stress)

Defined as Force/unit area and usually measured in g/mm^2 , Kg/cm^2 , MN/m^2 or p.s.i.

e.g.   PMMA 8,000 p.s.i., HEMA 60 p.s.i., Silicone 200 p.s.i.

Tensile Strain

Defined as the extension (elongation)/unit length and usually expressed as a percentage.

e,.g.   PMMA 5%,   Hema 140%,   Silicone 44%

Young's Modulus is a ratio i.e. Tensile Stress / Tensile Strain

Bulk strain = change in volume / original volume

Bulk Stress = Increased force/unit area

Bulk Modulus = Bulk Stress/Bulk Strain

Shear Stress = Force/unit area

Modulus of Rigidity = (Shear Modulus) =   Shear Stress / Shear Strain

The elastic limit is not exceeded when a shear stress is applied. The solid recovers to its original shape when the stress is removed. As the tensile stress on a material is increased it stretches and the elongation at any given time after the stress has been applied can be found by measuring the length of the test piece and comparing this with the original length before the stress was applied. The strain can be measured within seconds after the stress has been applied or a constant force can be applied for a long period and the elongation measured with time, but in parameter measurement these will generally not be as important as the short term stress applied to a SCL. As the stress is increased there is normally a linear increase in the strain over a range of stress values. However, stress may reach a point where strain increases without any corresponding stress increase. This is termed the 'yield point', The stress value at this point is important because if a greater stress is applied damage will occur and the material will not recover. The stress and strain values at the yield point are relevant when comparing materials. It should be remembered that all materials do not show this 'yield point' but some merely fracture. Hence recording the stress and strain at breaking point is also a useful method of comparing materials (Port, 1983a). Thus some materials will have stress and strain values at the yield point but all will have stress and strain values at the break point.
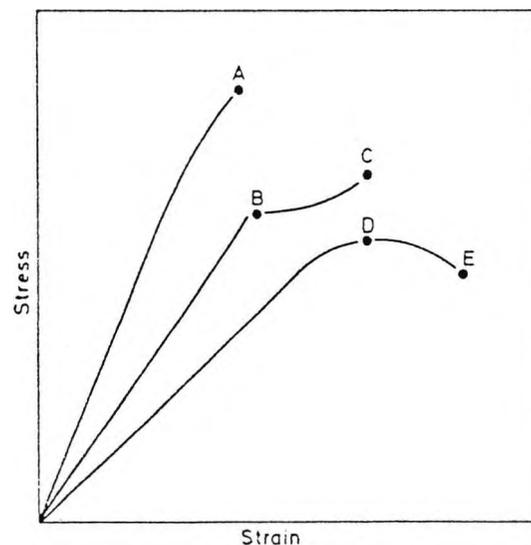
Figure 1.2 Stress-strain curves for three materials: (A) tensile strength and elongation at break; (B) tensile stress and elongation at yield; (C) tensile strength and elongation at break; (D) tensile strength and elongation at yield; (E) tensile stress and elongation at break. From Bier and Lowther, 1977.

It is also important when comparing materials on a certain test to always use the same testing temperature. More work needs to be done in testing materials after SCLs have been in use for months, as well as the effects on properties after heating of lenses (which can degrade the polymer) and after the use of storage and cleaning solutions.

Recovery from elongation

The time for a material to return to its normal dimensions is of importance. A point can be reached where the test material will not return to its original length after an increasing stress has been applied. This is termed the 'elastic limit'. This point is often difficult to determine and the yield point is normally used, one can investigate the elastic properties in several ways, one can apply the stress on a continuous scale or in discrete steps up to a given value and then decrease the stress in either discrete steps or continuously towards zero whilst recording the response of the material.

When measuring SCLs one needs to know if the recovery period is long or short. Does complete shape recovery occur? How long does a 75% (for example) recovery take? Ideally, the lens shape should be fully recovered before measurement of parameters, In some cases where there is an irreversible negative creep factor this may build up with increasing flexures to give a constant or increasing change in the measured parameters. More work in this field is clearly needed especially as more and more materials for SCL manufacture are brought to the market.

The irreversible changes are generally greater with the higher water content materials. Elastomers e.g. silicone rubber, do not in general exhibit these irreversible changes. The elastic properties of SCLs especially compression, deformation and recovery to load have been extensively reported by Ng (1974) and Kikkawa (1980). The latter studied lathed and spin cast lenses as well as comparing thin and standard lenses.

Tear Resistance

Tearing can be a considerable problem with flexible lenses. Tear resistance is tested by clamping a test specimen in a device with two jaws which can be separated at a constant rate of travel. The force in Kg to produce a tear is determined. Naturally, weakness in the surface or edge of the specimen will produce poorer results.

Hardness

The hardness of a given lens material is an important quality with the advent of substances which have various degrees of hardness and where the material can be changed by a slight variation in the chemical properties which allow different amounts of water absorption.

The Rockwell Hardness Test

A selected steal ball is allowed to indent the specimen material with a given load applied. The indentation indicated is used as a zero. A second, greater load is then applied for 15 seconds. The additional indentation indicated after this period indicates the hardness. A relatively large thick specimen has to be used and the results are not very accurate for soft materials.

The Shore Durometer

The instrument has a surface indenter with either a flat or rounded end. The instrument consists of a footplate through which the indenter moves. A soft material will give a greater indentation than a hard material. The foot is placed against the material which is on a flat surface and then the indenter under a given (selected) force depresses the surface. The amount of indentation depends
a) on the force applied, and
b) the time of reading the indentation after the force has been applied.
Specimens should be at least 6 mm thick,

The Moh Scale

This uses a series of materials of different hardnesses (from talc to diamond) and each is used to try and scratch the surface. Thus the harder the material surface the harder the material will be needed to impart scratches on it.

The melting or softening point

The ability of a CL material to withstand temperatures up to 120°C (approximately the temperature used in autoclaving) and routine temperature elevations during heat sterilisation processes is relevant. The SCL must return to its original shape and form so that it once again fits the eye.

Hydration

Most CL materials absorb some water when immersed. The amount taken up can be expressed as a percentage weight change

i. e.
$$\frac{\text{wet weight - dry weight} \times 100}{\text{wet weight}} = \text{water content (\%)}$$

$$\frac{\text{wet weight - dry weight} \times 100}{\text{dry weight}} = \text{water absorption (\%)}$$

The rates at which a material hydrates and dehydrates are important. A hydrogel lens can be dehydrated in a temperature controlled oven with vacuum extraction. The lens can be weighed at known intervals until a consistent minimum is recorded. Conventionally, a hydrogel is the xerogel in saline or distilled water. If the lens is weighed again at known intervals there is always the inaccuracy of a surface fluid and this will not be constant for each weighing. Better results can be obtained by placing the xerogel in a temperature controlled container and have a slow flow of very high humidity air passing through the container.

If a material absorbs water, its dimensions change. The nature of the expansion must be

obtained in order to predict the fully hydrated dimensions. One type of Hoya SCL material has a water content of 35% and quotes its expansion as 16% for diameter and 22% for thickness, Thus with a dry lens with a diameter of 11 mm the hydrated form will have a diameter of 11 x 1.16 = 12.76 mm and the dehydrated thickness value of 0.15 mm becomes 0.15 x 1.22 = 0.183mm for the hydrated form at 20°C. In such a case where the transverse and longitudinal expansion factors are unequal then the hydrated radius will be elliptical if it was cut spherically in the xerogel state, It has been assumed that where the same linear expansion factor is measured for thickness and diameter then the hydrated radius on the SCL will also be spherical if the dehydrated radius was spherical. It is perhaps relevant that most tests for linear expansion are conducted with linear specimens with flat surfaces whereas they are ultimately related to three dimensioned curved surfaces. The relevant expansion factors can be simply found by scribing marks on a dry specimen and accurately measuring the distance between these with a travelling microscope. After the specimen has been fully hydrated, the distance between the marks is again measured at the correct temperature.

$$\frac{\text{wet measurement}}{\text{dry measurement}} = \text{expansion factor}$$

or,

$$\frac{(\text{wet measurement - dry measurement}) \times 100}{\text{dry measurement}} = \text{linear swell (\%)}$$

Porosity and Permeability

All lens materials apart from glass are made up of a loose network of polymer chains with interconnecting space between them. The average size of these open spaces or pores is important in terms of the size of molecules which might be 11Å in size and these penetrate most gel materials. Most inorganic ions are smaller than this e.g. Nitrogen 3.83 Å , Chloride 1.98 Å so that ions which are likely to affect the pH and osmolarity can enter the polymer. The charges on the ions and on the polymer will also affect the degree of ion

penetration.

Permeability of diffusion of ions and molecules through a contact lens can be important. The permeability is affected by initial concentration, temperature, pressure, thickness and surface considerations of the material. In order to standardise the effect of ions movement and hence hydration and water content it is imperative that the measurement medium is always the same in terms of ion type and concentration as well as being at a given temperature. The effect of pH, tonicity and temperature on the parameters of SCLs is dealt with below. SCL material tests and surface state examination have been considered by Hamano and Kawabe (1976) .

1.3   Measurement of rigid contact lenses

The essential measurements for a rigid lens are the BOZR, TD, BVP and centre thickness. A ring test was conducted by Port (1986) to determine measurement reproducibility with calibrated instruments for these major dimensions.

1.3.1   Radius determination

a)   Moiré Fringes.

The Toposcope was developed for back optic zone radius (BOZR) measurement of hard lenses. It reflects a bar pattern from the contact lens (CL) surface. The image is viewed with a microscope of varying magnification that has a second bar pattern in the eyepiece. The CL is floated on water under the microscope which is focused so that the fringes in the centre of the field are brought into sharp focus. The magnification of the microscope is changed until the fringes are parallel to the central index line seen in the field. The change in magnification is monitored by a dial which reads off the radius in mm' s. The bar pattern is reflected from the whole of the lens surface (one meridian) and a section right across the lens is seen in the picture. If the curvature is poorly formed or if it is aspheric then the image will be characteristically changed. This ability of the instrument would be very useful in investigating surfaces of soft contact lenses (SCLs) in order to detect asphericites. However, the instrument would have to be redesigned to enable the SCL to be viewed in saline. Either a wet cell or a suitable immersion objective would be needed. Gilman (1976) used the Toposcope to measure B & L Soflens SCLs in air. He encountered difficulties and the results were not very conclusive. Since then the instrument has not received much attention with a view to development in the SCL field. The disadvantage of the system is that only one meridian can be measured at one time. The principal meridians of a toric lens are not easily detected. Ludlam and Kaye (1966) evaluated the instrument for its use with hard lenses and found that a high degree of accuracy was possible and the measurements were not subject to focus errors, observer acuity and subjective differences

between observers. Janoff (1977) compared the Toposcope with the Radiuscope for validity and reliability, He found that 10 readings on the Radiuscope produced a Standard Deviation (SD) of 0.02 mm but the Toposcope gave SD values of 0.01 to 0.06 mm depending on the experience of the observer. Dickins (1971) cites Storey (1969) who found that the instrument had 'poor accuracy, particularly for peripheral radii'.

b) Mechanical Spherometers

A mechanical spherometer follows the same pattern as the spectacle lens measure except that the CL device has an annular footplate and a central plunger which moves from the footplate to the CL surface to measure the sagitta (sag) . A dial gauge converts the sag directly to a radius reading (normal graduations are 0.05 mm). With a hard lens the spherometer can easily scratch the surface if care is not taken in using it. If the back optic zone (BOZD) is smaller than the footplate (9 mm in the Obrig version) then the BOZR cannot be measured. It is quite useful in the CL manufacturing industry where a lathe cut surface of a button needs to be checked quickly. The device cannot measure toric lenses. As can be seen from section 1.4.1 many soft systems have used this principle to measure the sag and thence BOZR of soft lenses.

c) Keratometry

Scheiner in 1619 (Levene, 1965) outlined the basic principles of keratometry but it was not until the nineteenth century that real measurements began to be made (Kohlrausch, 1840 - cited by Helmholtz, 1909). He recorded the corneal radius by direct measurement of the reflected image from an object of known size. The image was viewed by a telescope which had its objective at a known distance from the eye. The original optical principle still forms the basis of keratometry today even though there have been some sophisticated improvements e.g. Zeiss (Oberkochen). Although traditionally developed for measuring corneal radii, the keratometer (ophthalmometer) can be used to measure the radii of hard CL surfaces. The lens is best mounted horizontally and viewed by way of a front silvered mirror at 45°. It is relevant to note that the aberrations produced by the paraxial reflected

points for a convex surface e.g. the cornea are different from those produced by the concave surface of a contact lens (Emsley, 1963) and due allowance has to be made for this (Bennett, 1966). For example, with the B & L keratometer, 0.01 to 0.03 mm has to be added for radii of concave surfaces. Keratometry enables toric surfaces to be measured and surface distortions can also be appreciated. Several of the earliest attempts (see section 1.4) to measure the BOZR of SCLs used the keratometer with the SCL mounted horizontally in a wet cell. A front silvered mirror or prism being used to view the lens (Forst, 1973; Chaston, 1973). The keratometer has also been used to appraise aspheric surfaces (Wilms, 1974; Wilms 1981).

d) The Radiuscope.

Drysdale (1900) developed a method to locate the centre of curvature of a spherical surface with a short radius of curvature. The method is now universally used to measure the BOZR of hard lenses and is certainly the most common method in use. Fletcher and Nisted (1961) found that with three observers taking 3 - 5 readings per lens, the range of readings was 0 - 0.03 mm indicating a very high degree of consistency. Andrews and Bord (1962) used the instrument to look for small radius changes when hard lenses were stored in various solutions. They reported changes of up to 0.03 mm implying an accuracy of greater than this (i.e. a smaller value numerically). Freeman (1965) gave a very complete account of the theoretical considerations of the radiuscope together with its performance and limitations. The radiuscope can also be used for toric surfaces and surface distortions can be recognised.

Several developments of the instrument have been made for soft lens use and the accuracy appears to be very good (Loran & French, 1978) . Port and Jameson (1982) reviewed the practicalities of lens measurement and surveyed typical instruments available at the time.

e) Interference Methods

The use of Newton's rings (Dickins and Fletcher, 1964) for hard contact lens measurement is very accurate. The method is really confined to the manufacturer for looking at hard lens

buttons after one surface has been cut and polished. Thickness and rigidity are essential; with a finished CL these factors are absent and the method is, therefore, of limited use. The method utilises a series of glass spherical templates. The glass hemispheres are ground to a high level of accuracy. The CL surface is placed in contact with the reference surface. The number of Newton's rings generated is a measure of the accuracy of the trial surface. Instead of looking for rings, a dye can be interspersed between trial and reference surfaces to detect discrepancies.

The matching of hemispherical surfaces was probably the first method of measuring SCL radii but this did not use interference.

1.3.2   Power measurements

The power of spectacle lenses can be obtained by neutralisation with lenses of the opposite power. The small physical aperture (BOZD) of corneal lenses makes this an awkward process. The focimeter is currently used for measuring spectacle lens power and models have become more accurate and sophisticated. There are instruments which use a projection system so that an image is focussed on a matt screen. Other systems e.g. Acuity Systems, Rodenstock, Hoya, Nidek can give objective, automated power measurements for sphere, cylinder, axis and prism. Some models print out the spectacle Rx. The main problem with a contact lens is that the steep curvatures of the surfaces will position the back surface away from the spectacle lens measurement plane. An error will result because of this, especially as the Back Vertex Power (BVP) increases in magnitude. Better designs of lens stops have enabled better measurements with CLs. Most focimeters of repute now have a stop that will bring the back surface of a CL into virtually the same position as the back surface of a spectacle lens In some cases an interchangeable stop is used for CL measurement.

A series of lenses of known power are used to calibrate the focimeter over its range (ISO 9342, 1996)

1.3.3 Total Diameter (TD)

Rigid lenses have been traditionally measured with a V-gauge, projector or a band magnifier. In either case measurement to 0.1 mm and sometimes 0.05 mm is possible (Port, 1987; ISO 9338, 1996)

Calibration is usually carried out with a series of metal reference discs of known diameter.

1.3.4 Thickness

The rigid lens is measured quickly and easily (ISO 9339-1, 1996). A spring gauge micrometer is used almost universally. A dial reads the thickness to 0.01 mm. The gauge can be calibrated with shims of known thickness.   If one is measuring centre thickness it is more appropriate to take the maximum value from a series of readings (for a positive powered lens) and the minimum value for a negative powered lens.

1.4　　　　　Measurement of soft lenses

A review of methods used in optometric practice was given by Port (1983b)

1.4.1　　　　The back optic zone radius measurement of soft lenses

The BOZR measurement of SCLs falls into four principal categories, expecially if one considers those commercial systems which have been, or are currently available. These are:

Sagitta determination

Keratometry

Use of the radiuscope

Curve matching techniques.

A review of radiuscopes for soft lenses was given by Port (1983b) and the situation is not significantly different today except for a few minor modifications to instruments.

a.　　　Sagitta Methods

From Fig. 1.4　 it is possible to use Pythagoras' theorem

$$r^2 = (r - s)^2 + y^2$$

and hence, $\quad r = \dfrac{y^2}{2s} + \dfrac{s}{2}$
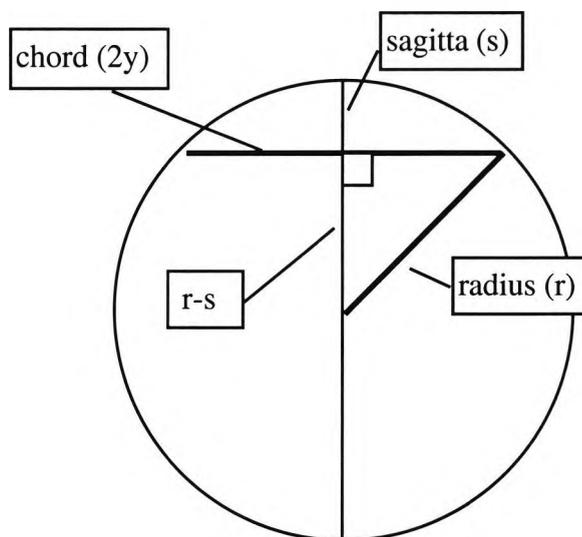
Figure 1.4.　 The geometrical principles used to determine the radius of curvature of a spherical surface.

In order to determine the radius, one has to know the chord diameter and the sagitta, When applied to a contact lens situation the SCL is supported on a cylinder or annulus of a known diameter and the sagitta is then found according to the method employed. It is important to

realise the primary limitation of the method i.e. that it will only give accurate results if the measured surface is truely spherical. If the surface deviates from this condition then errors over and above experimental errors are introduced.   The major problem with a flexible lens is to know whether the surface presented to the measurement instrument is spherical or aspherical.   The problem is later discussed at length in sections 1.5 and 1.6 and its experimental investigation is dealt with in chapter 5.

A number of other factors will affect the shape of the lens on its support and this relates to all SCL measurement irrespective of the system principle used.

The effects which have some bearing on the shape of the lenses during measurement are:

1. Gravity

2. The material and its elastic properties

3. The specific gravity of the lens related to its medium (usually air or saline)

4. The lens design (curves, thickness, diameter).

The other factor which relates to the size of the chord diameter chosen is the change of sag for a given change in radius.

Example	CHORD	Radius change	Sag change
	8.5mm	7.20 to 7.25mm	0.012mm
		9.40 to 9.45mm	0.005mm
	11.0mm	7.20 to 7.25mm	0.027mm
		9.40 to 9.45mm	0.011mm

Thus, using the smaller chord, any system has to be able to detect smaller increments to maintain accuracy throughout the radius range especially with the flat curvatures. However, it may well be that a compromise between low lens sagging or shape change and large sag increments with radius changes may be the best solution. It is now common practice to use a lens support diameter of 10mm.

The actual determination of the sagitta for a given chord can be achieved in several ways.

A) The use of a probe positioned centrally within the support cylinder or annulus.

The probe can be manually adjusted or motorised. In either case the distance the probe travels from the chord to the lens' posterior vertex is used as the sagitta. The end point can be found by alternative methods.

i.) If the lens is measured in air, an electrical circuit can be completed through the probe, lens and support when the probe touches the lens surface. Examples of this method are the 'Electrogauge' manufactured by Reid Prentice Ltd(UK) and the American 'Rehder Gauge' (Chaston and Fatt, 1980). Motorised systems (Hamano & Kawabe, 1978) using this principle are the Medicornea 'BC Tronic' (Duprat and Joinet, 1979) and the Neitz SM100 (Port, 1980 - Appendix 1).

ii.) The endpoint can also be ascertained by visual inspection (Brailsford, 1972) . This is usually achieved with a magnification system to view the probe approaching the lens surface e.g. the Wöhlk Spherometer (Loran and French. 1978) ; the Wet Cell Gauge by Contact Lenses Manufacturing Ltd (Goldberg, 1975) ; Titmus Eurocon (Höfer, 1977). Alternatively a magnified image of the probe and lens can be projected onto the screen to assess the touch point. Examples of this are the Optimec soft lens analysers JCF and JCB (Port, 1981; Appendices 6 and 9).

iii.) The probe can be arranged to stop at a predetermined distance from the lens surface (proximity testing). An example of this is the 'Soft Lens Measuring Gauge' which was marketed by Kelvin Lenses Ltd (Port, 1983c, Appendix 5).

B) Systems where no probe is used

i). A magnified cross section of the lens and support can projected onto a screen with a calibrated scale to enable the sagitta to be determined (Kawabe and Hamano, 1977).

ii). A radiuscope or travelling microscope can be used to measure the apparent distance between the lens vertex and the support. An example of this is the Union Optical 'Basescope' (Hirano et al, 1976) .

The main advantages of using an in-air system are that it is quick and relatively cheap but the disadvantages are that there is likely to be some flattening of the lens due to gravity effecting the lens mass and dehydration of the lens. With a lens in saline, the lens is likely to be maintained in its normal shape as the difference in density between the lens and its surrounding medium is minimal and secondly, the lens remains fully hydrated at all times. Although the process of measurement is likely to be longer and perhaps more expensive, the accuracy and repeatability of measurement is likely to be better.

The main limitations of sagitta system are:-

1. Aspheric surfaces cannot be correctly evaluated or detected.
2. Soft lenses with toric back surfaces cannot be measured.
3. There is no optical observation of the lens surface to enable distortions to be detected.

b. Keratometry

There are two main types of keratometer (ophthalmometer) -

i)   The object size is fixed (e.g. the Bausch & Lomb type of keratometer) and the doubling system is variable so that the two separated images can be correctly aligned.

ii)   In the alternative design the doubling is fixed (e.g. The Javal Schiotz type of instrument) and the object 'size' (separation) is changed in order to move the doubled images into juxtaposition.   Chaston (1973) used this instrument to measure the BOZR of soft lenses. If one is attempting to measure the vertex radius then obviously the points used on the reflective surface must be close to the optical axis. Different makes of keratometer have different separations of the reflective areas. With the Haag-Streit (Javal Schiotz) keratometer the separation of these areas is fairly constant for a wide range of radii (3. 35 mm ± 0.1 mm separation for radii 7.0 to 10 mm).   This constancy of separation is a very useful feature of the instrument.   As a contrast the Zeiss instrument has a separation of reflective areas of 2.9 mm ± 0.5mm over the same range of radii.

As the soft lens is almost universally positioned in saline, the normal scale values cannot be used as the scale relates to a cornea measured in air.   In order to calibrate the instrument one can adopt two methods. A series of hard lenses of known accuracy can be used and a linear regression equation obtained that links true radius of the surface with the keratometer reading (Holden, 1975). Alternatively, a correction factor is applied to the keratometer readings that takes account of the difference between the refractive indices of air and saline. This difference may well mean that the normal scale of the keratometer may not extend far enough on the flat side to accommodate all SCL surfaces that would need to be measured. The Littman device (Vogel, 1977) effectively extends the range of the West German Zeiss instrument. Carl Zeiss (Jena) and Rodenstock also market wet cell attachments to be used with their keratometers.   A keratometer can be used to measure toric surfaces and can be used for the BOZR and FOZR.

The low reflectivity from the soft lens/saline interface means that with some instruments a boosted light source has to be used. With a cornea in air the reflectance is 2.5% and for a contact lens of PMMA in air, the reflectance is 3.9%. With a hydrogel lens in saline the reflectance will generally be between 0.06 and 0.12% (Chaston, 1973). An assessment of

the mire shape can give information on lens surface distortion.

The operator has to use great care in positioning the lens in the wet cell (which is not normally temperature controlled) and often has to work in near dark conditions. Meniscus effects of the wet cell saline surface can be eliminated by floating a perspex lid on the surface. This does serve to reduce the transmitted light which is already at a low level . Small mire keratometry has been used effectively to look at the corneal topography so that these mires could be used with aspheric SCL surfaces,

c. The Radiuscope

The Drysdale principle (Drysdale, 1900) is optically simple. Firstly, an image is located and viewed on the curved surface. Secondly, the instrument is located such that the image is positioned at the surface's centre of curvature - the incident and reflected light use the same optical pathway The distance that the instrument travels to view the two images sharply gives the radius of curvature of the surface.

It has been suggested (Bennett, 1964) that Drysdale's principle could be used to measure corneal curvatures. He patented a system that would enable both images to be viewed at the same time - thus minimising errors due to movement. However, the design has not been commercially exploited as yet.   There is no reason why this method should not be used with soft contact lenses and Koetting (1973) postulated the idea. The main advantage of the radiuscope is that only a very small central area is used for measurement rather than two separated areas with keratometry The radiuscope enables the user to observe toric surfaces and to view surface distortions. To minimise light loss, radiuscopes with immersion objectives and high intensity light sources have been used to measure soft lens radii (Chamarro, 1974).   The 'Ultra-radiuscope' (Conoptica Laboratories, Spain) is such an instrument. Other devices have been used to enhance the images (Steel and Noack, 1977)

In common with keratometry there is the problem of light loss (Chaston, 1973) and again there can be confusion with reflections from the front surface of the lens. The lens is easily moved and one often has to work in dark conditions. The temperature of the wet cells should be controlled but the author has not encountered any such cells.

Peripheral distortions of a SCL can obviously affect sagitta readings and radius estimates obtained from them. Conversely, peripheral distortions will hardly affect the central reflections used in keratometry and radiuscope use. If saline is used as a measurement medium then again the radiuscope will measure the apparent radius of curvature.

A factor or linear regression equation will need to be applied to radius estimates to convert the result to a real radius.

d. Curve (Template) Matching

A. A SCL is matched for curvature to solid hemispherical templates of known radii

This was originally attempted in air (Wodak, 1972) . The SCL can dry out and stretch while the measurement is attempted especially if the lens is moved from template to template within a short period. The method was short lived because of severe limitations in usage and accuracy (Harris, 1973) . The same principle has been used with the lens and templates in saline. A series of hemispherical templates is used. They have radius increments of 0.2 mm so that interpolation to 0.1 mm is theoretically possible. A template with the lens resting on it is projected on to a screen.   The magnified image shows a cross section of the lens and a silhouette of the template. The operator attempts to match the BOZR of the lens to one of the templates in the series.   In the instrument that uses this principle (the Soft Lens Analyser by Hydrovue Inc., USA) the saline volume is quite small so temperature variation must cause errors. Some operators with experience have found the instrument satisfactory (Jenkins, 1981) but the author found it difficult to always obtain a clear image and found that there was some stretching of lenses over the templates.   The system was described by Lester and Lester (1979) and Davis and Anderson (1979). The latter found that measured radii differed from specified radii by 0.10 mm to 0.54 mm.

B.   Projection systems

In this case there is no comparative template in the same plane as the CL.   A series of templates of various spherical radii is printed on a screen (Söhnges, 1973) . A contact lens is projected onto the screen using a slide projector. The image shows a cross section of the lens. The screen is moved so that one of the screen curves aligns as closely as possible with the projected back surface of the lens. Interpolation is also possible. One of the problems encountered with this type of system is that in some cases it is difficult to get a good image of the posterior surface.   Secondly, it is sometimes impossible to get a good alignment over the whole surface i.e. it may be possible to align the centre well or the periphery well but not both. This phenomenon would suggest that either there is some bending of the lens during measurement or the surface is aspherical.   Temperature rises in the CL cell have been a problem with this type of system as the cell is sited quite near the projector bulb housing. Accuracy is claimed to be ± 0.1 mm (Loran, 1974) .

The Hydromarc Comparator (Frontier CLs Inc.) is a similar apparatus to the Söhnges system except that it is smaller. Whereas in the Sohnges system the lens has to be placed in a wet cell of specific design, the Hydoromarc device can accept lenses that are stored in clear vials.   It is possible that poor quality glass may affect the image and make measurement more difficult.

e.   Interferometry

El Nashar and Larke (1980) used an interferometric method to measure SCL radii.   Not all lenses proved to be suitable but results were obtained on low water content moulded lens with good quality surfaces. The method has not been adopted for general or research use.

1.4.2   Power

The measurement of BVP of a SCL is not particularly difficult. With a good quality, calibrated focimeter, fitted with the appropriate small stop (ISO 9337-1, 1999), reliable results can be achieved. The SCL surface should have surplus saline removed before the

measurement and the operator should avoid fingering the lens surfaces.

An example of a series of measurements is given in Table 1.4.2 to indicate the measurement consistency. The instrument was a Nikon projection focimeter. .

BVP (D)				
Lens	water content	Mean BVP	SD	Specified BVP
1	60%	-4.72	0.06	-4.25
2	60%	-4.32	0.16	-4.00
3	60%	-4.59	0.12	-4.00
4	80%	-3.31	0.12	-3.00

Table 1.4.2   The standard deviations obtained by the author on 4 soft lenses with four independent readings taken on each lens.

Sarver et al (1973) measured Baush & Lomb Soflens (38% water content) in air and found that the power stayed constant for 8 - 12 minutes. It is unlikely that the high water content lenses would remain constant for the same period. Surface drying and distortion would give poor end points.

The ISO Standard for soft lens requirements (ISO 8321-2, 1999) for power of SCLs gives an increased tolerance as the power increases. It may well be that with better materials, manufacturing techniques, and measurement apparatus the tolerance could be stricter expecially with the low water content materials. Pearson (1980 b) discussed the measurement of lens power with the lens in saline rather than in air. Rotlex and Visionix have developed systems to measure soft lens power in saline.

1.4.3   Total diameter

A soft lens cannot be measured properly with a band magnifier or V-gauge due to the flexure of the lens. In some situations a microfilm reader has been used to measure diameters, bandwidths and optic diameters of a hard lens.   The contact lens is placed in saline in a transparent wet cell (cuvette) convex side up (ISO 9338, 1996) The lens image is projected onto a screen integral with the instrument. A graduated scale (actual size) is placed beneath cuvette or the screen itself has a calibrated scale in order to assess the diameter.

1.4.4   Thickness

With soft lenses the gauge used for rigid lenses is liable to damage the lens. In any case accuracy is bound to be poor as there is no clear cut end-point with the micrometer and a soft lens as there is bound to be some degree of indentation. The American Rehder gauge is a low force gauge giving a resolution to 3dp (ISO 9339-2, 1998)

The basic principle has been used by Fatt (1977) where a screw micrometer is connected in series with an ohm-meter. The two poles of the micrometer are gradually moved together with the SCL resting on the inferior pole. At the point of contact where the superior pole just touches the lens an electrical circuit is made and circuit is completed through the lens. At this moment the ohm-meter will show that the circuit has been completed and the operator then reads the thickness directly from the micrometer. It is assumed that at the point of contact there has been no indentation.

A rigid lens radiuscope can be used as a travelling microscope to measure the apparent thickness of the lens in a wet cell.   Knowing the refractive indices of the saline and the material will enable the lens thickness to be ascertained. Alternatively, the radiuscope can be used to measure the real or apparent thickness of the lens in air. Pearson (1980 a) dealt very thoroughly with the measurement of SCL thicknesses. Port (1990) reported on the comparative results obtained with different methods.

1.5 Disparity between BOZR measurement of soft contact lenses using systems employing different principles.

Rs = specified radius;   Rm = measured radius

Forst (1973) studied 18 Hema lenses:-

Rs = 8.6 mm (N = 6); Rs = 9.0 mm (N = 6) ;   Rs = 9.4 mm (N = 6)

He measured them with a Söhnges projection system, a keratometer and wet cell and, thirdly, with a sagitta measurement in air. With the sag system he found 12 lenses flatter than Rs (up to 0.44 mm) and 6 lenses steeper than Rs (up to 0.2 mm). With the projection system he found about half the lenses flatter than Rs (up to 0.40 mm) and half steeper than Rs (up to 0.47 mm). Again with the keratometer method he found that half were flatter than Rs (up to 0. 11 mm) and half steeper than Rs (up to 0.07 mm) He concluded that the accuracy of the systems were as follows:-

Sagitta in air   ±0.14 mm

Projection   ±0.17 mm

Keratometer   ±0.07 mm

He did not give any SD for the results obtained. He admits that there must be a deformation factor with a lens resting on a ring (sag in air method) .

Bussacker (1976a) measured 22 Bausch & Lomb Soflens contact lenses (see Table 1.5.1)

Power	series	N
+1.75	N	(N = 4)
-2.25	B	(N = 8)
-3.00	B	(N = 5)
-3.25	B	(N = 5)

Table 1.5.1   Soft lenses used by Bussacker (1976a)

He used a Zeiss-Littman keratometer and wet cell and with the Söhnges projection system at 20 - 22°C. These spun-cast lenses have aspherical back surfaces and usually only the posterior vertex radius is given. This experiment enabled him to look at this small central area with the keratometer and the surface as a whole with the Söhnges system. However, he would be trying to align an aspherical image of the back surface with the spherical templates on the screen of the projection system and this would not be very reliable. He concluded that with plus lenses the radius determined with the projector system was around 0.15 mm flatter than the radius found with the keratometer. With minus lenses he found the complete opposite effect i.e, the radius with the projector system was about 0.1 mm steeper than that found with the keratometer. From this he thought that plus lenses show a flatter radius towards the lens periphery of the lens centre and minus lenses show a steeper radius towards the periphery when compared with the central radius. He put a range of 0.04 - 0.32 mm for this radius difference for centre/periphery and thought it depended on the cross sectional shape as to how large the difference became. However, his theories on hydration geometry that gave rise to these differences appear unclear and unconvincing especially as this aspect was dealt with in relation to spherical surfaces hydrating.

The effects of total diameter

Bussacker (1976 b) continued his investigation and concluded that larger diameter lenses showed more disparity between the two systems than the small lenses. With ten Weicon 38% water content lenses (TD = 15 mm) (5 lenses +5.00 D and 5 lenses -5.00 D) he found values shown in Table 1.5.2

	+5.00 D	-5.00 D
keratometer	Rm 0.1mm flatter than Rs	Rm = Rs
projector	Rm 0.3mm flatter than Rs	Rm 0.2mm steeper than Rs
	Measured values of BOZR	Measured values of BOZR

Table 1.5.2   Results obtained by Bussacker (1976b).

This was the effect found in his 1976a paper. The original concept was also born out when he tested 15 mm Hydroflex lenses. Of these lenses, the minus lenses checked with a keratometer were closest to Rs whilst those plus lenses checked with a keratometer tended to be furthest from Rs (on the steep side). The lenses checked with the projector seemed to be more uniformly steep for both plus and minus lenses. When he moved to the smaller 12.5 mm Hydroflex lenses he tested 12 lenses (all -2.00 D) and found that the keratometer gave Rm values within 0.1 mm of Rs but in conflict with the larger lenses these showed that the radii measured with the projector were approximately 0.2 mm flatter than the radii measured with the keratometer, With the Weicon 13 mm lenses (N = 12, all -5.00 D) he found the projector and keratometer determined radii within 0.1 mm of each other and generally within 0.1 mm of Rs.

With the larger Flexicon 14.5 mm lenses he found results as shown in Table 1.5.3

	+5.00 D	-5.00D
Projector	Rm 0.7mm flatter than Rs	Within 0.1mm of Rs
Keratometer	Rm 0.5mm flatter than Rs	Rm flatter than Rs by 0.3mm

Table 1.5.3   Results found by Bussacker using 14.5mm Flexicon lenses.

This tied in with the original 1976 concept but interestingly it was the projector with the plus lenses that gave values closest to the specified radii.

It is unclear in Bussacker's work if all the lenses were measured under the same conditions and whether each lens was subjected to more than one trial. He did not speculate on the other causes of his findings and it may well be possible that the differences could have been due to flexure effects of plus and minus lenses rather than exclusively to the cross sectional effect.

Bussacker (1978) re-examined the Flexicon lenses and quantified the differences between keratometer and projector radii values for various minus powers. He also expanded on his hydration theories by referring to the anisotropic hydration of lenses explaining that if the transverse expansion is not compensated for equally by the longitudinal expansion then the increase in power (i.e. a greater difference between posterior and anterior curvatures) resulted in a greater difference between the central and peripheral radii (see Table 1.5.4)

Flexicon	POWER	Central-peripheral radii difference
	-1.00D	0 to 0.1mm
	-4.00 D	0.35mm
	-10.00 D	0.50mm

Table 1.5.4 Bussacker's results showing the difference between peripheral and central portions of lenses of different powers.

Thus the difference in radii estimates between the projector and keratometer methods increased as the power increased.

Holden (1977 a) acknowledged that the projector system gave an average radius of the whole surface whilst the keratometer gave radius over a very small area. He found that a series of 24 lenses were 0.24 mm flatter when measured with a projector than with a radiuscope, Compared with the known dry radius mean this gave values of either 1.133 or 1.166 for the radius expansion factor. He could not explain this difference in radius by flexure effect depending on whether the lens was measured with concave side up or down but hypothesised on the BOZR and TD expanding by different amounts (i.e. the transverse and longitudinal expansion factors not being equal due to material anisotropy) . This gave rise to an aspheric back surface on hydration which gives a lower sag than expected with his

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lenses. At the same time he proposed an alternative hypothesis viz that the peripheral portion of the lens spreads (due to less substance) and the sag is smaller than expected.

Loran and French (1978) used 5 systems to measure a single 40% water content SCL. They used:

a.   A Zeiss (Oberkochen) keratometer

b.   A Nissel Ultraradiuscope with immersion objective

c.   A CLM gauge

d.   A Wöhlk spherometer

e.   A Söhnges projection system

Five readings were taken on each lens although whether these were 'independent' readings was not clear. With the Wöhlk spherometer, the lens was immersed in saline after every 5 readings. One may speculate from this information that for the other measurements, the lens was left in position throughout the 25 readings and was not subjected to any handling and recentration.   The results are shown in Table 1.5.5

Instrument	Mean Rm (mm)	SD (mm)	SE (mm)	Range (mm)
Nissel	7.25	0.023	0.004	0.10
Zeiss	7.35	0.051	0.010	0.26
Söhnges	7.35	0.076	0.015	0.30
CLM	7.29	0.096	0.019	0.35
Wöhlk	7.35	0.170	0.034	0.60

Table 1.5.5   Results of different instruments measuring the BOZR of one soft lens (Loran and French, 1978)

They concluded that most instruments need an average of 3 - 5 readings to be taken to obtain a reasonable mean. They also thought that the British Standard tolerance for BOZR of soft lenses of ±0.1 mm was realistic and acceptable.

Although the principles involved in many of their systems were different, the results were

reasonably uniform.

Forst (1979) measured several series of lenses using a keratometer and wet cell and with an electronic sag gauge. In the first group of 19 lenses the specified spherical inner radii (Rs) varied from 7.7 to 9.2 mm and the powers varied from -11.00 D to +10.00 D.

	Mean Rm	Range
Sagitta (in-air)	0.003mm flatter	0.3mm Flatter to 0.4mm steeper
Keratometer (in saline)	0.12mm flatter	15 flatter; 4 steeper

Table 1.5.6   The results of BOZR measurements using keratometry and sagitta determination (Forst, 1979)

This result was unusual as one might expect that the in-air measurements (sag) might well be flatter than the keratometer results as there would have been some gravitational effect on the lenses which effectively might flatten the lenses. However, without more data on the power, size of lens support, any dehydration etc the causes are difficult to explain.

In his second group of lenses, this time made by a different manufacturer (13 mm total diameter, all minus powered, N=9) the results were as one might expect (Table 1.5.7)

	Mean Rm	Range
sag device Keratom.	0.17mm F 0.01 S	0.1 to 0.3mm F 0.01S to 0.11 F

Table 1.5.7   BOZR values measured with keratometry and sagitta determination. Lenses were larger than those in Table 1.5.6 (Forst, 1979)

When he measured a similar group of lenses, this time with a total diameter of 15mm , 90% measured flatter with the keratometer than with the sag. device - essentially a reversal of the previous series and the only difference was the lens size .

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Finally, he measured a series of lenses with aspheric back surfaces (Rs 7.4 - 8.5 mm). With the sag device all the lenses bar one measured flatter than Rs and the mean value was 0,33 mm flatter than Rs. With the keratometer the mean Rm was a mere 0.002 mm flatter than Rs. The results tie in with the expected result that for a lens measured by sag and keratometry, a flattening aspheric back surface, the sag value will indicate a flatter radius than the keratometer.

Holden (1978) reported that lenses (SCLs) were found to be up to 1.0 mm in error from Rs. He admitted there was no satisfactory model to show how the dry xerogel was changed by hydration into the fully hydrated lens. His own system (Holden, 1975) proved to be repeatable to 0.02 mm (SD 0.06 mm) when lenses were measured, boiled, cooled and re-measured.

With his apparatus he studied 24 Contavue (Hydron) lenses. The mean dry BOZR was 7.42 mm. With his system the mean wet BOZR was 8.41 mm (giving an expansion factor of 1.133). When the same lenses were measured using a profile system the mean BOZR was 8.65 mm (this gave an expansion factor of 1.166) .

In order to check if the lens mass was bending the lens he measured radii with the lenses both convex side up and concave side up. He measured the BOZR and FOZR of a series of Soflens lenses and the BOZR of a series of Hydron lenses (see Table 1.5.8)

Lens supported	Soflens		Hydron
	BOZR	FOZR	BOZR
concave side up	8.82mm	9.34mm	8.55mm
convex side up	8.80mm	9.34mm	8.54mm

Table 1.5.8   BOZR values obtained using keratometry (Holden, 1978)

It was quite clear from the results above that the position of the convex lens surface, whether up or down, during measurement did not affect the radius measurement of low water content lenses. Holden added to his previous hypotheses (see above) by stating that whereas flat discs expand isotropically when hydrated, curved specimens hydrate anisotropically. He thought the surface treatment (lathing and polishing) of the xerogel material to obtain the curved surface gave rise to surface and internal stresses that resulted in the anisotropic expansion.

Chaston (1975) measured a series of Hydron lenses with the keratometer and the results are shown in Table 1.5.9

Rs (mm)	Minus lenses	Plus lenses
	mean BOZR (mm)	mean BOZR (mm)
8.08	8.10 ±0.2	8.15 ± 0.25
8.39	8.40 ±0.2	8.45 ± 0.35
8.71	8.70 ±0.4	8.60 ± 0.45
9.06	9.05 ±0.2	8.90 ± 0.20
9.50	9.50 ±0.2	9.36 ± 0.30

Table 1.5.9   BOZR values determined with keratometry using both plus and minus lenses (Chaston, 1975)

The overall results showed that the minus lenses were very close to the Rs values whereas the plus lenses showed more variation from the Rs value. The SD values were quite high which probably indicated the effects of handling and lack of temperature control of the saline . The evidence presented was not clear - many of the experiments were not subject to calibration using rigid lenses.

What was generally clear was that the central radii (vertex radii) as measured with keratometer methods generally showed closer correlation to Rs than radius estimates from the other systems that use a major part of the lens' concave surface. In many cases the periphery of the lens appeared flatter than the centre (indicating a surface of elliptical form

with the major axis parallel to the lens diameter) but Bussacker's work indicated that the geometry will influence the peripheral shape (plus and minus lenses being flatter and steeper in the periphery respectively compared with the centre) and certainly this work should be repeated under strict conditions with various materials.

The significant difference in radius values obtained with keratometry and sagitta (or projector) methods strongly suggests that the lenses intended to be spherical are actually aspheric .

This asphericity may be purely due to the transverse and longitudinal expansion factors (EF[T] and EF[L]) being different. Sammons (1981) considered a mathematical explanation of this phenomenon. If the EF(T) is greater than EF(L) then one will obtain lenses with a periphery flatter than the centre if the dry BOZR is spherical. The shape of the cornea is of this form so a SCL with a similar shape may well be an advantage in some respects (in terms of creating a fluid pump it may be a disadvantage).

Holden (1975) showed that how the lens is supported in saline is unlikely to affect the BOZR obtained. With air measurements this argument may not apply and there may very well be some degree of bending due to gravity.

Stresses within the material may also create anisotropic expansion and thence aspheric surfaces. The stress may come from the polymerisation process or it may be produced during the machining and polishing of the dehydrated lens.

If bending does occur during measurement then this will be related to the design of the support, the dynamic properties, the physical size of the lens, its cross sectional shape (power), specific gravity etc. Comparative measurements would be easier if all lenses were supported in the same way e.g. convex side up on a ring of 10mm, in the same solution. Flexure would then be the same for different systems. There is a body of thought that has considered that a sag value (above a given chord) may be a better indicator of the lens shape than a radius value (Garner, 1976; Rezwick, 1976; Bibby, 1979; Port, 1979a; Holden 1978) . Wichterle (1981) proposed a system related to volume under a soft lens,

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Effect of power

When Port (1992a) examined batches of lenses made of a mid water content material, he found that the nominal hydrated BOZR value did vary according to the power of the lens indicating that the cross sectional profile of the lens did have some effect on the final polymerised form of the lens even though the moulds for the xerogels all had the same BOZR. The finding was not significant from the wearer's perspective as the different hydrated BOZR values did not affect the fitting characteristics of the lenses (Port, 1992b). If the lens design was for a thicker lens then the effect may have been significant.

1.6 Accuracy and Reliability

Chaston (1975) looked at the diameters of finished lenses. She found that 68% were correct, 27% had a 0.25 mm error and 4% had a 0.5 mm error. The lenses tested were presumably low water content lenses. Testing conditions were not specified. However, the results showed that this particular dimension was one of the more easily controlled by the manufacturer and in the same way one of the more easily checked by the CL practitioner. In the same study she looked at power measurements of Hydron lenses (see Table 1.6.1)

Cumulative frequency	Error
62%	<= 0.25 D
70%	<= 0.37 D
79%	<= 0.50 D
83%	<= 0.62 D
90%	<= 0.75 D

Table 1.6.1   Power errors found in Hydron lenses by Chaston (1975)

Sarver *et al* (1973) had investigated the power of Bausch & Lomb (B&L) Soflens SCLs. They tested minus lenses in the range -0.75 to -9.00 D and found that the lenses were anything from correct to -1.50 D in error with a mean of -0.82 D (SD ±0.32 D) .

The soft lens will be affected by temperature and environmental factors and this will have some effect on the refractive index, thickness and shape of the lens surfaces. Bearing in mind the high power of the CL lens surfaces due to the steep curvatures, small changes in refractive index and radius curvatures will give rise to power variations. The lower water content lenses appeared to be more immune to these changes so that studies relating power and diameter changes may only show small changes compared to higher water content materials.

Forst (1973) looked at errors of SCLs when they were measured by keratometry and a projector method (Söhnges). With the HEMA lenses in question he found that the keratometer method gave errors of 0.11 mm flatter than Rs to 0.07 mm steeper than Rs

whereas the projector method gave errors of far greater magnitude (0.40 mm flatter to 0.47 mm steeper than Rs) . In a subsequent study (Forst, 1974) he only used the keratometer to examine lenses from various manufacturers. With one type of lens (N = 43) he found 30 lenses steeper than Rs by a mean value of 0.3 mm (range 0.1 to 1.0 mm) and 13 lenses flatter by a mean value of 0.25 mm (range 0.05 to 0.50 mm). In another type of lens he found 9 out of the 9 lenses tested were flatter than Rs and with 3 other manufacturers the lenses all tended to be on the steep side.

Koetting (1975) using the Söhnges projector system attempted to measure 350 B & L Soflens SCLs. Whilst it was admirable to use such a large sample the exercise was of limited value as a B&L Soflens has an aspheric back surface and the Söhnges 'templates' are spherical. Perhaps he tried to match the central part of the lens but this is not made clear. In any case he concluded that 80% of the lenses tested were within 0.1 mm of Rs and 6.6% deviated from Rs by 0.2 mm.

Hanks (1977) reinforced this view of the Soflens when he implied that the reproducibility as ascertained with flattening criteria was 90%.

Kemp (1979) also used the Söhnges projector system but looked at lathe cut 29% water content lenses (Rs 7.6, 8.0, 8.4 mm; powers -2.00 to -5.00 D) and he found that the lenses were between 0. 05 mm steeper than Rs and 0.5 mm flatter than Rs.

Chaston (1975) used a keratometer and wet cell to measure the BOZR of SCLs and found that the mean BOZR for minus lenses was within 0.02 mm (S D 0.4 mm) . The plus lenses were from 0.07 flatter than Rs to 0.14 mm steeper than Rs (SD 0.45 mm). Although the means indicate relatively good accuracy the high SDs show that a large number of trials are necessary to reach a meaningful mean value of BOZR with keratomatic measurement.

Bussacker (1976a and 1976b) used the keratometer and projector to look at various low water content lenses, Again he found that keratometry could produce BOZR values close to Rs whilst the projector showed greater variations when the same lens series was measured. He concluded that the minus lenses gave flatter readings than keratometer results and the plus lenses gave steeper values than the keratometer results. Errors of up to 0.6 mm flatter than Rs and 0.2 mm steeper than Rs were found.

Kawabe and Hamano (1977) measured 5 minus lenses in the Rs 8.4 - 8.8 mm range by their sagitta method. Four lenses were between 0.1 to 0.2 mm steeper than Rs and the remaining lens was 0.04 mm flatter than Rs.

Holden (1977a) reported that 60 lenses ordered from the same manufacturer had a mean Rm value 0.24 mm steeper than the mean Rs value. He used his own design of wet cell with a Zeiss keratometer. He tested his own apparatus (Holden,1977 b) using two observers in 20 trials and found a system accuracy value of two SDs (i.e. 0. 1 mm) . He noted that high powered lenses tended to show greater variability than the low powered lenses.

Barr and Lowther (1977) used a B & L keratometer and wet cell to examine three types of SCL. Their saline was at 'room temperature' and had a pH of 7.4. With the 72 B&L Soflens SCLs they found that most lenses were steeper than Rs according to the linear regression equation: -

$$y = 0.61 + 0.9x$$

With 37 Naturvue lenses a similar situation existed and the linear regression equation was: -

$$y = 4.5 + 0.47x$$

With 22 Hydrocurve lenses a lesser effect was noted with the expression:--

$$y = 2.08 + 0.75x$$

The mean for each lens was obtained from 6 independent readings and SDs of 0.06 to 0.12 mm were found. They concluded that : -

      60% of Soflens were within 0.150 mm of Rs

      60% of Naturvue were within 0.275mm of Rs

      60% of Hydrocurve were within 0.225mm of Rs

In respect of other parameters, they found that two thirds of the lenses were within 0.25 D for power; two thirds of the lenses were within 0.04 mm of central thickness specification and the same percentage were within 0.4 mm of total diameter specified.

Holden (1978) using a sagitta method of determining the BOZR looked at 27 Toyo lenses and found that the Rm value was 0.12 mm flatter than the mean Rs.

Port (1980) using a sag measurement in air to determine the BOZR of a range of materials in various powers and radii found that the lenses were flatter than Rs in 90% of lens means (see appendix 1) . It would appear that there was a gravitational effect on most of the lenses to achieve these flat results. Neither the power of the lenses nor the radius seemed to have effect on the SD which had a mean and modal value of 0.03 mm.

Davis and Anderson (1979) using a projection/template matching system (The Hydrovue Analyser) measured 70 lenses (10 lenses from each of 7 manufacturers) . The Durasoft lenses (-2.00 to -4.00 D) ranged from 0.4 to 0.8 mm flatter than Rs with a mean of 0.54 mm.

The Hydromarc lenses were from 0.0 to 0.25 mm flatter than Rs for the minus lenses and 0.15 to 0.25 mm steeper than the Rs for the plus lenses. This is the opposite finding to Bussacker (1976a) but the CL material was different.

With the third manufacturer, 7 of the lenses (N = 9) were flatter than Rs (range 0. 1 to 0. 3 mm), one was on specification and one was 0.4 mm steeper than Rs,

The A0Soft (minus) lenses were 0.06 mm steeper than Rs (range 0. 1 flatter to 0. 3 mm steeper) .

With the Naturvue lenses (plus and minus) 8 lenses were flatter than Rs (0. 1 to 0. 5 mm flatter) and 2 lenses were 0.1mm steeper than Rs.

The plus and minus Hydrocurve lenses showed that 9 were steeper than Rs (range 0. 1 to 0. 8 mm steeper) and one was as specified.

With the B & L Soflens the results are probably invalid as an aspheric surface of the lens was 'matched' with a spherical template. Six of the 10 lenses were from 0.1 to 0.9 mm flatter than Rs. 3 were 0.1 to 0.2 mm steeper than Rs and one was as specified.

Forst (1979) used two systems to assess the BOZR measurements. These were the keratometer plus wet cell and an in-air sag measurement device.

The first group of lenses showed that the group measured mean was 8.45 mm compared with a group specified mean value of 8.44 mm. When measured with the keratometer most of the results were within 0.2 mm of Rs. The maximum error was 0.7 mm flat and 0.25 mm steep. With the spherometer the measured mean was 8.58mm for the group which gives a difference between keratometer and spherometer means of 0.18 mm. No overall trend showed with lens power related to Rm. The difference between the measured and specified means (sag in air) was 0.14 mm indicating lenses measuring flatter than specification. Port (1980) found that HEMA lenses were 0.13 mm flatter than specification using similar apparatus. Port found that for the 7 materials examined, lenses were on average 0. 24 mm flatter than Rs.

The results of Forst and Port lend credence to the theory that there is some sagging of the lens in air to produce flat measurements.

In his second group of lenses Forst measured lenses from another company. The findings were very similar. The mean Rs value was 8.2 mm. With the keratometer the mean Rm was 8.19 mm (variation was within 0.1 mm) with the spherometer the mean Rm value was 8.37 mm (0. 17 mm flatter than Rs) .

In his third series he looked at lenses with aspheric back surfaces. With the keratometer the measured mean was 8.02 mm compared with the specified mean of 8.01 mm. With the spherometer the measured mean was 8.37 mm. If one takes the simplistic assumption that the sagging factor was 0.17 mm (as found in the first two series) then subtracting this from Rm still indicated a flattening of 0.2 mm compared with Rs and the vertex radius measured by keratometry. If one makes a second assumption that the lenses were specifically designed to have aspheric posterior surfaces they would have a form similar to the cornea i.e. an aspheric form which flattens away from the vertex. An example of this is the Soflens design. The difference of 0.2 mm would thus show how the keratometer was measuring the vertex radius whilst the sag device took account of the whole curved surface above the measurement chord and thus showed a flatter radius for Rm.

The term 'radius' cannot be strictly applied as the sag formula only applies to spherical surfaces but it convincingly shows how errors can be manifest if an aspherical surface is assumed to be spherical.

The overall picture regarding SCL accuracy related to BOZR is unclear, Because of the multiplicity of polymers in use, the different measurement systems, and the different environments for lens measurement there are no real trends at present. In order to appraise lens accuracy the following exhaustive tests and conditions should be met:-

1.   Standardised measurement environment.

2.   The material is known.

3.   The lens diameter is set for tests.

4.   A range of powers is tested e.g. +15.00. +10.00, +5.00, plano, -5.00, -10.00, -15.00 D

5.   A range of normal radii is tested e.g. 7.8, 8.3, 8.8, 9.3mm.

6.   A vertex radius measurement is taken in saline (keratometer).

7.   An assessment of the surface from sagitta determination to determine the peripheral effects of the surface. This should also be done in saline.

8.   A comparison of the previous two values with Rs.

Only in this way can one know how a particular material will behave in relation to its diameter, power, radius and design. The specification of the vertex radius and the sag (over a chord of about 8 - 10 mm) may ultimately be more informative to the CL practitioner. However, it should be remembered that the reproducibility is not always good although it is better with the established materials with low water contents. One may get two lenses with identical vertex radius measurements and they are supposed to have the same periphery but if they are checked with sag devices or projector systems then one sees disparate results (see above) which indicate that the lenses will not fit a particular eye in the same way. Material characteristics and manufacturing techniques must provide both a reproducible vertex radius and a peripheral section.   In terms of fitting the latter may be the more important aspect.

SCLs examined in the papers considered above have shown errors of 0.2 mm to be quite common. For trial lenses which often have radius increments of this value to be subject to this sort of error is clearly absurd and puts the fitting of SCLs by trial and observation on a very unscientific basis. BS 5562: 1978 indicated a tolerance of ±0.1 on BOZR but it appears this was rarely met. The current version of this Standard (ISO 8321-2, 1999) indicates a tolerance of ± 0.2mm. If there is an error inaccuracy which affects all lenses consistently this is not serious for the practitioner but when the reproducibility is also suspect the errors are compounded and without being able to check lenses thoroughly the practitioner is placed in a difficult situation, For example if a SCL Rs is 8.00 mm and Rm is 8.30 mm and another lens Rs 8.20 mm measures 7.9 mm then there are going to be problems from all aspects.

Farlow (1980) correctly assessed the situation when he stated that the manufacturer and polymer chemist blamed each other for errors in parameters. Only when the full data is published along the lines suggested above can one really know how the polymer chemist's material is behaving after having been subjected to the overall designs, machining and polishing strains of the manufacturer. When it is finally placed in a standardised environment and is fully hydrated then measurements can be made on equipment that has been assessed as accurate and reliable. Methods such as contained in ISO 10344 (1996), (saline for contact lens lens testing) have sought to address these problems so that the CL industry can verify lenses in a more standardised fashion.

1.7   The effects of environment on soft lens measurement

The acidity or alkalinity of a solution is normally defined by its pH value (this is related to the Logarithm of the hydrogen ion concentration).   SCLs are normally stored in 0.9%, NaCl solution (normal saline) and this has an osmolality similar to tear fluid.   Unbuffered normal saline will have a pH which varies over a wide range . At any point in time the pH will depend on the amount of absorbed carbon dioxide and hence weakly dissociated carbonic acid in solution.   The degree of generally alkaline salts that leach from the container will also affect the pH.   Manufacturers often add preservatives (bacteriostats) eg Chlorhexidene and these can alter the pH of solutions.

Carney and Hill (1976) found that freshly made saline changes from 6.52 to 6.50 in ten hours.   Heating it raised the pH to 7.34   Masnick and Holden (1972) reported that pH and tonicity charges could produce clinically significant changes in water content and therefore lens' parametric variations would occur.   They further concluded that the higher water content materials were more susceptible to environmental changes than the lower water content ones.

It is probably more accurate to say that ionic materials are more susceptible to environmental changes that non-ionic materials. De Meo (1997) found that lenses made from Etafilcon A decreased approximately 1mm in diameter when the osmolality was changed from 150mOsm/Kg to 450mOsm/Kg despite the pH remaining constant.   He also showed that when the tonicity (ionic strength) was decreased from 0.15 towards zero (with pH and osmolality remaining constant), the lens diameter increased by 2.5mm.

Bennett and Holden (1977) used Menicon soft lenses that were stored in Hydrocare (Allergan) storage solution. These low water content lenses (29%) generally flattened by 0.3mm when the pH of the solution was changed from 8.06 to 9.17.   They found that there

was initially a small steepening followed by a small flattening over a period of two weeks. Such changes are also reported by Höfer (1976) who studied lenses of a single BOZR placed in solutions of varying pH values. The solutions of pH 6.0, 7.0, and. 8.0 flattened the lenses slightly (0.05mm) over seven days but the pH 5.0 solution flattened the lens by 0.4mm over the same periods The material was Weicon (38%water content).

Gumpelmayer (1975) found that materials were generally resistant to pH change but changes in the order of 0.13mm in radius could be expected but occasionally changes of 0.35 and 0.45mm were seen. Poster and Skolink(1974) reported on the Bausch and Lomb Soflens (40% water and 60% HEMA) and found no significant change in diameter and sag for pH changes from 5.0 to 8.0 but there was a definite change when the tonicity was changed eg diameter 12.0mm in water and 12.25m 1.8% NaCl solution. Harris et al (1973) examined eight solutions and Harris et al (1974) examined nine different solutions. The BOZR was assessed with hemispherical templates so high precision was unlikely, Harris found that there could be changes of radius and could be accompanied by either a diameter increase or decrease. Sometimes there was a diameter change without any apparent radius charge. However, the radius measurement method was of dubious accuracy.

Hodd (1981) investigated the effect of cleaning solutions on lens parameters and Kemp (1979) looked at BOZR changes with various soaking solutions. He used lenses made from 29% water content material. He measured lenses in the low minus range; these had BOZRs of 7.6, 8.0, and 8.4mm. He did not quantify the temperature and tonicity of the six solutions used. He generally found that the lenses were anything from 0.05mm steeper to 0.5mm flatter than the specified radius. It was impossible to conclude that the environmental variable was responsible for the change.

Gumpelmayer (1975) investigated radius changes in relation to temperature change. He found that HEMA was resistant to temperature change but two other materials showed steepening of the BOZR by 0.4 and 0.5mm when the temperature was raised from 20°C to

50°C.   Figure 1.7 shows an unidentified material whose water content decreased significantly with a temperature rise of 80°C whereas the HEMA material remained stable. Chaston and Fatt (1981) reported the effect of temperature on the BOZR of high plus soft lenses.
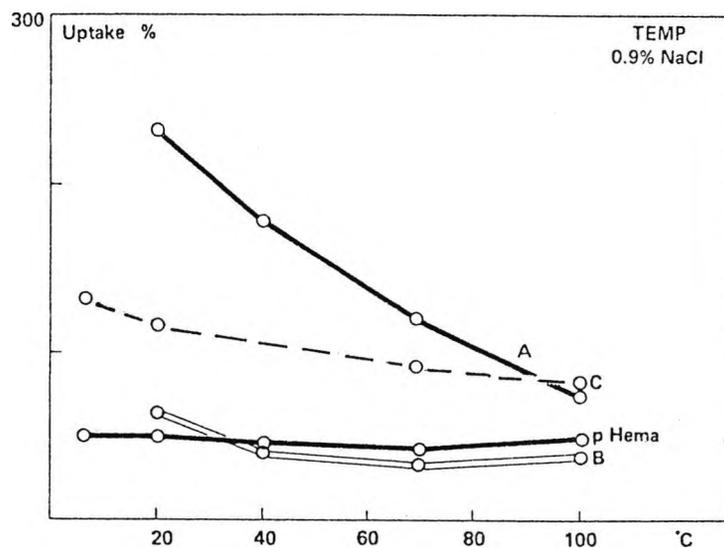
Figure 1.7.1 Equilibrium water content and temperature for polyHEMA.   A, B, and C indicate gels of unidentified chemical structure.   (Courtesy of Hydron Lens Ltd.)

It is clear that, where possible, environmental variables should be standardised or at least measured when dimensional measurements are taken. ISO standards relating to contact lens measurement and developed over the last 15 years have taken this into account.   The lower water content materials appear to be less affected by environmental changes than the higher water content materials. The pore size may be relevant but material ionicity is probably more significant.

As far as pH, is concerned a buffer may well help the situation (Kemp,1979).   However,

the addition of other electrolytes besides NaCl may alter the osmolality and this factor could well have an effect on lens parameters. NaCl solution can be specified to a standard value as can pH and temperature but the unknown effect of buffer electrolytes may give rise to measurement errors. Thus to avoid having to keep the osmolality to a limited range, it is probably as well to use double glass-distilled water and standard Analar NaCl without any other agents and make up the saline solution regularly. If fresh solution is used regularly the medium should always be within a stated pH band. This simplistic approach makes it easy for all CL laboratories and practitioners to make up a solution for lens measurement. If the tonicity is standard and the pH and temperature are confined to reasonably narrow bands then comparative measurements begin to take on some meaning.

1.8   RATIONALE

In order to measure soft lenses they have to be handled. There is a process of transference from the storage solution to the measurement apparatus. Whether the measurement is done in air or in saline there is some bending or flexing of the lens itself. The recovery of these deformations during measurement affects the measurement variance. Part of this variance has been shown (Port, 1981) to be directly related to the water content of the lens i.e. the measurement reliability worsens as the water content increases.

Systems that measure BOZR in air are simple and quick to use but there is generally a sagging of the lens on its support and this generally results in lenses appearing to be approximately 0.2 mm flatter than expected (Port, 1980).   It was also shown (Port, 1982a) that a soft lens in air can change its shape quite rapidly due to evaporation from the anterior (convex) surface of the lens during measurement. The effect was found to be independent of the lens water content but plus lenses changed shape more than minus lenses in the apparatus tested. Thus for the above reasons in-air measurement of soft lenses is likely to be inaccurate and the method would not seem to have a future as soft lenses are generally becoming thinner; thinner lenses need a medium denser than air for support if their true shape is to be investigated. There is also going to be evaporation at a higher rate from a thin soft lens than from a thick soft lens (Bilton and Guillon, 1984)

The systems that use a keratometer have several limitations. The light reflectance from the saline/lens interface is poor .   Most systems use only small wet cells. These are not temperature controlled and changes in ambient temperature can change the saline temperature quickly and result in saline refractive index changes and lens dimension changes (see section 1.7). Thirdly, both this method, like the radiuscope, only examine the vertex radius of the soft lens. No information is available from the lens periphery and this, because of the very much larger area, has more relevance to the lens fit on an eye. To the operator there is some confusion with reflections from two surfaces and he has to apply factors or equations to the keratometer reading to obtain radius estimates of the soft lens.

From the evaluation of the Kelvin system (see Appendix 5) it was clear that having a lens in saline and having a system of measurement that did not physically interfere with the lens

could produce good repeatability. It was concluded that if the environment was well controlled, reliability and accuracy could be further improved.

In the early part of 1975 the author (Port, 1975) conceived the idea (believed to be original as no other similar ideas have been published) to use ultrasound to measure the sagitta of soft lenses in saline and thence determine the BOZR. Early ideas were encompassed in a short project. In essence the concept likened the sag measurement of a soft lens in saline to the measurement of ocular anterior chamber depth using an ophthalmological ultrasonic probe and equipment.

The first experiments by the author were carried out with a very simple arrangement (see Chapter 4)

Ten Bionite lenses tested with the original apparatus had a mean SD(time) of 0.02 μsecs. The potential of the method for soft lens radii measurement was reported (Port, 1976 and Appendix 3)

As a result of this work it was decided to embark on a longer term project in order to refine the apparatus and method as well as to explore the measurement of other soft lens dimensions and parameters with ultrasound.

The rationale for further development can be summarised as follows:-

1. The measurement of sagitta to give radius estimates was well established in soft lens instrumentation.

2. In order to keep the velocity of sound 'constant' and thus be able to use ultrasound effectively it was necessary to keep the environmental parameters within narrow bands. A secondary and beneficial effect of this 'constancy' is to minimise any soft lens parameter changes due to environmental changes during measurement. This is especially important for the high water content materials. The concept of soft lens measurement under standardised conditions is encouraged.

3. Ultrasound measurement of sagitta does not involve any mechanical contact with the lens once it has been centred on its support. The repeatability of measurements is therefore likely to improve. As more thin lenses and higher water content lenses were introduced to the contact lens market, this aspect becomes increasingly

important.

4. Sag measurements can be used for estimates of the volume contained by the posterior lens surface.

5. A system that does not use visible light may be more practical.

6. A previous pilot study had shown the potential of BOZR measurement with ultrasonic techniques.

8. As useful ultrasound reflections were obtained from soft lens surfaces, it is feasible that other parameters could be measured using this technology.

Chapter 2   Basic Acoustic Principles

2.1   Properties of sound

Sound is the mechanical vibration of particles of a medium around a position of equilibrium. The highest frequency of vibration audible to the human ear is 2OKHz; vibrations with a higher frequency than this are termed ultrasound. Ultrasound(ultrasonics) is used extensively in industry, medicine and research (Carlin, 1960, Frederick, 1965. Blitz, 1967). According to its effects ultrasound, may be divided into two categories - active and passive. Active ultrasound produces physical and/or chemical changes e.g. Cleaning, drilling, welding and emulsification as well as biological changes in tissues and organisms. Passive ultrasound has considerable less power than active ultrasound and may be used for diagnosis, measurement, flaw detection and a number of other applications. Ultrasonic pulses are of great significance in determining depth or length. In passive ultrasound small amplitudes of the the vibrating particles are executed. On the whole, these amplitudes do not deviate from a sinusoidal form. When sound wave travels through a medium at velocity(c) the relationship between wavelength (λ), period (t), and frequency(f) is

$$\lambda = c.t = c / f$$

where λ is measured in mm, velocity in Km/second and frequency in KHz.

The wavelength can always be defined where the ultrasonic waves are transmitted continuously or in pulses.

The main types of ultrasonic waves encountered are:

1.   Longitudinal waves,

2.   Surface (Raleigh) waves

3.   Lamb waves

4.   Transverse waves.

The most relevant are the longitudinal waves which can travel in any medium. These waves occur where the particles of the medium, vibrate rectilinearly in the direction of propagation. This movement produces alternating compression and rarefaction of the particles causing simultaneous fluctuations in its volume.

Propagation Velocity

There are a number of different types of velocity. The most significant are referred to as 'phase velocity', 'group velocity' and 'signal velocity'. Phase velocity is the speed with which a phase is propagated along a wave. It refers to a condition existing along the line of propagation that seems to show a change in phase travelling with, and superimposed on the wave itself. Group velocity is the speed with which the envelope of a wave is propagated where the wave amplitude is modulated. The carrier frequency must be high for such a condition to manifest itself. It is the velocity most often considered in ultrasonic work. Phase and group velocities may have the same or different values. A material is said to be dispersive if the two velocities are different and signals of different frequencies travel with different velocities.

Normally, the velocity is not dependent on frequency or wavelength but only on the compressability and density of the medium. In fluids, the velocity (c) of longitudinal waves is given by

$$c = (\text{ fluid density . fluid compressibility }^{-1})^{-2}$$

The propagation velocity of ultrasonic waves depends upon the elasticity of the medium. In liquid and gaseous substances this depends upon the the pressure and density of the medium. But for a few exceptions, only longitudinal waves travel in these media. Their velocity in the given relation being

$$c = (K. q^{-1})^{-2} = ([y.q]^{-1})^{-2}$$

where K is the adiabatic modulus of the elasticity of the volume, q is the density and y is the adiabatic compression.

The rate of propagation of ultrasonic wave velocities changes with temperature and in most cases it decreases where there is a rise in temperature. In water the rate increases to a maximum of $1560 m.second^{-1}$ at a temperature of 73°C. Above that temperature there is a

drop in velocity. (Willard, 1947). Electrolytic solutions follow the same temperature velocity pattern as water. The concentration of the solute affects the density and this affects the velocity. The velocity of sound in 0.9% saline is about 0.6% faster than in water. Mikailov and Shutilov (1965) gave the following data shown in Table 2.1

NaCl solution strength	velocity(m/sec)
1 %	1494
4%	1527
10%	1594
14%	1639
(All at 20°C)	

Table 2.1   Velocity of sound in various saline strengths.

The propagation velocity of longitudinal waves in solids is given by

$$ c \; = \; \left(\frac{E\,(\,1\text{-}u\,)}{q\,(\,1+u\,)\,(\,1-2u)} \right)^{-2} $$

The passage of ultrasonic waves through a medium is characterised by the following main parameters:

• Displacement of particles from the horizontal position

• Acoustic velocity(v) of the vibrating particles around the horizontal   position

• Acoustic pressure(p) of the vibrating particles

• Acoustic intensity (i)

The acoustic impedance (z') is given by $p.v^{-1}$. In the case of plane progressive waves, the acoustic impedance is real and is said to be the "characteristic impedance". This constant is an important factor expressing the medium and has substantial influence on the reflection and change of ultrasonic waves at boundaries of two media. It is expressed by the equation

$$ z' \; = \; qc \;\; (\text{units } 10^{6}\,\text{Kg.m}^{-2}\,\text{s}^{-1}) $$

Typical values would be water 1.65;   Cornea 1.55;   Aluminium 16.9;   Perspex 3.2

Acoustic power(Watts) is a product of acoustic pressure(p) and surface velocity (v_s).

But it is more normal to express energy in terms of intensity (i) rather than power.   i = p.v

Reflection of Ultrasonic Waves

The reflectance at an interface of two media is determined by the angle of incidence and the acoustic impedances of the two media.   The reflection coefficient (R) is given by

$$R = ([\, m\text{-}1 \,] \,/\, [\, m\text{+}1 \,] \,)^2$$

where m is the ratio of the acoustic impedances of the two media.   The amount of energy reflected increases as the impedance difference between the two media increases. Measurable reflection does not always take place at the interface.   A certain minimum thickness is required. The smaller the difference between the impedances the greater must be this thickness. R is zero at a layer surrounded on both sides by a second medium when the thickness of the layer is a whole number of half wavelengths.   Examples of R are given in Table 2.2

Interface	R
Water ~ cornea	3%
water ~ aluminium	82%
water ~ glass	80%
water ~ perspex	32%
water ~ steel	93%

Table 2.2   The acoustic reflection coefficients of various media

Refraction of Ultrasonic waves

When ultrasonic waves strike an interface refraction occurs as well as reflection. In solids changes from longitudinal waves to transverse waves are also seen but transverse waves cannot exist in liquids .

Refraction is governed by Snell's law, ie

$$\frac{\text{Sin (angle of incidence)}}{\text{velocity in medium \#1}} = \frac{\text{Sin (angle of refraction)}}{\text{velocity in medium \#2}}$$

and this holds for transverse and longitudinal propagation velocities

Attenuation

In passing through a medium the energy and pressure present in the wave are reduced according to the properties of the medium. Firstly, there is absorption of the waves; mechanical energy is changed into heat owing to the internal friction of the vibrating particles and this is found in all media. Secondly, in non-homogeneous and polycrystalline media, reflection, refraction, scattering, and diffraction occur. Owing to the influence of damping by the medium the pressure of ultrasonic plane waves drops at a distance (d) from the source according to the relation

$$P_d = P_o \, e^{-ad}$$

where $\quad P_o \quad$ is the initial acoustic pressure

$\qquad$ a $\quad$ is the attenuation coefficient.

a is given by the expression

$$d^{-1} \; 20 \, \text{Log} \, [\, P_2 / P_1 \,] \quad \text{dB mm}^{-1}$$

In solids $\quad a = B_1 \, f + B_2 \, \phi \, f$

where B_1 is the constant expressing loss by absorption

$\quad B_2$ is the constant expressing loss by scattering

$\quad \phi \, f \quad$ is the function of frequency depending on the ratio of the wavelength and the grain size of the medium. For non-crystalline structures $\quad B_2 \, \phi \, f \quad$ is not used in the equation.

Attenuatation in liquids depends almost solely on viscosity factors. The attenuation coefficient is temperature dependent. In water the coefficient decreases as the temperature increases.

2.2 Electro-acoustic Transducers

There are several ways of producing ultrasonic waves. Piezo-electric crystals are very common in low power applications. Materials commonly used are quartz, lithium sulphate, Barium titanate, lead zirconate and Rochelle salt. Piezo-electric devices convert electrical energy into mechanical energy and *vice versa,* hence they are well suited to the transmission and reception of ultrasonic waves.

For optimum directivity 20 wavelengths is normally chosen as the minimum diameter of the crystal. For a 20MHz crystal this would be 1.5mm. Additional control of the sound beam can be achieved by adding lenses and shaping the elements (see below). Transducer design depends on the intended application. The primary considerations are frequency, beam properties and resolving power. Very attenuative materials require low freqencies. Good directivity is obtained with small transducers but, at the same time, they are limited by the amount of energy they can emit. Units with larger diameters and focusing lenses have been used successfully to provide high sensitivity and narrow beam width.

Resolution

The resolving capability of the transducer is influenced by transducer damping and transducer frequency. Damping is important because it determines the time required after excitation for the transducer to fall to a quiescent state and be ready to receive echoes. The shape of the electrical input excitation pulse and the backing of the crystal have damping effects. The damping of the neighbouring media will also be relevant.

Resolution capability can be improved by increased frequency. Increasing the damping also increases the resolution but this is not always practical because increased damping also increases the energy lost resulting in the the transducer becoming less sensitive. Good damping usually means that a pulse contains 2 to 4 cycles whereas poor damping will result

in many more cycles ("ringing"). Regardless of the method of damping, the objective is to provide the greatest possible amount of ultrasonic energy in the shortest period of time. Usually there is a compromise between damping, resolution, frequency, beam pattern and penetration.

Beam Pattern and Propagation

The beam pattern is determined by the geometry of the transducer face and the frequency. For a plane(flat) circular transducer radiating into water, the energy is initially propagated in a cylindrical beam being equal to the crystal diameter.

At a distance P from the transducer the beam begins to diverge merging into a conical beam. The distance P is given by:

$$P = 0.167 \, d^2 \, f$$

where d is the crystal diameter(mm) and f is the frequency (MHz)
The divergence (θ) can be calculated from the equation:

$$\text{Sin} \, \theta \;\; = \;\; 1.22 \, \lambda \, d^{-1}$$

At a distance of 2P, the diameter of the beam is 1.4 d.   The region between the transducer face and P is referred to as the near field and beyond P as the far field.

The intensity distribution within the beam is not uniform.   In the far field the maximum intensity lies on the axis.   Because of beam divergence the intensity falls off with distance and the maximum intensity at 2P is half the maximum intensity at P.   In the near field, due to intereference effects, the intensity distribution is more complex.   At a distance 0.5P there is no energy on axis but two off-axis maxima.   At 0.25P there are three maxima, one on-axis and two off-axis. The number of maxima and minima become more numerous towards the transducer.

Although the main portion of the energy propagates as described, 15% of the energy travels outside this beam in the form of side lobes.   These side lobes travel at a different angle to the main beam and show up on the intensity distribution as secondary maxima outside the main beam. Side lobes are also present in the near field.

The beam width determines the azimuthal resolution of the transducer ie the resolution across the beam. For optimal azimuthal resolution a beam as narrow as possible is required. This is obtained by using the highest frequency consistent with the materials used. Beam width is usually defined as the distance between two lateral loci where the intensity is one tenth that on the axis. The beam width of a plane transducer can be reduced by a factor of three to five times by use of a weakly focusing transducer. As a rule the diameter(d) of such a transducer is much greater than a plane transducer of the same frequency. A focusing transducer has its face concave or a supplementary concave lens attached to the transducer face with adhesive. A further reduction in beam width can be achieved by 'strong focusing'. The diameter of the beam(d_f) in the focal plane is given by:

$$d_f = 3.66 \ A \ d^{-1}$$
where A is the radius of curvature of the face or lens in mm

and d is the transducer face diameter(mm).

With strongly focusing transducers the focus or waist of the beam is only short. There is strong convergence towards the focus and strong divergence after the focus (Port, 1982b) Typical beamwidths used in ophthalmological transducers are beween 2 and 5mm. Thus most curved interfaces can be considered flat. The amplitude of the echo is essentially independent of distance but the inclination of the interface of the transducer does affect signal amplitude. If the interface is inclined some ten degrees then the amplitude is reduced to a tenth.

For a given beam width, increased curvature of the interface does give a longer echo which can obviously induce measurement errors. To minimise the echo duration and approximate a flat surface, the beamwidth must be as narrow as possible when curved surfaces are investigated.

Resonance and Standing Waves

Pulsing the ultrasound results in the vibrations decaying between successive pulses; thus standing waves cannot build up to anything like the same degree as with continuous systems. Resonance shows up in the pulse as a swelling of the pulse envelope (rather like the longer duration pulse from a curved interface) and it is more noticeable with smooth

surfaces than rough surfaces. This can be another source of error in time measurements.

Physical side effects of ultrasound

The most usual effects are cavitation local heating,quartz wind and fog production.

Cavitation is associated with low frequencies and high intensities. Changes such as bacterial destruction, depolymerisation and mixing of immiscible liquids have been attributed to cavitation.

Sound converts to heat with a definite ratio (Joule's equivalent). Particularly strong effects are noted at interfaces of immersed solids in liquids and in bubbles. Heating increases as frequency increases due to increased absorption. At least 3 Watts cm^{-1} are needed to create aqueous fogs. Low power transducers (eg ophthalmological models) use only a few milliwatts. Chemical effects do not occur at low intensities, 10 - 20 Watts cm^{-1} are normally used for this purpose.

2.3   Instrumentation for ultrasonic visualisation

Main components of an echoscope

l.   **The transmitter.**   This generates an electrical impulse which is applied to the transducer.

2.   **The transducer.**   This component converts the electrical pulse into an acoustic wave pulse which propagates at a certain velocity and in a certain beam pattern towards and into the media being examined.   Any acoustic impedance discontinuity that is met by the beam results in some energy being reflected - the amplitude of the reflected pulse being proportional to the mismatch in impedances.   If pulses are reflected back to the to the transducer the crystal will convert the reflected acoustic wave back into electrical energy. Due to mismatching and ringing the electrical impulses(reflected) will be longer than the transmitted impulses.

3.   **The receiver.** This detects and amplifies the reflected electrical echoes.

4.   **Oscilloscope screen.** Voltages from the receiver deflect the horizontal trace on the screen and causes vertical deflections which indicate the presence of echoes.   This type of visual display is called a time/amplitude display or A-Scan.

Separate components

a.   **Timing circuit .**   This merely synchronises all the operations.   After one cycle has, finished the timing circuit must act to initiate a new cycle.The operating rate is termed the repetition frequency and is usually around 1000 times per second so that a stable display is obtained.

b.   **The transmitter.**This is probably the least important component. It is required.

only to provide an adequate electrical impulse to energise the transducer. The voltage is normally 50-100v. The shape and duration of the pulse can be altered according to the pulse required from the transducer.

c.   **Sweep circuit.** In the A-scan system the Cathode Ray Tube beam is driven horizontally from left to right forming the so called 'time base'. The repetition frequency of the timing circuit is usually the same as the repetition rate of the sweep voltage.

d.   **Marker circuit.** Distances can be read directly from the oscilloscope screen if it has a calibrated raster. Alternatively a separate marker trace can be provided on the screen and the distance between displayed pulse envelopes car be measured by comparing this distance with the marker trace. The timing marks may be provided by gated oscillators triggered from the timing circuit thereby turning them on only for the sweep duration.
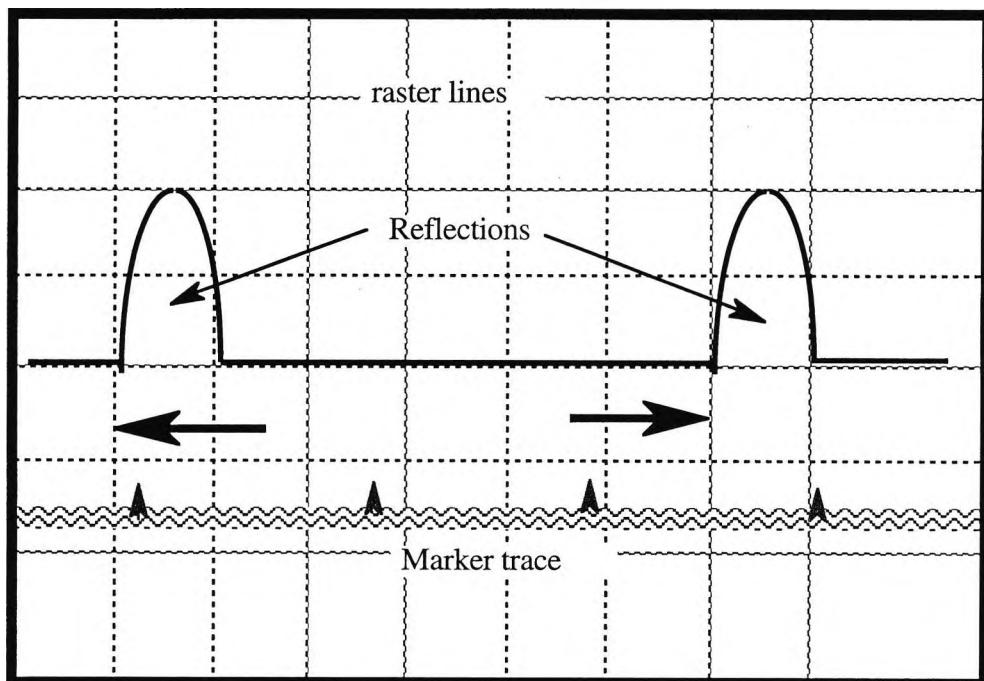
Fig 2.3.1   A diagram of two ultrasound reflections shown on an oscilloscope screen. The RTT can be obtained by noting the time between the two corresponding points on the marker trace. In this example, the trace has $1.0\mu s$ marks and $0.1\mu s$ marks and the *RTT is $2.6\mu s$ A vertical line of the raster is used to make the alignment between the reflections and the trace. The x axis of both can be expanded to make the measurement easier and one can estimate the measurement to $0.01\mu s$.

e.   The amplifier. The ultrasonic echoes received by the transducer produce electrical voltages from 10^{-4} to 10^{-1} volts.   To achieve full height of the echoes on the display the voltage must be 100 to 200V.   An amplification of about 110dB is required for this purpose.   The signal having been amplified is then rectified and a pulse envelope applied before being displayed on the screen. The amplifier is expected to fulfil three basic requirements viz, amplification, bandwidth, and dynamic range.   The latter two are necessary for good resolution.   Sufficient bandwidth is necessary to convey short pulses without distortion.   The capacity of processing signals whose voltages may differ by several orders is termed 'dynamic range'. Narrow band amplifiers are usually characterised by their large dynamic range.

f.   Control circuits.   These can be connected to the RF amplifier to change the receiver gain after the transmitted pulse has been emitted.   This circuit is known as Sensitivity Time Control(STC) or Time Varied Gain (TVG). This type of circuit is used where one expects reduced amplitudes from more distant objects because of absorption and beam divergence.

The general problem of how to observe differences in echo strength, whether the echoes are strong or not, while still maintaining gain high enough to see small echoes has been addressed in various ways. One such way is the use of logarithmic amplifiers. In a linear display doubling the gain doubles the signal height on the screen whereas in a log. amplifier the scale is distorted to achieve two effects. Firstly, the gain for low amplitude signals is increased so that very weak signals can be seen. Secondly, gain is decreased for very strong, signals so that they are not magnified unduly but can still. be differentiated from weaker signals.

Ultrasonic equipment often has a 'limiting' control.   This destroys the amplitude variation information of the larger echoes and accentuates the smaller ones. Envelope detection can destroy the fine structure of echoes thus reducing the accuracy of time measurements. It also removes the smaller signals from the display. Echoes are sometimes differentiated to

receive very narrow pulses. Differentiation is a technique in which only the changes in waveform are displayed. The process also removes information by displaying a long echo as a short pulse.

Accuracy can be enhanced by having different magnifications applied to the visual display. A delayed time base enables selected portions of the echo train to be shown on the screen at higher magnification and this facilitates measurement between echoes. The time marker trace is simultaneously magnified when the 'delay' control is used.

In practice, the occurrence of errors with the pulse method may result in the appearance of a non-exponential peak decrement and of spurious peaks on the screen.   These errors may occur as the result of non-parallelism of surfaces, diffraction, and the non-piston-like motion of the transducer. Further errors may be introduced by a phase change on reflection at the specimen interfaces and the transducer/medium interface.   These errors depend on wavelength and the dimensions of the transducer and specimen.

Resonance can also give rise to errors.   Care must be taken that the desired axis of propagation is accurately perpendicular to the transducer axis. Further accounts of errors in the pulse method have been given by Morse and Garend (1959) and McSkimin (1961 and 1964).

g. The attenuator. An attenuator, calibrated in dB, is employed to measure the relative height of echoes. It is connected between the transducer and the amplifier input. In this way amplifier non-linearity, by which both small and large signals could be amplified, is eliminated. Attenuation of up to 80dB is usually possible, The control is also used for measuring the attenuation of various materials.

h. Interval timer/counter.   that can be attached to the ultrasound apparatus to measure the time (RTT) between two chosen reflections. It utilises part of the pulse envelope to trigger a clock "ON" and the same part of the second envelope to trigger the clock "OFF" (Fig 2.3.2) It also has the ability to average RTT values over a specified period (gate time).

At the end of the gate time the average is displayed.
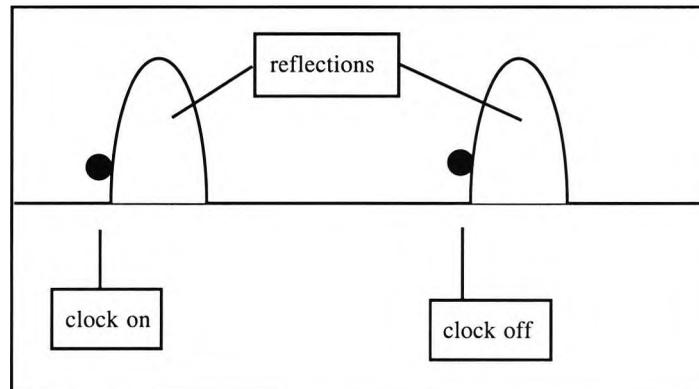
Fig. 2.3.2   The use of an interval counter to measure the RTT between two reflections visualised on the oscilloscope. The trigger points can be on any selected corresponding parts of the reflection envelopes

Chapter 3   EXPERIMENTAL METHODS

3. 1   Apparatus used for measurement of radii and thickness of soft lenses

The apparatus to hold the contact lens, saline and ultrasonic transducer was designed and developed by the author. This is described in section 3.2. Various models were used for different experiments and these are referred to in the appropriate part of the text.

Ultrasound apparatus

An 'Ultrasonoscope' Mark 10 was used to display the reflected ultrasound signals. The equipment incorporated the transmitter, receiver and amplifier that pertain to the signals going to and from the ultrasound transducer.
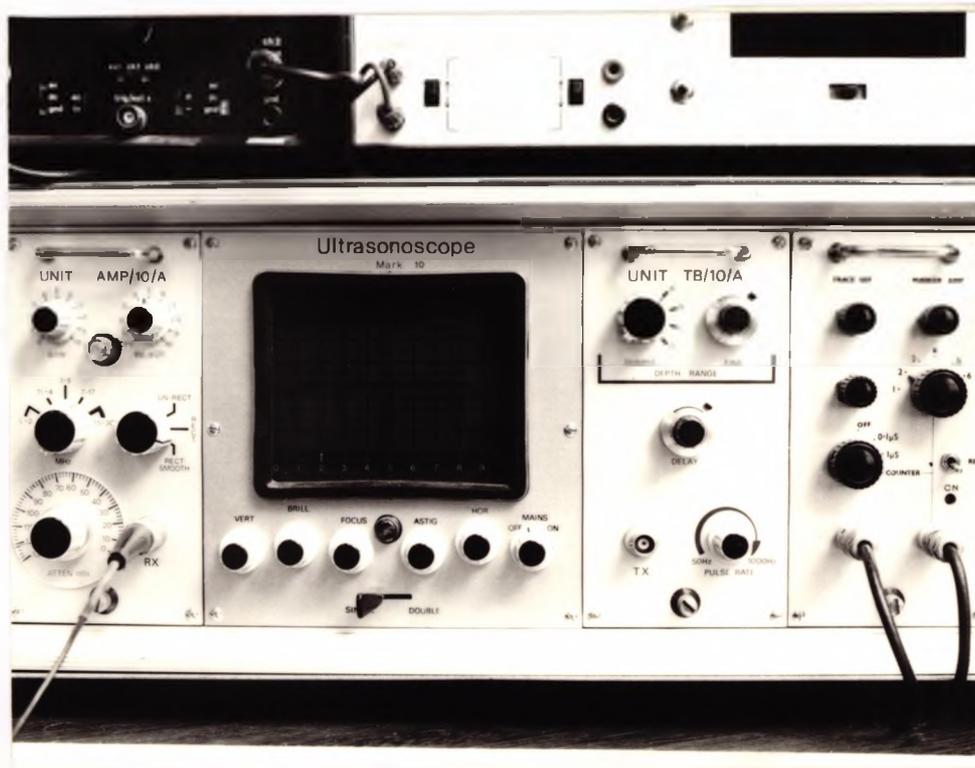
Figure 3.1 The Ultrasonoscope. Supplementary controls are on the far right panel. The screen and raster are on the larger panel.

A conventional 'Tektronics' low cost oscilloscope was also, used in conjunction with the Ultrasonoscope (see Fig. 3.2 and section 3. 2) .
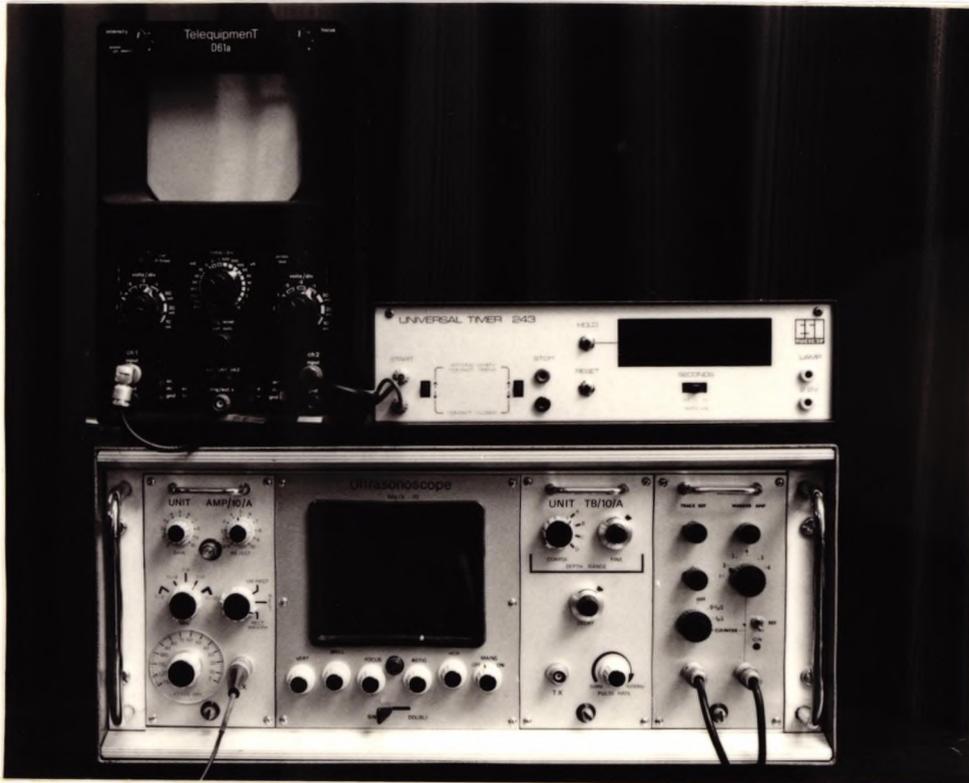
Figure 3.2   The Tektronics oscilloscope and interval timer on top of the Ultrasonoscope

Time measurements

A laboratory interval counter (see Fig. 3.2) was employed to measure the round trip time (RTT) of an ultrasound pulse from the transducer to an interface and back to the transducer. This had a variable gate time and enabled an averaged reading to be presented at the end of the gate time. The Ultrasonoscope display had a time marker trace and enabled RTT to be measured by an alternative method.

Transducers

Two ultrasonic probes were used. The first was an ophthalmological probe with a frequency of 20MHz (see Figs. 3.3 & 3.4). This had a focal length of 50 mm and a beam width of 3mm. The second probe was designed specifically for the project. This had a frequency of 25MHz, a 60 mm focal length and a beam width of 1.5 mm.

Figure 3.3   A transducer showing the outer stainless steel casing and the inner concave transducer face

Figure 3.4   A side view of a transducer showing the cable connection to the Ultrasonoscope. The attachment is on the opposite end to the transducer face.

Saline

All lenses were measured in saline except where in-air measurement devices were tested. 0.9% saline was prepared with Analar sodium chloride and glass distilled water. This is the tonicity assumed to be normal for the eye and most contact lens storage solutions have this same tonicity. Fresh solution was prepared each day except where lenses were left in the measurement apparatus overnight for measurement the following day.

Measurement of velocity of sound in saline

A simple piece of apparatus was constructed (see Fig. 3. 5) . The apparatus was substituted for the contact lens support in an early version of the ultrasound measurement system (see Fig. 3.6).
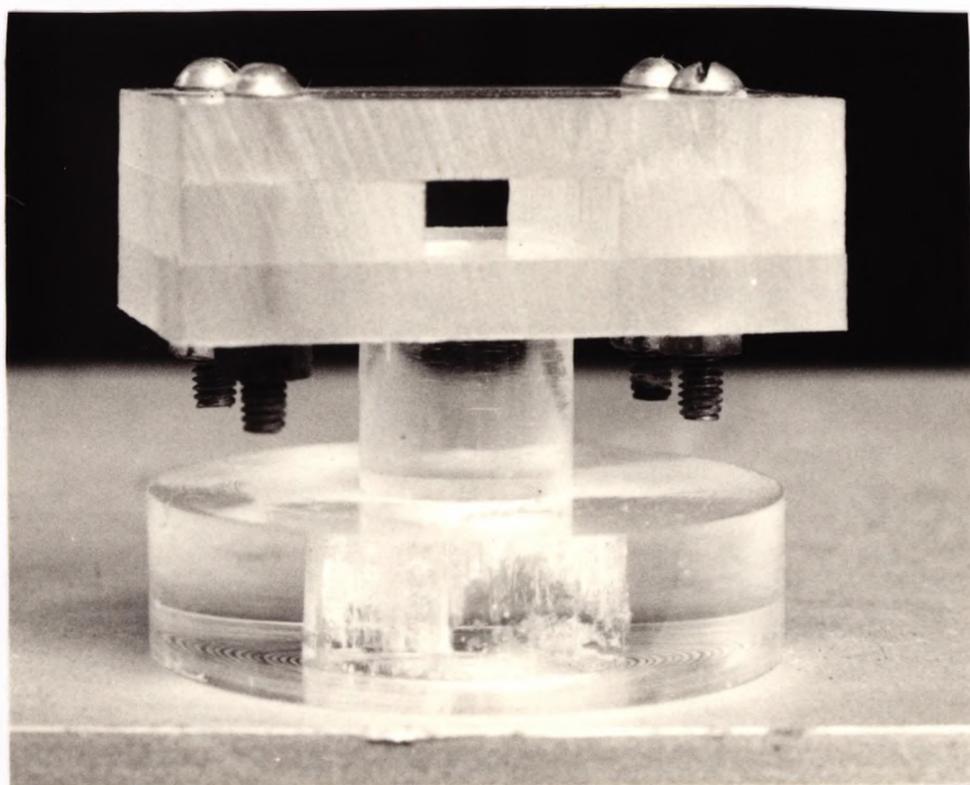
Figure 3.5   The device used to create a known thickness of saline in order to measure the velocity of sound at specified temperatures. The device is positioned in the apparatus in place of a soft lens support. The saline gap (4.47mm) is positioned in the waist of the ultrasound beam.
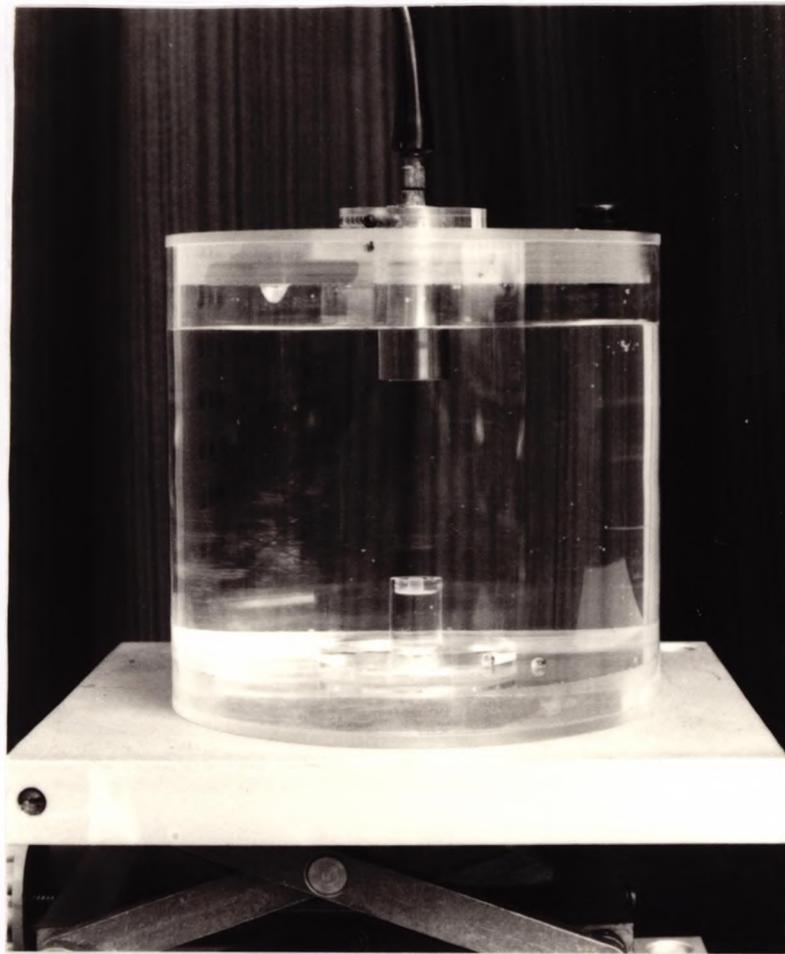
Figure 3.6 An early version of the measurement apparatus showing a contact lens support at the bottom of the saline. For measurement of sound velocity, this support was removed and the device in Fig. 3.5 substituted.

This device was manufactured from PMMA and created a parallel layer of saline of known thickness. Knowing the thickness and the time taken for sound to travel across this space enabled the velocity of sound at a known temperature to be calculated from

$$velocity \ (v) = distance \ / \ time$$

The RTT for the gap was measured on the interval counter or by means of the marker trace. Half of the RTT value gives the time taken for sound to traverse the gap.

In this device the gap width was 4.47 mm

Thus, $\qquad v = \dfrac{4.47 \times 2 \times 10^{-3}}{RTT \times 10^{-6}} \qquad$ metres/sec

This procedure was used to obtain the velocity for a range of temperatures and a graph obtained. The saline temperature was checked using a narrow range laboratory mercury thermometer.

Methods

A soft lens was removed from its storage solution and vial and placed on the lens support of the measurement apparatus. With in-saline systems the lens was given time to attain equilibrium with its new environment before it was measured. After measurement the lens was removed from the apparatus and returned to its storage solution and vial. It was left there for at least five minutes before a subsequent measurement was made.

In the case of in-air measurements the lens was removed from the storage solution and vial and the surplus surface saline drained off onto an absorbent paper tissue. The lens was then centred on the lens support of the apparatus, After a single measurement had been made the lens was returned to its storage vial. In this way, the lens to be measured was subjected to the normal range of flexures and deformations that are inevitable when a soft contact lens is measured. This type of measurement was defined as 'independent'.

With in-saline systems it was normal to measure, for example, four lenses. In this instance the four lenses were removed from their vials and all placed in the saline containing the lens support, The lenses were left in designated positions for at least ten minutes to attain equilibrium with the new environment. The first lens was then placed on the lens support ring and a single measurement taken. It was then removed from the support and replaced in the apparatus saline. The second lens was then measured in the same way and similarly for the third and fourth lenses. When this cycle had been repeated five times (20 measurements) each lens had been subjected to five 'semi-independent' trials. Between measurements the lenses were still subjected to handling, centring, repositioning and flexing within the apparatus saline but did not undergo the flexing caused by removal and replacement to and from the storage vial.

Chapter 4   Development and evaluation

4.1   Development of the ultrasonic apparatus

4.1.1   Measurement of BOZR

The previous apparatus developed by the author (Port, 1975) as prototypes (see Figs, 4.1 & 4.2) had several practical disadvantages. These were as follows:-

1.   The transducer holder had to be removed to place a lens in the saline. When the measurement had been completed, the transducer holder had to be removed again.

2.   The contact lens was positioned some 6 cms below the saline surface. Thus it was quite difficult to position the lens accurately on the pillar when operating from above the surface.

3.   The anterior and posterior surfaces of the lenses were not separately resolved and this created measuring difficulties.

4.   The whole apparatus was placed in a thermostatically controlled water bath to keep i t   a t constant temperature.   It was not easy to locate the apparatus firmly and to see the lens at the same time.

To overcome these shortcomings a new model was developed.   This was again constructed from PMMA. The design is shown in   Figs. 4.3 and 4.4
In this model the lens was only 1cm under the saline surface. Lens placement and manipulation was therefore much easier.   The transducer itself was not moved before, during or,   after lens measurements.
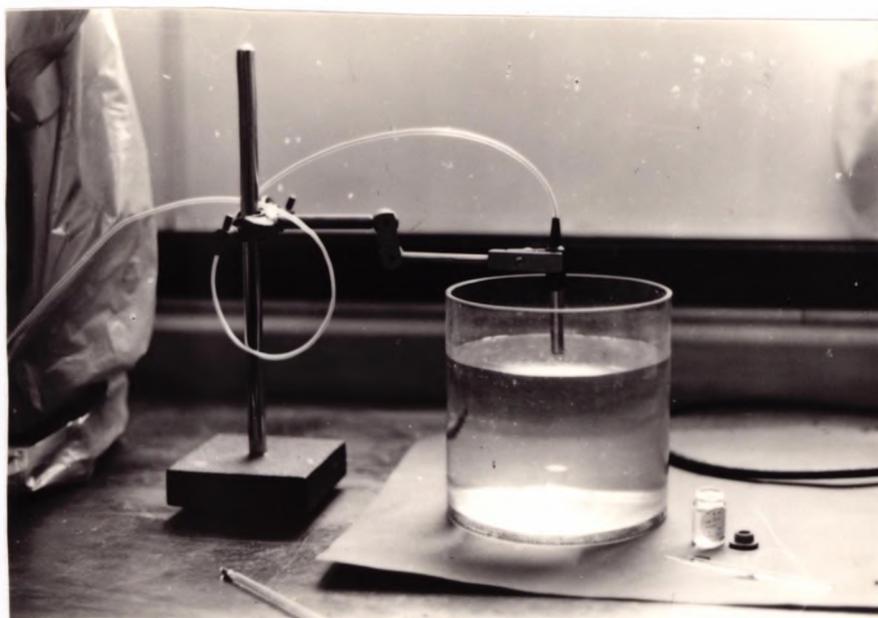
Figure 4.1   The first prototype apparatus (Port, 1975). There was no temperature control system and the transducer axis was not accurately centred on the lens axis
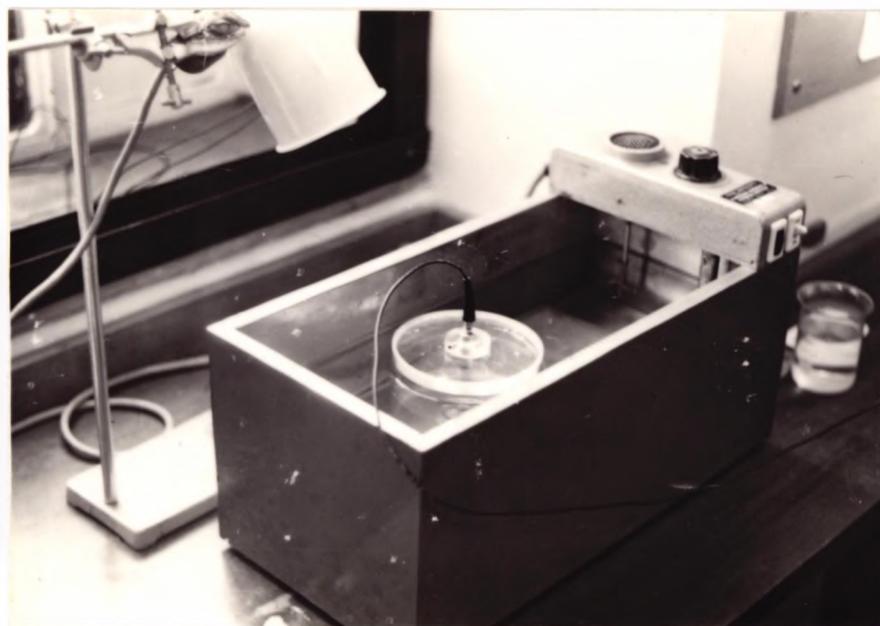
Figure 4.2   The Mk II aparatus (Port, 1975) . Concentric construction allowed the transducer axis to be aligned with the support cylinder's axis. The apparatus could be placed in a water bath to control temperature.
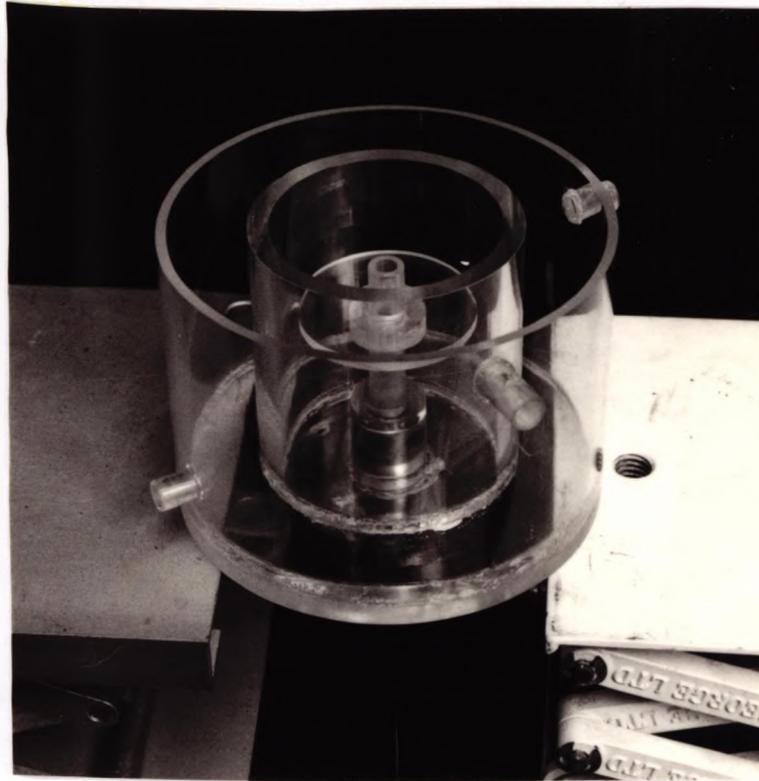
Figure 4.3   The Mk III apparatus shown without saline and without tubes connected to the water jacket..   For measurement purposes a perspex lid covered the water in the external jacket but allowed access to the central measurement cell.
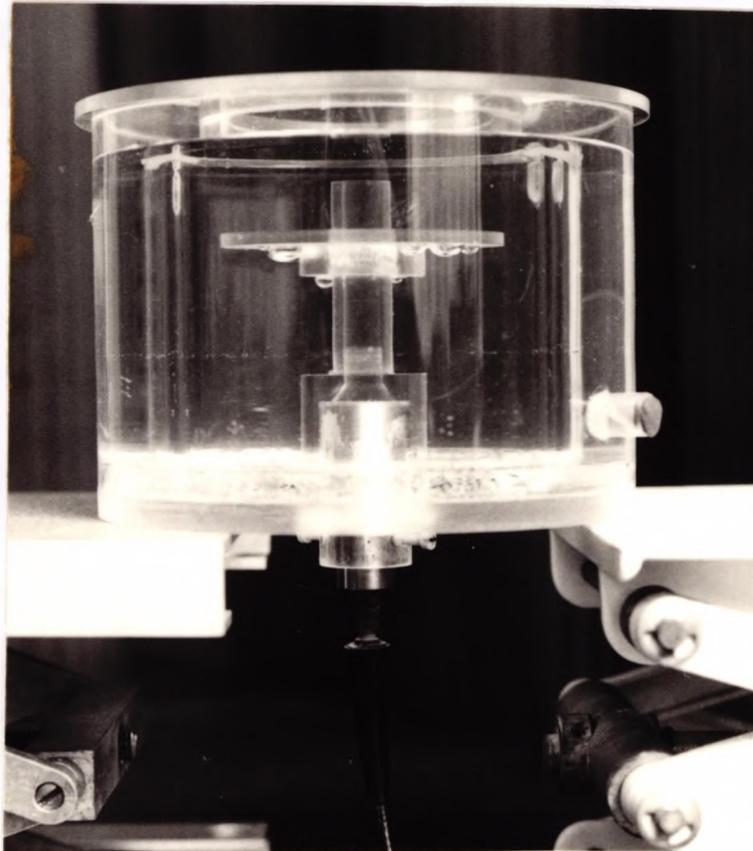
Figure 4.4   Elevation view of the Mk III apparatus.   The transducer can be seen at the bottom of the measurement cell. The contact lens is supported on the hollow cylinder above the transducer. The circular shelf both enabled test lenses to be kept in saline at the correct temperature and prevented lenses from falling to the bottom of the measurement cell.

Rather than immersing the apparatus in a water bath, a water jacket was made around the saline cell. This was more convenient and lens observation was not impeded. The tubes carrying the water to and from the thermostatic water bath were not an inconvenience, The temperature of the saline cell once having reached equilibrium maintained very good stability (±0.5°C). The fact that the apparatus was made from perspex gave a good insulation as did the 4 mm thick saline cell wall. The small area of saline exposed to the air minimised heat loss.

In an attempt to better resolve the lens surfaces a higher frequency transducer was designed. The frequency chosen was 30 MHz. The diameter of the transducer face was 3 mm and was made a little smaller than the original transducer in an attempt to reduce the beam width and hence some of the errors that occur with curved surfaces (see chapter 3)

Below the top of the lens pillar a perforated disc was incorporated (see Figs. 4.3 and 4.4). This had two purposes. Firstly, if the lens fell off the support pillar it only had some 15 mm to fall, retrieval and repositioning was simple. The perforations were not large enough to let a lens pass through. Secondly, the perforations enabled a small series of, say, four lenses to be stored in the measuring saline and adjust to the environment. Thus the separate trial for each lens now meant that the lens was taken from the perforated shelf on to the pillar, measured and returned to the shelf. This meant shorter working times but still maintained the independence of each measurement (see section 3.1) . It was suggested by Chaston and Fatt (1980) that there was a time lapse of several minutes when they measured a lens on ultrasonic apparatus before the sag value was stable. They suggested that this could be due to the distortion of the lens caused by handling and placement from the vial on to the pillar. The author feels that it is more likely to have been caused by the different environmental variables of lens vial saline and measuring cell saline. When a lens was placed on a shelf in the measuring saline as described and then placed on the pillar for measurement the measurement itself was stable within a few seconds. It was customary to leave the lenses on the perforated shelf for about 4 to 5 minutes before commencing measurements.

In the first two prototypes there were three reflections visualised on the oscilloscope. These emanated from the three interfaces viz

      1.   anterior lens surface/saline

2.   posterior lens surface/saline

3.   saline/lens support

The relevant interface reflections related to sagitta were 2 and 3. Thus it was necessary to measure the RTT between these. This was simply done from the time marker calibration trace superimposed on the scope screen below the reflection envelopes. Interface 3 was constant and interfaces 1 and 2 varied with the lens sagitta and lens thickness. Interface 3 was a constant distance from the transducer face.

With the new arrangement of the transducer the lens rested on a hollow cylinder in order to allow the ultrasound beam to reach the lens. Thus there was no reference surface which was constant. The obvious solution was to place a thin membrane across the top of the cylinder. This would not have affected the beam to any extent and was constant, A slight disadvantage would have been that the membrane could be damaged and it woudl not have been quite so easy to measure the diameter of the pillar top. Another idea was to place a wire through the pillar, say, 5 mm below the surface of the pillar. This would have been strong and would not interfere with the lens or the measurement of the pillar. Another advantage of the wire would have been that there would have been no accumulation of air bubbles as there might have been below a membrane (air bubbles would have seriously affected the ultrasound beam) .

It was eventually decided not to use either of the two ideas above but to introduce a novel alternative, i.e. a pulse was artificially generated within the apparatus that was time locked to the transducer face. This always appeared at a constant time and the variables were again those interfaces related to the lens surfaces. Supplementary controls were added to the Ultrasonoscope to enable this pulse to be switched off or altered in position. The pulse amplitude was constant.

At this time it was decided to make further improvements on the measurement of the RTT. It was a lengthy procedure to align a peak with part of the screen cursor, note the time markertrace value then align the other peak and note the second time marker trace value and finally arrive at the difference between these two time values to give the actual RTT. This was usually done twice to improve accuracy.

It was decided to employ an interval counter. This could measure time to the required accuracy and had the added advantage that the gate time could be varied according to the needs of the experiment.

A characteristic of this equipment is that it averages a number of values at the end of the gate time and displays this until the next average is displayed.

To take advantage of the visualised display it was necessary to add some additional facilities to the circuitry. As three peaks (reflections) were displayed on the Ultrasonoscope display, two of these had to be selected and provide on and off triggers to the counter. Circuits were added to enable any pair of the three peaks to be selected i.e. 1 and 2, 2 and 3, or 1 and 3 by means of a rotary switch on the control panel.

A secondary oscilloscope was also used to assist with the visualisation and provide a cheaper alternative to the Ultrasonoscope. On this secondary oscilloscope two traces were displayed. The upper trace was a duplicate of that on the Ultrasonoscope showing the three reflections (one artificial and two real).   The lower trace showed which of the two peaks had been selected for RTT measurement.

Signal levels to trigger the counter for the counter were adjustable on the back of the interval counter. The apparatus in general worked very well. It was particularly noticeable that the general handling and placement of lenses was more efficient and the RTT times were obtained within a few seconds.

Conversion graph and equation.

Working with the earliest prototypes had shown that the graph of BOZR against RTT did not always follow the expected graph of theoretical sag against radius . One might postulate that this was due to resonance and artefacts in the transducer arrangement. Because of this it was decided to rely more on conversion graphs than on theoretical calculation of sag (and radius) from the RTT knowing the sound velocity.

Fourteen plano-convex spherical templates manufactured from PMMA to two Newton's Rings were used for the conversion graphs. The centre thickness was made as large as possible from the buttons available.

The apparatus was stabilised at the required temperature and all instruments were switched on for at least 30 minutes to reach stability (failure to do this resulted in electrical drift and spurious results).

Each radius template was measured independently four times and the mean RTT for each radius was plotted against the specified radius (see Table 4.1).

The equation $BOZR = 1.873x^2 - 16.452x + 43.570$ ($r = 0.995$) enabled a radius to be established from a RTT (x).

BOZR (mm)	mean RTT (μ seconds)
7.60	4.00
8.00	3.91
8.10	3.83
8.20	3.75
8.30	3.71
8.40	3.67
8.50	3.64
8.60	3.60
8.70	3.57
8.80	3.54
8.90	3.51
9.20	3.43
9.60	3.32
9.80	3.28

Table 4.1   The BOZR of calibration reference pieces plotted against RTT values in order to establish a relationship between the two.

Transducer Appraisal

The 30 MHz probe certainly managed to resolve the thin lenses into their component surfaces and this meant that the counter could be used effectively with these lenses. However, the intensity was lower than with the 20 MHz probe and this was a disadvantage when dealing with high water content lenses.   In these cases the amplitude was sometimes insufficient to trigger the counter despite the gain being at maximum,   There was no scope for the gain to be altered in the existing instrument.   On balance, it was felt that the 20 MHz probe was more practical.

Using the above apparatus showed up two deficiencies.

•   The temperature control of the saline depended on the rather large   thermostatic water bath with its water being pumped up to the cell's water jacket via rubber

tubes.

- It was not possible to meaure the FOZR of lenses.

To obviate the need for the water bath a heating circuit was designed. A thermistor to monitor the saline temperature was positioned in the saline at the same level as the top of the support pillar.
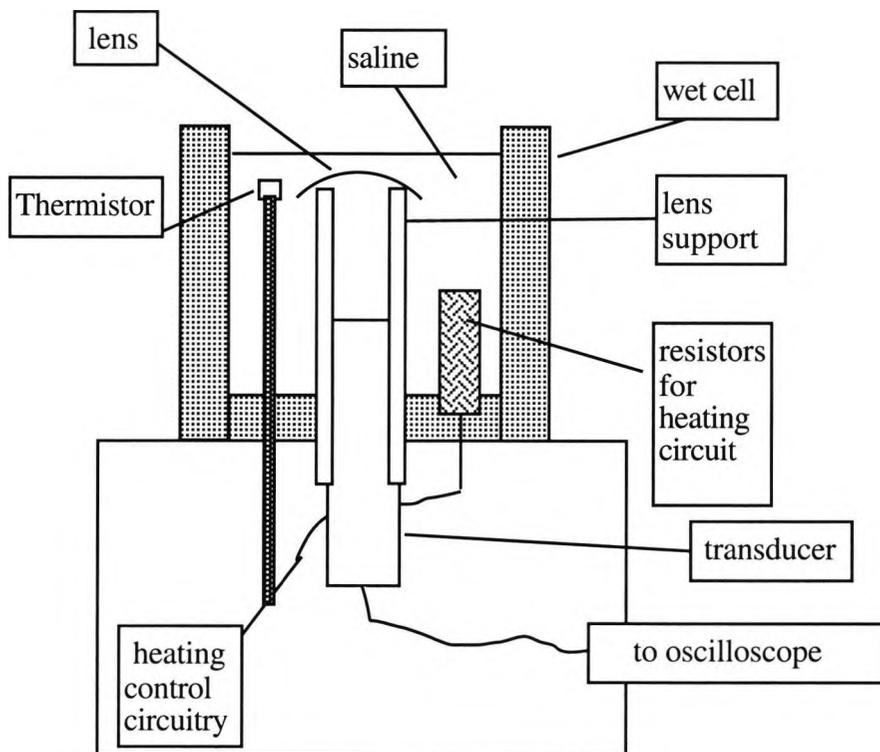
Figure 4.5   Diagrammatic version of the final design to measure the BOZR of soft lenses.

At the bottom of the saline cell three insulated resistors were incorporated to heat the saline. The wet cell was positioned on top of a suitable metal box which housed the control circuitry and hardware. Thus, the size of the measurement apparatus was reduced dramatically to a single unit of compact size (see Fig. 4.5).

A control knob on the front of the box adjusted the temperature and a LED alongside

indicated when the heating circuit was on. The current through the resistors was pulsed. If a large current was needed to heat the saline to the predetermined value the pulses were 'continuous' and the lamp stayed alight; as the temperature approached the set value so the pulses of current were shorter until at the correct temperature there was no current. At temperature stability only short pulses of current were required when the temperature fell by a fraction. A conventional narrow range laboratory thermometer was used to check the temperature. The final design is shown in Figs. 4.6 and 4.7. With the new temperature control system the mean SD (t) dropped to 0.006 μs. in the final apparatus.

The results showed no correlation between radius and repeatability or between thickness and repeatability. It was clear that the reliability of measurement was related to the material.

A total of 76 lenses was examined (8 different materials) Each lens was tested independently (see section 4.1) four times. The modal value for SD (radius) was 0.02 mm, 58% of all the lenses had a SD of 0.04mm or better.
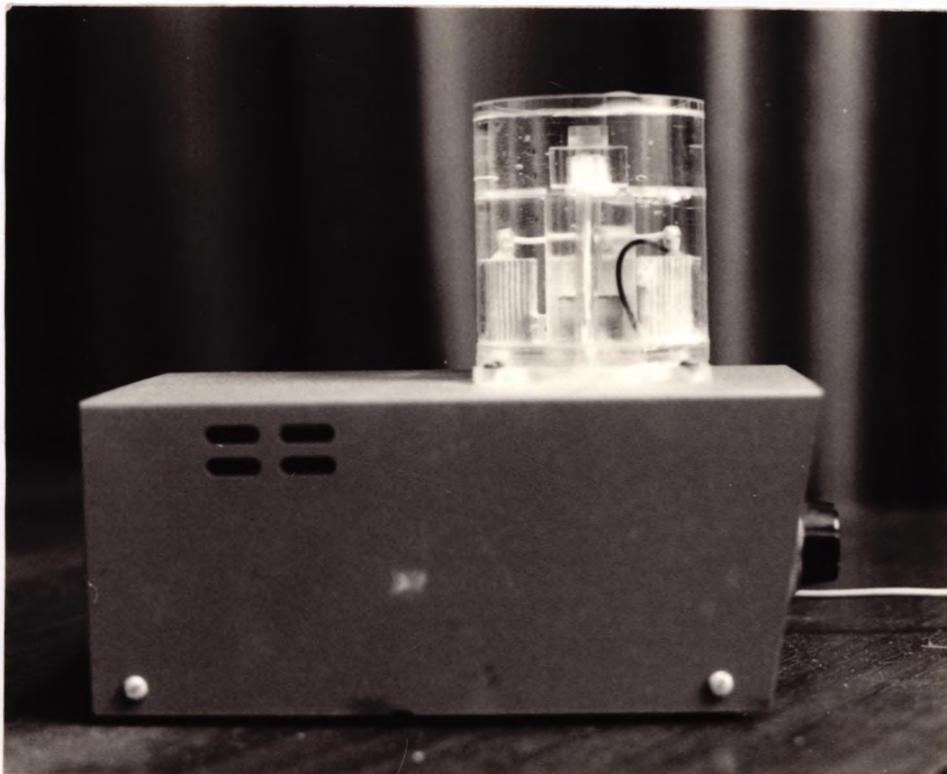
Figure 4.6   Side view of the final design
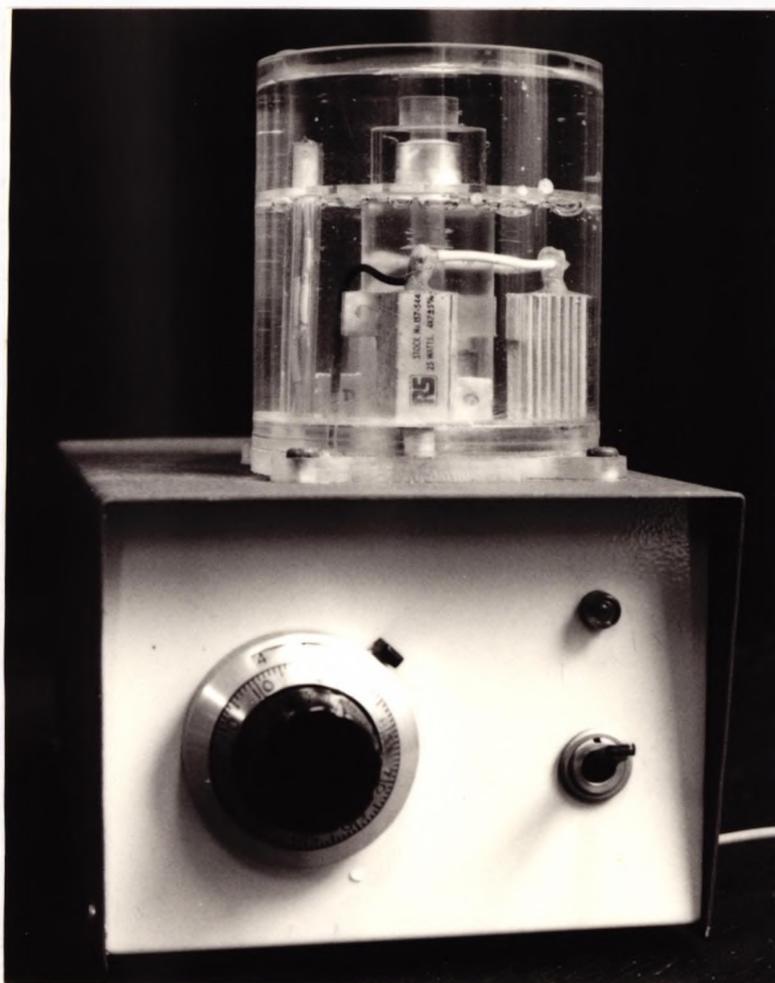
Figure 4.7   Front view of the final apparatus showing the saline filled wet cell on the top of a metal box which housed the saline heating circuitry. The temperature control is shown on the left side of the front panel.

4.1.2   Measurement of FOZR

To provide this facility the pillar design was altered so that either the lens rested on the normal cylinder (for BOZR measurement) or an additional collar was placed on the pillar which accepted the front surface of the lens. The chord diameter was again a nominal 10 mm (see Fig. 4.8) .
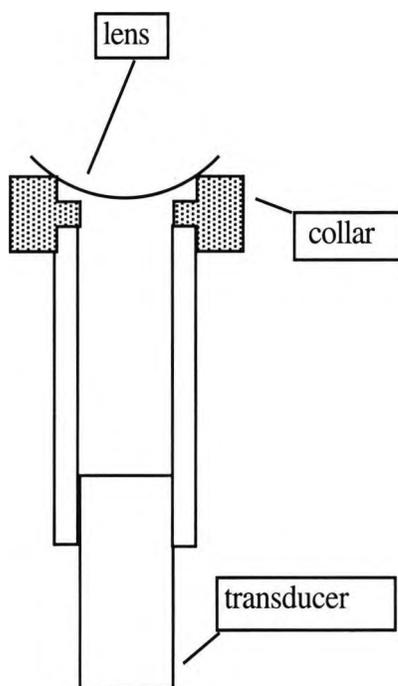
Figure 4.8   The collar fitted over the lens support cylinder in order to measure to FOZR. NB the chord diameter is maintained at 10mm.

Calibration (conversion) graphs were obtained using precision steel balls which had been checked with an engineer's micrometer.

For FOZR measurement the lens surfaces were in a slightly different position than when BOZR was measured. The position of the reference pulse was changed by means of the appropriate control on the Ultrasonoscope supplementary panel.

The measurement of FOZR is rarely needed in general practice if one knows the BOZR, power and thickness. Also, as many lenses are lenticulated to some degree on the front surface it is not accurate to measure the FOZR over 10 mm as the lenticular portion may be inside this diameter.

It is generally quicker and simpler to centre a lens with the convex side down and for this reason, in some of the experiments described later, the FOZR was measured in preference to the BOZR.

4.2 Measurement capabilities of the system

4.2.1 The measurement of BOZR

Objectives

1a To assess any difference in SD between independent and semi-independent trials

1b To assess any difference in BOZR measurement using a solid PMMA base for the reference signal (Mk II apparatus) compared with the improved model (Mk IV) which used an artificially generated reference base.

2a To assess any flexural changes prior to measurement.

2b To assess the repeatability of the system.

3a To assess the difference between BOZR values when the dimension is obtained by calculation and from a conversion graph.

3b To assess the differences in RTT values derived

    a. from the interval counter

    b. from the oscilloscope marker trace

3c With these tests completed, to take BOZR measurements for lenses of various powers and materials.

Experiment 1

Objectives

- To assess any difference in SD between independent and semi-independent trials

- To assess any difference in BOZR measurement using a solid PMMA base for the reference signal (Mk II apparatus) compared with the improved model (Mk IV) which used an artificially generated reference base.

- To assess any differences between the interval counter and the marker trace values for time (RTT).

Materials

Mk. II and Mk. IV apparatus

Radiuscope to be used as a travelling microscope.

Lenses.

Five Hydron Europe p-Hema lenses were used. The specified BOZR was not known. The powers were as follows:-

Lens no.	Power
1	-0.75 D
2	-1.50 D
3	-2.00 D
4	-3.00 D
5	-6.75 D

Method

The radiuscope was used as a travelling microscope to measure the real centre thickness of the lenses. A steel ball (radius 8mm) was mounted where a rigid lens is normally mounted. It was adjusted so that its apex aligned with the optical axis of the instrument. The instrument was zeroed on the apex of the ball. The soft lens was mounted convex side on the steel ball . The lens was centred by eye so that its edge was as close to the horizontal as possible. The radiuscope was then adjusted to focus on the anterior surface of the lens. This gave the real centre thickness of the lens.

The ultrasound apparatus was switched on for at least 30 minutes in order to stabilise.

Each lens was subjected to 5 independent trials in each apparatus and 5 semi-independent trials in each apparatus.

RTT measurements with the Mk IV apparatus were made with the interval counter . With the Mk II apparatus an additional set of 5 independent trials was carried out utilising the marker trace from the oscilloscope screen besides those using the interval counter.

BOZR values were obtained from the RTT using conversion equations.

RESULTS

All lenses had a centre thickness of 0.30 mm ±0.02 mm

The temperature of the 0.9% saline was 20°C ±0.5°C. The pH was 6.00

Apparatus Mk	Mean SD (time) μsecs	Range	Mean SD (radius) mm	Trial type
IV(IC)	0.015	0.013 to 0.017	0.030	independent
ditto	0.010	0.006 to 0.012	0.030	semi-independent
II(IC)	0.009	0.004 to 0.014	0.035	independent
II(MT)	0.010	0.007 to 0.013	0.025	independent
II(IC)	0.008	0.005 to 0.017	0.026	semi-independent

Table 4.2 The standard deviations produced with two different pieces of apparatus and the comparison of independent with semi-independent trials. IV(IC) refers to Mk IV apparatus and Interval Counter.   II(MT) refers to Mk II apparatus used in conjunction with the marker trace for RTT values.

Radius values (mm)				
Mk. IV apparatus			Mk II apparatus	
lens no.	Ind.	semi-ind	Ind.	Semi-Ind.
1	7.77	7.86	7.95	7.93
2	7.77	7.86	7.94	7.93
3	7.98	8.09	8.19	8.16
4	7.98	8.05	8.23	8.16
5	7.86	7.99	8.05	8.00
mean	7.87	7.97	8.07	8.03

Table 4.3   Mean radius values obtained using five lenses with the Mk II and Mk IV versions of the apparatus. Independent (Ind.) and semi-independent (Semi-ind.) values are compared.

DISCUSSION

Both tests using the Mk II apparatus with the solid base (SB) had a very slightly lower SD

(time) than the same tests with the Mk IV apparatus using the Pulse Base (PB). This was almost certainly due to some electrical instability and the reference pulse not being time-locked accurately enough.

The difference in SD using independent and semi-independent trials was only very slight $(0.001\mu s)$ with this material. For a stable material in a stable environment it was possible to obtain SD (time) values in the region of $0.01\mu secs$ using either piece of apparatus. It was therefore concluded that the semi-independent trials used gave the same level of repeatability as trials being carried out independently. In view of the time saved, the semi-independent trials were adopted for future use unless specified otherwise.

Converting each RTT value to a radius gave SD (radius) values between 0.025mm and 0.035mm. For the Mk IV apparatus there was no difference between the SD using using independent trials and the SD using semi-independent trials.

Use of the marker trace showed that the SD (time) was of the same order as that obtained with the interval counter.

It is therefore concluded that the use of semi-independent trials and the use of the interval counter gives repeatable results in a much shorter operator time than those obtained with the marker trace and independent trials.

The Mk IV system gave lenses BOZR values approximately 0.13mm steeper than the Mk II system. However, the difference between the two sytems was lowest when the results from the semi-dependent trials were compared.

Port (1975) found that PMMA FLOM lenses when measured on the Mk II system gave BOZR to within 0.02mm of the values found with a radiuscope.

Experiment 2

Objectives
- To assess any flexural changes prior to measurement.

- To assess the repeatability of the system.

Prior to lens measurement the lens will be handled and flexed. When the lens is resting on the support during measurement there may well be some gravitational and/or distortion effects on the lens. To test the hypothesis of some flattening and/or distortion occurring, the sag can be monitored simply by recording the RTT over a period of time. If there was significant flattening then it would be more relevant to take the highest sag value rather than a mean or modal value to give a radius value for the lens.

Materials
Mk IV apparatus.

Interval counter with its gate time set at 10 seconds. This time period enables a large number of values to be averaged every 10 seconds and the average displayed every 10 s. It enables the observer to tell quite easily when stability had been achieved. A gate time of say 60 s would significantly lengthen the time of the experiments without any significant improvement in accuracy.

Conversion equations to obtain BOZR values.

20 Menicon p-HEMA lenses all powered -3.00 D with specified BOZR values between 8.0 and 9.2mm.

Environment: Temperature 20.5°C± 0.5°C ; pH 5.8 ; 0.9% saline

Method
The lenses were subjected to three different treatments. It was decided to use the modal and mean values as opposed to the mean value. If the lens had been flattened the true RTT value would be the highest value as the lens gradually regained its true shape. If the lens was distorted, one may have or or two low readings for example and then 4 readings all the same when stability had been achieved. For this reason the modal value was closer to the true value than a mean.

A lens was taken from the storage vial and transferred to the support pillar in the apparatus. It was centred with the aid of a plastic spatula or rod. As the vial temperature and apparatus

saline were close only a minute was needed for the lens to equilibrate (this could not be standardised as the lens fell from the support on occasions and had to be recentred). After this time six consecutive readings were taken from the interval timer (total time one minute). The lens was removed from the apparatus and returned to the storage vial. The modal value (Treatment 1 [TR1]) and highest values (Treatment 2 [TR2]) were noted. This constituted one independent trial. The remaining lenses were tested in the same manner. Three independent trials were made on each lens.

Treatment 2 was repeated on the following day using lenses 1-15 to assess repeatability on a day to day basis. This was termed Treatment 3 (TR3)

The time plan was as follows:

Lens removal from vial; checking lens form, lens placement & centration	*30s*
Equilibration	*60s*
6 displayed readings	*60s*
Lens removal and return to vial	*10s*

Total for one trial	*160s*	
Time for 20 lenses	*53 m*	
Time for 3 trials on 20 lenses	***2 hrs 40 m***	

RESULTS

	Rs [mm]	TR1	TR2
N mean (mm)	 8.60	20 8.68	20 8.63
error range (mm) lenses steeper than Rs. lenses flatter than Rs. lenses on spec.		0.05 S 0.32 F 4 12 4	0.05S 0.19F 6 11 3

Table 4.4   Radius values obtained using the modal value of six RTT values (TR1) and the largest of six RTT values (TR2) for each independent trial. Rs is the specified radius.

	Rs	TR2	TR3
N		15	15
mean(mm)	8.53	8.57	8.53
Error range (mm)		0.05S- 0.15F	0.10S- 0.14F
Lenses steeper than spec		6	7
Lenses flatter than spec.		8	8
Lenses on spec.		1	0

Table 4.5   The greatest RTT value was taken for each independent measurement for 15 lenses (TR2) and this was compared with the same method one day later (TR3). Rs is the specified radius.

Student t-test		
	TR1/TR2	TR2/TR3
df	19	14
t	2.61	2.21
critical value (5%)	2.09	2.14
F	1.12	1.21
critical level (5%)	2.17	2.51

Table 4.6   Statistical comparisons of the treatments referred to Tables 4.4.and 4.5

Discussion

Statistically, TR1 and TR2 were significantly different at the 5% level. But the difference was only 0.05mm steeper and one can conclude that there for this low water content material and using fairly thick lenses, there was very little deformation occurring after the lens had been placed on the lens support. Similarly, for the repeatability test (TR2 and TR3), there was a statistically significant change at the 5% level but the difference in means of only 0.04mm was not significant in terms of practical soft lens measurement.

In the treatment 2 and 3,

73% of the lenses were repeatable to ± 0.05mm or less

93% were repeatable to ± 0.10mm or less

100% were repeatable to ±0.15mm or less.

Experiment 3

Objective

- To determine the BOZR using firstly the RTT value obtained from the interval counter and a conversion equation (obtained from a series of PMMA reference pieces - see Section 2) and secondly, by using the same RTT value but obtaining the BOZR by calculation. The latter method converts the RTT to a distance knowing the velocity of sound at the specified temperature. This distance is the sagitta of the lens surface above the lens support. The sagitta can then be converted to a radius using the expression :

$$BOZR = [\ d^2 / 8s\ ]\ \ + [\ s/2\ ]$$

where d is the diameter of the lens support and s is the sag.

Materials

Mk IV apparatus.

Interval counter with its gate time set at 10 seconds.

Contact lenses:

20 Sauflon 55 (S55) lenses of mixed powers from +20.00 to -20.50 D	(1-20)
10 Sauflon 70 (S70) lenses powered from +17.25 to -6.00 D	(21-30)
20 Sauflon 85 (S85) lenses powered from +18.75 to -16.00 D	(31-50)

Method

The saline in the apparatus to have a nominal value of 20°C.

Experiments 1 and 2 (above) had shown that highest RTT value from a series of 6 displayed values was unlikely to differ significantly from the modal value. Similarly the repeatability was not significantly different when semi-independent trials were used compared to independent trials. Hence for this experiment, the highest RTT value was chosen out of 6 displayed values for each of three semi-independent trials on each lens.

RESULTS

Environment 0.9% saline, pH 5.8 - 6.1

Temperature :

S55: 1-9 @ 18.8°C; lenses 10-14 @ 21.0°C ; lenses 15-20 @ 21.2°C;

S70 : 21 - 30 @ 21.1°C ± 0.2°C

S85: 31-40 @ 19.5± 0.1°C ; 41-50 @ 21.4°C ± 0.3°C

Material	----------- Mean BOZR (mm) -------------			
	Rs	Conv. Eq (CE)	Calculation (C)	C - CE (mm)
S55 (+)	8.35	8.67	8.91	0.24
(-)	8.32	8.47	8.67	0.20
S70	8.16	8.61	8.91	0.31
S85 (+)	8.04	8.24	8.43	0.19
(-)	7.95	8.34	8.55	0.21

Table 4.7   A comparison between radius values obtained using RTT values from the interval counter and either determining the BOZR with a conversion equation (CE) or using a calculation method(C)

Discussion

The consistent finding was that all lenses measured considerably flatter than their specified BOZR irrespective of which method of determining the BOZR was employed. The accuracy of the ultrasound system had been <0.05mm based on rigid test pieces and the discrepancy was therefore due to the lenses being either spherical and flatter than intended or the hydrated form was aspherical.

The calculation method of obtaining the BOZR from the RTT showed that values were consistently 0.2mm flatter than those using the conversion equation. A reason for the sag value being too small is most likely to be attributed to the ultrasound beam being reflected

from a highly curved surface and paraxial reflections are being used to obtain the RTT. Unless a transducer could be made with a very narrow beam of sufficient intensity, it appears that a conversion equation based on calibration pieces is preferred.

Experiment 4

Objective

- To determine the BOZR using firstly the RTT value obtained from the marker trace on the oscilloscope and a conversion equation (obtained from a series of PMMA reference pieces - see Section 2) and secondly, by using the same RTT value but obtaining the BOZR by calculation.

Materials

Mk IV apparatus.

Interval counter with its gate time set at 10 seconds.

Contact lenses: 20 Sauflon 85 (S85) lenses powered from +18.75 to -16.00 D

In view of the time needed to investigate all 3 materials, it was decided to limit the material to one viz S85.

Method

The same S85 lenses were used as in experiment 3 above.   In view of the extra time needed for marker trace measurement for each lens, only two semi-independent trials were carried out. From each RTT value obtained, the BOZR was again calculated using both the conversion equation and the calculation method.

RESULTS

---------------- mean BOZR (mm) -----------------
(Marker trace used to obtain RTT values)

	Conv. Equation (CE)	Calculation (C)	C - CE
S85 (-)	8.20	8.37	0.17
S85 (+)	8.14	8.28	0.14

Results of experiment 3 for comparison purposes
(Interval timer used to obtain RTT values)

	Conv. Equation (CE)	Calculation (C)	C - CE
S85 (-)	8.34	8.55	0.21
S85 (+)	8.24	8.43	0.19

Discussion

The difference in radius values using the marker trace and the interval timer were also significant. The BOZR values of all the S85 lenses were approximately 0.14mm steeper when the marker trace was used. The difference was always in the same direction for each lens implying there was a systematic error occurring. When using the marker trace, it is conventional to measure the time from one peak to another. To encourage accuracy the screen magnification has to be large. This implies that both signal peaks cannot be on the screen at the same time. The operator also has to interpolate between the 'peaks' of the marker trace itself. Conversely, the interval counter is triggered by a constant voltage level of both signals and there is no subjective adjustment. There is also the possibility of same consistent difference in the accuracy of the timer circuits although this seems rather remote. In view of the time taken per measurement and general convenience it was decided to use the conversion graph in conjunction with interval counter as the best method of obtaining radii. This allows for any errors in timing and beam pattern to be eliminated.

4.2.2 Measurement of FOZR

A similar series of experiments was performed using the system to measure FOZR rather than BOZR. For the conversion equation 5 steel balls of nominal radii 7mm to 11 mm were used. A micrometer was used to verify the diameter of the balls.

Experiment 1

Objective: To determine the SD obtained using values from HEMA lenses and S55 lenses.

Materials: Mk IV ultrasound equipment.
Contact lenses: 12 Hydron HEMA lenses and 10 Bausch & Lomb HEMA lenses (B and N series   powered -1.00 to +6.00); eight Sauflon 55 lenses.

Method

The method was exactly the same as that used for the BOZR experiments except that the lens was placed convex side down on the lens support. The Hydron lenses were subjected to four semi-independent trials and the Bausch & Lomb lenses to five semi-independent trials

RESULTS

Hydron lenses Saline 20.8°C, pH 5.0-5.5		Bausch & Lomb lenses saline 20.1-20.5°C, pH 5.5	
mean FOZR (mm)	SD (mm)	mean FOZR (mm)	SD (mm)
8.51	0.01	8.64	0.03
8.28	0.02	9.08	0.01
8.67	0.03	8.93	0.04
8.83	0.01	9.18	0.04
8.96	0.04	8.93	0.01
9.24	0.02	9.00	0.03
9.26	0.01	8.93	0.01
9.32	0.04	7.91	0.01
9.47	0.05	8.00	0.03
9.63	0.09	7.98	0.01
10.20	0.05		
10.07	0.02		
MEAN SD	0.032mm (SE 0.015mm)		0.022mm (SE 0.009mm)

Table 4.8   FOZR values and SD values for two types of HEMA lens

..mean FOZR (mm)	SD(mm)
8.80	0.04
8.02	0.06
8.36	0.04
8.89	0.03
9.78	0.04
9.61	0.06
9.94	0.02
10.45	0.04
	The mean SD was 0.04 (SE 0.018)

Table 4.9   FOZR and SD values for Sauflon 55 lenses Saline temperature 20.0± 0.3˚C; pH 5.8

Discussion

The SD values obtained (0.02 to 0.04mm) were in the same order as those found when the BOZR was measured. A difference was found between the two HEMA lens types but the mean was 0.027mm and the S55 material lenses showed a mean of 0.040mm.

Experiment 2

Aim: To obtain SD values from mean measurements taken on three different days and four different days.

Materials

Mk IV equipment. Two batches each of 9 of lenses comprised of S55 and S70 soft lenses

Method

The apparatus was set up and stabilised on each consecutive day. Each lens was subjected to two semi-independent measurements.   When the three day trial had been completed, the second batch of lenses was used for a similar trial which spanned four days.

RESULTS

Mean FOZR (mm)	SD (mm)	Range of means over the 3 days (mm)
9.48	0.06	9.46 - 9.51
8.46	0.13	8.60 - 8.74
9.16	0.16	8.94 - 9.29
8.90	0.20	8.68 - 9.10
8.76	0.11	8.62 - 8.87
8.95	0.15	8.78 - 9.10
8.01	0.06	7.97 - 8.04
8.96	0.29	8.56 - 9.12
8.97	0.24	8.65 - 9.19
The mean SD was 0.15mm (SE 0.09mm)		

Table 4.10   Variation in FOZR and SD values of Sauflon 55 and
Sauflon 70 lenses when measured on 3 different days.
Saline temperature 20.0± 0.5°C; pH 5.2 ± 0.3

Mean FOZR (mm)	SD (mm)	Range of means over the 4 days (mm)
9.08	0.12	8.96 - 9.19
10.14	0.08	10.10 - 10.22
8.16	0.06	8.08 - 8.21
8.37	0.08	8.30 - 8.49
8.07	0.17	7.96 - 8.37
7.83	0.22	7.71 - 8.30
8.69	0.22	8.36- 9.06
8.05	0.18	7.92 - 8.35
7.65	0.11	7.53 - 7.83

Table 4.11   The means, SDs and ranges for FOZR obtained
on four different days with S55 and S70 lenses.
Saline temperature 20.1± 0.5°C;   pH 5.2 ± 0.3
The mean SD was 0.12mm (SE 0.06mm)

Discussion

The mean SDs were 0.15mm and 0.12mm for the three day and four day trials. This compares with a SD of 0.04mm (SE 0.018mm) when 5 semi-independent measurements were taken for medium water content lenses on the same day. Thus, the SD worsened by a factor of 3 when day to day values were compared. This is perhaps the most rigorous test of the equipment and method. On first sight, the SD obtained on a single day is particularly good but there is not a high level of repeatability on a day to day basis. In effect, mean values varied by as much as 0.54mm on the 3 day trial and 0.70mm on the 4 day trial. However, if each mean had used five or six measurements to obtain a mean, the results would have been better.

Experiment 3

Aim

To obtain radius values using both the marker trace on the oscilloscope screen and the interval counter; to compare the differences with those found in BOZR measurements.

Materials

Mk IV equipment, 9 Sauflon 55 and Sauflon 70 lenses.
Interval counter to measure the RTT. The highest value of six comsecutive values was used. The gate time was fixed at 10 seconds.

Method

Each medium water content lens was subjected to four semi-independent trials using both the interval counter and the marker trace on the oscilloscope screen.

Results

Saline temperature 20.0°C ± 0.4°C ; pH   5.8

Mean FOZR (interval counter)   8.72mm   (mean SD 0.034mm)
Mean FOZR (marker trace)   8.87mm (mean SD 0.039mm)

Discussion

The marker trace values were 0.15mm flatter than those obtained using the interval counter. The individual means were anything from 0.07 to 0.27mm flatter with the marker trace. The difference between the the two methods is of the same order as that found when the BOZR measurements were considered.   However, in that situation the marker trace radii

were steeper than the interval counter radii. The finding lends some credence to the idea that the presenting surface shape to the beam, the beam width, the parts of the the signal envelope used for marker trace measurement and interval counter triggering all contribute to the differences in values. Even with this difference, an equation based on calibrated test pieces will give better radii values than a system which uses calculated values purely from the time measurement.

Repeatability, as indicated by the SD, was poorer with the 55% and 70% water content materials than with the 40% materials.

Chapter 5   Further uses of the ultrasound equipment

A technique had been developed that enabled a soft lens to be measured in saline without mechanical interference. It was decided to investigate other properties and dimensions of hydrogels with the same apparatus in order to assess if this novel approach could be used to better effect than existing technology.

The areas of investigation were as follows:

5.1   Temperature effects on hydrogel lenses

5.2   The measurement of centre thickness

5.3   The measurement of lens power

5.4   The measurement of water content

5.5   The assessment of surface morphology

5.1 The effect of temperature on hydrogel lenses.

It has been previously established (Chaston and Fatt, 1981) that as the temperature of a hydrogel increases the water content decreases. As far as soft contact lenses are concerned, the main temperature range of interest is that between 20°C (storage temperature) and 30°C (temperature of the cornea). When a hydrogel is taken from its storage vial it is at room temperature and when placed on the eye it will gradually equilibrate with the anterior surface temperature of the eye. The decrease in water content implies:

a.   A steepening of the BOZR and FOZR

b.   A decrease in total diameter

c.   A decrease in thickness

d.   A decrease in oxygen permeability.

Objectives

To determine the effects of temperature on the BOZR and FOZR of lenses manufactured from different water content materials.

Materials

The velocity of sound in normal saline was determined using the saline gap of 4.47mm as described previously. The temperature was monitored with a glass, narrow range, laboratory thermometer.

Ultrasound apparatus and normal saline as described(Mk II apparatus including water bath and heater for velocity measurements; Mk IV for radius measurements)

Lenses

Bionite 45%,

Hydron HEMA 40%,

Sauflon 55%, 70% and 85% water content lenses

Method

a. Velocity determination

The Ultrasonoscope and interval counter were switched on for at least 30 minutes to stabilise. Saline had been cooled in refrigerator to a temperature of 10-12°C. The saline was then transferred to the apparatus (Mk II) with the saline gap device. Care was taken that no bubbles existed in the saline space. The gap was 4.47mm (see Chapter 3).

The RTT(μs) was noted for every temperature rise of approximately 1°C. After the temperature stabilised at room temperature the heater was switched on to enable temperatures up to 35°C to be monitored. The thermometer was used to stir the saline to ensure adequate mixing around and through the device.

The velocity at temperature t was caluated from the equation

$$V_t = [\, 4.47 \times 2 \times 10^{-3}\,] / RTT_t \times 10^{-6} \quad \text{m/s}$$

The coefficient of expansion of PMMA is too small to significantly affect the saline gap being measured by ultrasound.

b. Radius determination

Cooled, fresh saline at approximately 15°C was placed in the wet cell. The lens was placed in the apparatus as described previously to measure either the BOZR or FOZR. Between each recording of RTT the lens was removed from the lens support and repositioned to enable saline mixing to occur on both sides of the lens. The temperature of the saline was allowed to rise as described above. The temperature control on the Mk IV apparatus was only changed in small increments in order to give the operator time to mix the saline and take RTT values accurately. RTT values were recorded at approximately every 1°C rise in temperature(t).

The sag was determined by caluation as follows:

$$sag_t = V_t \times RTT/2 \times 10^3 \quad \text{mm} \quad (\, V \text{ in m/s}; \ RTT \text{ in s}\,)$$

The radius was calculated as follows:

$$radius_t = (\,[d^2]/8s\,) + s/2 \quad (\, d = \text{diameter of lens support. } s = sag_t\,)$$

FOZR was determined on one Bionite lens, 3 HEMA lenses and 5 Sauflon 70 lenses all of

different radii. BOZR was determined on 2 Sauflon 55 lenses, 2 Sauflon 70 lenses and 10 Sauflon 85 lenses.   The Sauflon 85 lenses were tested only at 20°C and 30°C as previous results had shown that the changes between these two temperatures were linear.

Results

The equation correlating saline temperature to sound velocity was as follows:

velocity (m/s) $= 0.002x^3 + 0.109x^2 +1.005x +1439.1$ (r = 0.999) where x is the temperature

The Bionite and HEMA lenses showed no significant change of radius in temperature in the range 20 - 30°C. The change over 10°C was only 0.065mm steeper.

Lenses of higher water contents showed a linear relationship between temperature and radius over the range examined. The two Sauflon 55 lenses showed a mean steepening of 0.185mm/10°C

The seven Sauflon 70 lenses showed a mean of 0.33mm/10°C (range 0.26 to 0.41)

The ten Sauflon 85 lenses showed a mean steepening of 0.39mm/10°C (range 0.28 to 0.46)
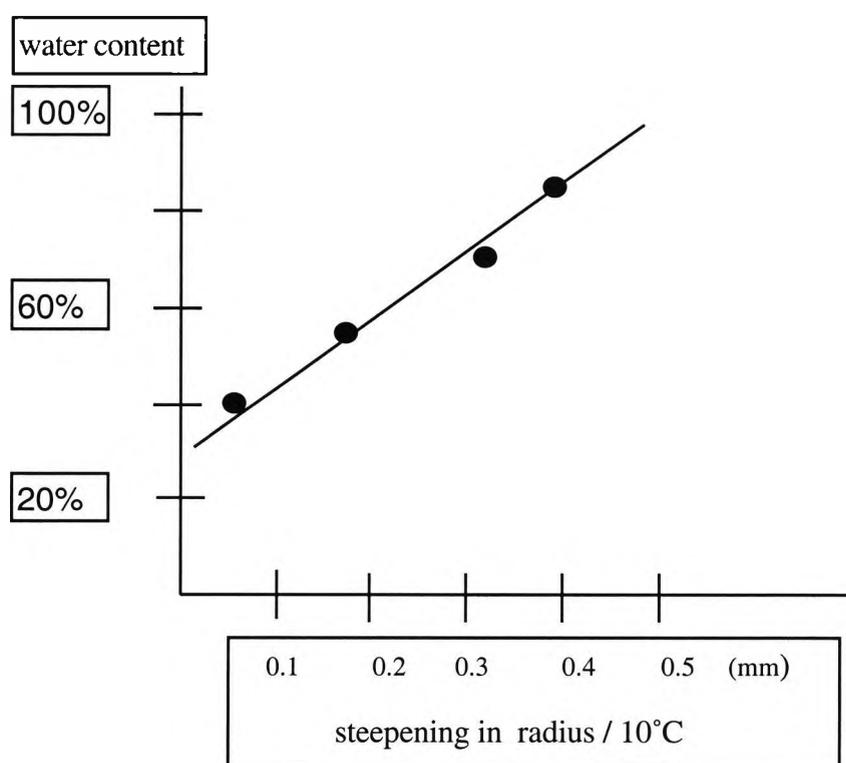
Figure 5.1   The steepening effect of temperature on hydrogel materials of different water content

5.2   The measurement of centre thickness

Pearson (1980a) summarised the methods utilised for measuring centre thickness of soft lenses.   In his own experiments he found SDs between 0.007mm and 0.015mm when measuring lenses 20 times by various methods.   The Fatt method (Fatt, 1977) achieved SDs in the region of 0.003 to 0.004mm.   Pearson concluded that a tolerance of ±0.03mm for soft lenses would be satisfactory.   (It is conventional in much of the contact lens industry that measurement accuracy of instruments is half the tolerance [BS 5562,1978]).

In order to measure the centre thickness of a soft lens in saline using ultrasound it is necessary to know the velocity of sound through the material at the specified temperature. This information is not readily available and is difficult to determine experimentally.

Objectives

1.   To obtain conversion equations to enable centre thickness of specified soft lens materials to be obtained from the ultrasound apparatus.

2.   To assess the effects of the ultrasound beam being first incident on either the convex or concave surface.

3.   To consider other methods of centre thickness determination besides using a conversion equation.

Materials

AO Radiuscope

Steel ball (radius 8.5mm)

Black flat PMMA sheet

Mk IV apparatus

Soft lenses in three different materials

Humphrey Instruments Ultrasound Microscope (USM)

Wet cell to be used in conjunction with the USM

Experiment 1:

Aim: To assess the method of using a travelling microscope to measure the thickness directly. The lens would be placed either on a steel ball or on a flat rigid sheet and the results from both methods are compared.

Materials

AO Radiuscope

Steel ball (radius 8.5mm)

Black flat PMMA sheet

10 soft lenses (Sauflon - 85% water content) of different powers (-1.00 to + 20.50) to create different centre thicknesses.

Method

A series of 10 soft lenses of different thickness was measured optically (Harris, 1973) using two variations as follows:

a) The radiuscope was used as a travelling microscope. It was first focused on the uppermost point of a steel ball and the radius measured by the conventional method (Drysdale, 1900). The aerial and real images were centred in the field of vision during this process thus ensuring the optical system was centred on the apex of the steel ball. The radiuscope was then zeroed. The soft lens was removed from the storage saline and the surplus saline was removed with a paper tissue . The lens was then placed on the steel ball (concave side of the lens on the ball) and centred visually so that its edge appeared horizontal from all angles. By this means, the centre of the lens was as close as possible to the apex of the steel ball. The radiuscope was then refocused on the centre of the convex surface of the lens. The difference between the two values gave the real centre thickness. 10 lenses were tested and each was subjected to 4 independent trials.

b) Instead of using a ball bearing to support the lens, a flat black PMMA sheet was used. In this case the radiuscope was first focused on the sheet and zeroed. The contact lens was then removed from the saline and the surface saline removed as above. It was then laid on the sheet with its concave surface uppermost. Care was taken not to have any saline left on the back surface of the lens which would have given an artificially high thickness measurement. The radiuscope target image could be seen macroscopically on the lens surface; the lens (and its support) was manipulated until the image appeared to be in the centre of the lens. The radiuscope was then focused on the centre of the concave surface. The scale reading gave the real centre thickness.

10 lenses were measured. Each lens was subjected to four independent readings.

RESULTS　　　　**THICKNESS (mm)**

	Mean	Range	Mean SD	Range
Method a)	0.290	(0.18 - 0.48)	0.0083	(0.004 - 0.017)
Method b)	0.294	(0.18 - 0.49)	0.0106	(0.004 - 0.023)

A paired t-test on the thickness values obtained gave a t value of -1.309 and the critical value (2.262) was not exceeded. The difference between the mean values was not significant (p=0.223)

In view of the small difference between the SDs for the two methods it was decided to use method 'b' as it was easier to centre the lens under the radiuscope and the images obtained were clearer.

Experiment 2-Assessment of the ultrasound RTT related to centre thickness

Aim

As in previous experiments the peak to peak RTT could be obtained either from the time marker trace on the oscilloscope or from the interval counter using a given trigger level on the signal envelope. The aim of experiment 2 was to assess if there were significant

differences between the two methods for this purpose,

Apparatus

Ten soft lenses of varying thickness in the same material (Sauflon 55)

Ultrasound Mk IV system including the interval counter.

Method

Ten lenses were tested using both methods of assessing the RTT through the lens. Values were taken from both the interval counter and the marker trace on the oscilloscope screen. Each lens was subjected to four independent measurements.

Results

The saline temperature varied between 19.4 and 21.8°C

Using the interval counter gave RTT values from $0.16\mu s$ to $0.49\mu s$ and the mean SD was $0.008\mu s$ (range zero to $0.016\mu s$). RTT values obtained from the marker trace were very highly correlated and averaged only at $0.01\mu s$ longer than those values obtained with the interval counter. The mean SD was $0.003\mu s$.

Conclusions

Although the SD was smaller with the marker trace it took much longer to obtain the results. In view of this it was decided to use the interval counter.

Experiment 3.   Obtaining a conversion equation

Aim

To obtain an equation that would enable RTT values obtained with the ultrasound system to be converted to a thickness value in mm. Each material would need a separate equation.

Materials

Ten Sauflon 85 lenses; twelve Sauflon 70 lenses; nine Sauflon 55 lenses

AO Radiuscope

Black flat PMMA sheet

Mk IV apparatus including interval counter

Method

For this experiment the RTT was obtained using the interval counter and the results were compared with those acquired by method 'b' above (experiment 1).

Each lens was subjected to four independent trials in air and four in saline as described above.

Results

Temperature range 19.9 to 20.4°C

The results are summarised in Table 5.2.1

..	RTT μs	SD μs	tc mm (expt 1)	SD mm
S70 Maximum Minimum	0.42 0.30	0.011 0.004	0.36 0.29	0.017 0.002
mean		0.006		0.011
S55 Max. Min.	0.40 0.24	0.020 zero	0.40 0.23	0.05 zero
mean		0.005		0.02
S85 Max. Min	0.56 0.14	0.010 0.004	0.55 0.16	0.05 zero
mean		0.005		0.02

Table 5.2.1   Ultrasound values, real thickness values and SDs related to the measurement of centre thickness.

The data obtained was linear in nature and a typical example is shown in Figure 5.2.0
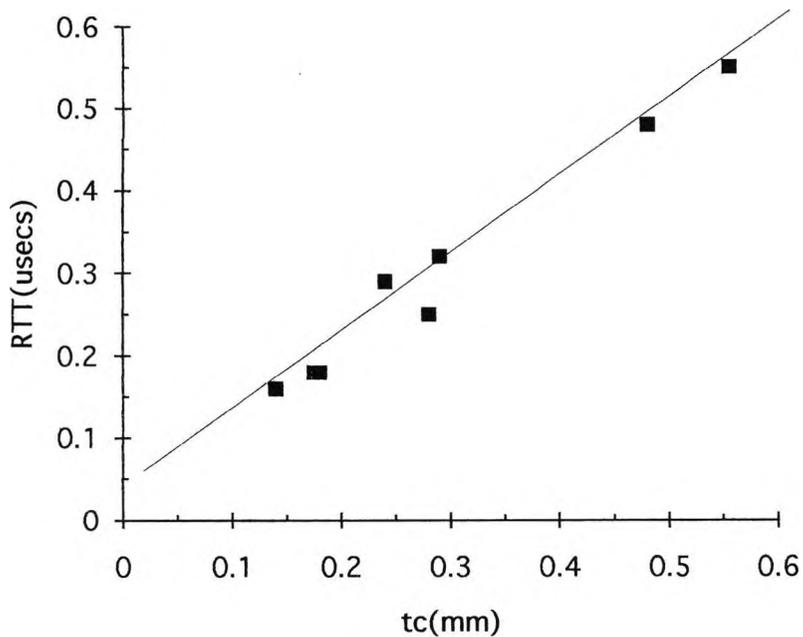
Figure 5.2.0   The relationship for S85 material when the centre thickness measured with a radiuscope (as a travelling microscope) was compared to the RTT values obtained using ultrasound.

Conversion equations were obtained by linear regression (Runyon and Haber, 1973) as follows:

S55 $\qquad$ t_c(mm) = 0.664 RTT (μs) + 0.087

E.g. $\qquad$ *RTT = 0.26μs then tc = 0.26*0.664 +0.087 = 0.26mm*

S70 $\qquad$ t_c(mm) = 0.994 RTT(μs) - 0.013

S85 $\qquad$ t_c(mm) = 0.972 RTT(μs) + 0.015

Discussion

In this experiment, it was possible to devise a system of measurement based on calibration of soft lenses initially using the radiuscope as a travelling microscope. The RTT values obtained were only relevant for a saline temperature of 20˚C . There are sources of error in the radiuscope itself and currently a low force gauge (ISO 9339-2, 1998) would be preferable for measuring the soft lens thickness compared to the in air method described above.

Experiment 4.   Surface curvature and the incident beam

As reported earlier, the ultrasound beam extends laterally beyond the lens axis and therefore the curvature of the surface will affect the RTT displayed. To assess this effect when measuring centre thickness the RTT values obtained when the beam was incident on the front surface were compared to the RTT values when the beam was incident on the back surface of the lens.

Aim: To assess the effect of the ultrasound beam being either incident on the concave surace or the convex surface when assessing the centre thickness.

Materials

Contact lenses

	Thickness range	BOZR range(Rs)	Power range
HEMA	0.25 - 0.40mm	7.8 - 8.8mm	-6.00 to +4.00 D
Sauflon 55	0.25 - 0.33	7.7 - 9.1mm	-9.50 to + 6.00 D
Sauflon 70	0.16 - 0.53mm	7.9 - 9.1mm	-5.50 to + 5.75 D
Sauflon 85	0.14 - 0.75mm	7.5 - 8.4mm	-10.00 to +15.50 D

AO Radiuscope

Black flat PMMA sheet

Mk IV apparatus including interval counter

Method

 Each lens was placed in the apparatus in two different positions ie

i) with the convex surface of the lens facing the transducer

ii) with the concave surface of the lens facing the transducer

The centre thickness of each lens in air was also measured using the radiuscope (as

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described above in experiment 1)

Each measurement was a mean obtained from four independent readings.   Between 8 and 12 lenses were used for each material.

Results

HEMA: (N=8) Temperature 19.9 to 20.4°C; pH 6.4

mean RTT (Cx surface)	$0.345\mu s$
mean SD	$0.004\mu s$
mean RTT (Cc surface)	$0.361\mu s$
mean SD	0.006

In a paired t-test, the t value was 5.38. From tables the critical level for df 7, 0.01 level was 2.998. The critical level was exceeded indicating a significant difference

Sauflon 55: (N=12).   Temperature 19.8 to 20.8°C   pH 6.2

mean RTT (Cx surface)	$0.287\mu s$
mean SD	$0.004\mu s$
mean RTT (Cc surface)	$0.295\mu s$
mean SD	$0.006\mu s$

Paired t-test.   Critical value 2.718 (df 11; 0.01 level)

The t value between convex and concave surfaces was 5.83, again exceeeding the critical level indicating a significant difference at the 1% level.

Sauflon 70 (N=9). Temperature 20.6 to 22.0°C pH 6.8

mean RTT (Cx surface)	$0.280\mu s$
mean SD	$0.006\mu s$
mean RTT (Cc surface)	$0.280\mu s$
mean SD	$0.006\mu s$

Paired t test. Critical value 2.31(df 8; 0.05 level)

The t values between the two conditions was -1.403 and the difference was not significant (p = 0.198)

Sauflon 85: (N=10) Temperature 19.7 to 20.6°C pH 6.7

mean RTT (Cx surface)	$0.531\mu s$
mean SD	$0.006\mu s$
mean RTT (Cc surface)	$0.0540\mu s$
mean SD	$0.005\mu s$

Paired t test. Critical value 2.262 (df 9; 0.05 level)
The t value was -3.708 indicating a significant difference (p = 0.002)

Material	RTT(Cx)	RTT(Cc)	Cc-Cx
HEMA	0.345	0.361	0.016
S55	0.287	0.295	0.008
S70	0.280	0.280	0.000
S85	0.531	0.540	0.009

Table 5.2.2   The differences between RTTs for the transducer beam being incident on the front(Cx) side and concave (Cc) side. The concave values are the same or slightly higher than the convex values as would be expected.

Discussion

Although the results show statistically significant differences in some materials the practical effect is very small ie ~ 0.01mm. Table 5.2.2 shows that there were no differences that could be attributed to material . Having the lens with its concave side towards the transducer gave slightly shorter RTT values as would be anticipated. The slightly peripheral portions of the lens would be providing the first (earliest) reflection whereas having the convex surface towards the transducer enabled the substance on the lens axis to provide the earliest reflection and therefore the more accurate result.   However, unless one was dealing with hyperthin lenses an error in the region of 0.01mm is not of any clinical consequence.   In the case of the hyperthin lenses (tc ~ 0.04mm) the instrumentation would be unlikely to resolve the surfaces well enough to give adeqaute signals for analysis. A higher resolution with good damping would be needed and to achieve this a higher frequency transducer would be required.

Alternative method of measuring thickness utilising ultrasound

Fig. 5.2.1 shows a contact lens in saline with its centre thickness as BC. Points A and D represent points along the lens/transducer axis. The distance BC = AD - AB - CD. A and D can be either real objects placed in the ultrasound beam eg wires or membranes, or virtual objects (generated as reference pulses which are time locked to the transducer face) but the principle is exactly the same with both cases.
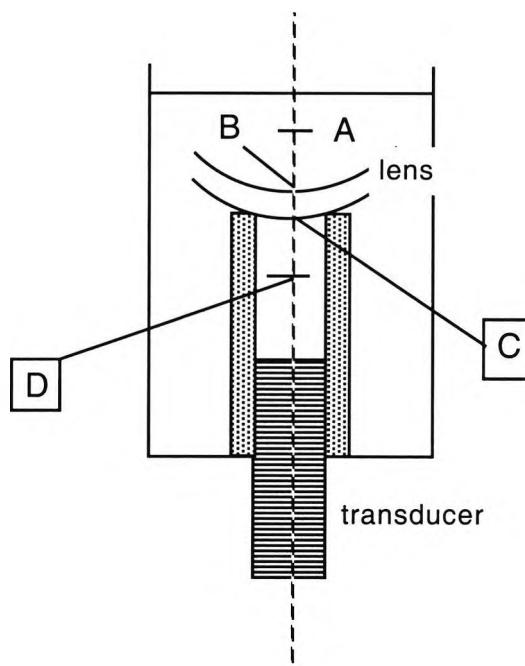
Figure 5.2.1 A method for determining the lens thickness in saline without knowing the velocity of sound through the lens material itself.

The method would be as follows:

The distance between A and D is determined without the contact lens in position. RTT(1) is the relevant time measurement . The lens is then placed on the support cylinder with its convex surface towards the transducer. The distance AB is then found from RTT(2) and similarly RTT(3) is used to determine the distance CD. If an interval counter is used it is only necessary to switch between the relevant signal envelopes to obtain the necessary

RTTs.

Knowing the velocity (v) of sound in saline at the specified temperature the thickness of the lens (BC) is given by :

$$BC = 0.5[\, RTT(1) - RTT(2) - RTT(3) \,] \, v$$

The main advantages of this method are :

1. That it is easy to obtain the velocity of sound in saline at a variety of temperatures (Chapter 3) so that centre thickness determination can be made at any reasonable temperature under controlled conditions.

2. It is not necessary to know the velocity of sound in the material in question.

3. The measurement is made in saline rather than air.

4. The method can be easily validated using rigid contact lenses of known thickness.

The disadvantage is that if the two surfaces were not resolved by the sytem used then the value of RTT(3) could not be obtained and the thickness measurement would be impossible.

Experiment 5

Aim: To assess the feasibility of the indirect method of measuring centre thickness using a high resolution transducer.

Apparatus: Humphrey Instruments Ultrasound Microscope (USM)

Wet cell for holding contact lenses (see below), test lenses, saline,

Kennedy micrometer (Jaser Electronics, 1 Castle Mews, Rugby)

The USM has a transducer frequency of 50Mz and is used primarily to obtain B-scan images. The instrument is used clinically to image structures in the anterior segment of the eye. The real time image can be frozen by means of a footswitch. Measurements of objects and tissues eg tumours can then be carried out using electronic cursors on this frozen image.

In the design of the wet cell to hold the lens it was necessary to construct a contact lens 'shield' because the USM transducer head was always moving and the turbulence created either dislodged the contact lens or distorted the surface.

The B-Scan image represented a real space some 5mm x 5mm. It was therefore necessary to design the wet cell so that the shield, lens and lens support top were all within this area.

The USM was calibrated for a velocity of 1580m/s at a temperature of 35°C. This a compromise value for the various eye tissues at normal body temperature. When the cursor on the USM was used to measure any distances it displayed the value based on these parameters. All distances to be measured were in normal saline where the velocity of sound is approximately 1490 m/s and the temperatures used were below 35°C. Hence a correction factor was needed to convert the displayed values to real values .

The wet cell was constructed from brass, aluminium and PMMA. The contact lens was supported on a hollow brass cylinder. The outside diameter was 11.00mm and the inside diameter was 10.00mm. A moveable PMMA cylinder of the same diameter (10mm) was used inside this support. When the sag of the lens' back surface was being measured the top of this PMMA cylinder was level with the top of the brass cylinder (see Figure 5.2.2).

Figure 5.2.2 The outer wall of the wet cell is shown on the left. This would normally be fitted to the baseplate of the cell on the right. In the centre of the base plate the brass lens support is seen. Within the brass hollow cylinder is a movable PMMA core. The top of the core is positioned level with the top of the lens support when sag measurements are taken.

The top of this hollow brass cylinder was notched in two places to obviate any lens distortion when the contact lens was being positioned.

A thick PMMA disc was painted black and placed over the brass cylinder (Figure 5.2.3) so that if the contact lens fell from the lens support it could be easily retrieved. The top of this disc was approximately 3mm from the top of the brass cylinder. Three equally spaced vertical holes (6mm diameter) were made in this disc besides the central hole.
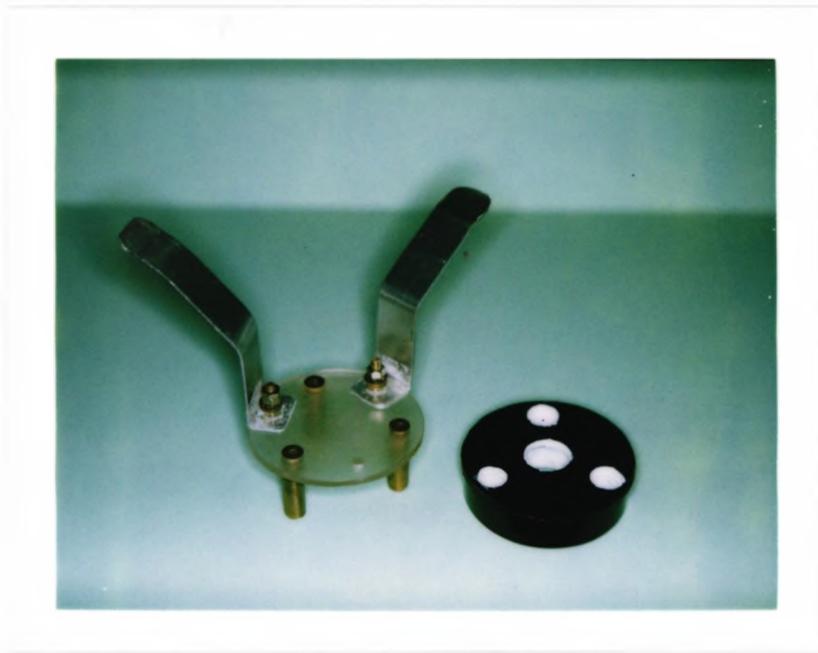
Figure 5.2.3   On the left is the 'shield' which separated the transducer head from the contact lens. The shield could be removed from and replaced in the wet cell by means of the aluminium handles. On the right is the black PMMA disc which was placed over the lens support.   There are three holes in this disc which allow the legs attached to the shield to pass through.

The shield took the form of a horizontal PMMA sheet nominally 2mm thick.   This was separated from the top of the lens support by approximately 3mm . The shield was attached to three brass legs 4mm in diameter (Figure 5.2.3) which passed through the 6mm holes in the black disc to the bottom of the wet cell.   Two aluminium handles were attached to the shield so that it could lowered into position and removed when necessary. The shield also was used as a reference plane when the thickness of a contact lens was measured. Figure 5.2.4 shows the shield in relation to the top of the lens support.

Figure 5.2.4   The outer wall of the wet cell is seen on the left.   The other components are seen on the right. The lens shield is in situ and is just above the brass lens support.   The three supporting legs of the shield pass through the black disc and rest on the baseplate
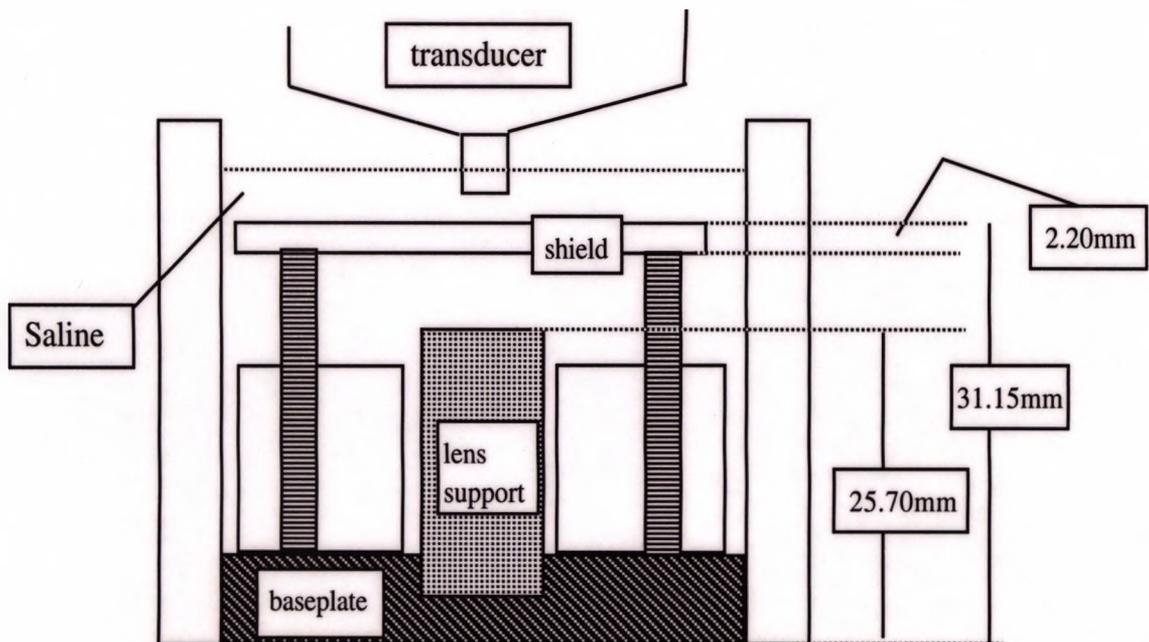
Figure 5.2.5   The measurements taken with the micrometer in order to deduce the distance from the top of the lens support to the lower surface of the shield .

The measurements of critical parts of the wet cell were checked using the Kennedy micrometer and are shown in Figure 5.2.5

Test lenses

Three PMMA lenses with the following specifications were measured.

	BOZR (mm)	FOZR (mm)	TD (mm)	BVP (D)	t_c (mm)
lens					
1.	8.40	8.66	14	-3.00	0.10
2.	8.70	9.14	14	-2.00	0.15
3.	9.00	9.67	14	-1.00	0.20

Five HEMA lenses (38% water content) with the following specifications were measured.

	BOZR (mm)	TD (mm)	BVP (D)	t_c (mm)
LENS				
1.	8.30	14	-3.00	0.07
2.	8.50	14	-2.50	0.09
3.	8.70	14	-2.00	0.11
4.	8.90	14	-1.50	0.13
5.	9.10	14	-1.00	0.15

The PMMA lenses were checked on a Topcon radiuscope and an Optimec instrument to ascertain the radius. The HEMA lenses were only checked for radius values on the Optimec.

The rigid lenses were checked on a Nissel dial gauge micrometer for thickness and the soft

lenses were checked on a Rehder soft lens thickness gauge. The principles of this instrument are given in ISO 9339-2.

All lenses were checked for power on a Nikon projection focimeter.

Each parameter measurement was taken as the mean of four independent values.

Conversion factor

Using the Kennedy micrometer, it was established that the distance from the lower surface of the lens shield to the top of the lens support cylinder was 3.25mm. Using 20 independent measurements of this distance, the USM gave a mean value of "2.343mm". This was the 'perceived' value for the distance using the instrument's own internal values for velocity and temperature. Thus, the conversion factor to obtain real, normal saline distances at room temperature from the USM values was 3.25/2.343 = 1.387

Method

The wet cell was assembled without the shield and filled with saline (Steri-wash 0.9% W/V; Steripak Ltd, Runcorn). A lens was placed convex side up on the brass lens support and centred. The shield was carefully lowered into position. The USM instrument was switched on and the probe was brought into close proximity to the upper surface of the shield (Figure 5.2.5). By observing the real time image on the instrument's monitor it was possible to centre the probe above the centre of the contact lens. This was done by observing the shape of the images and the intensity of the lens image in particular. When an optimum image was obtained the image was frozen by means of a footswitch. From the frozen image on the screen an electronic cursor was utilised to make three measurements viz

1. Lower surface of shield to upper surface of lens ('top')

2. lower surface of lens to lens support ('sag')

3. Lens support to lower surface of shield ('total')
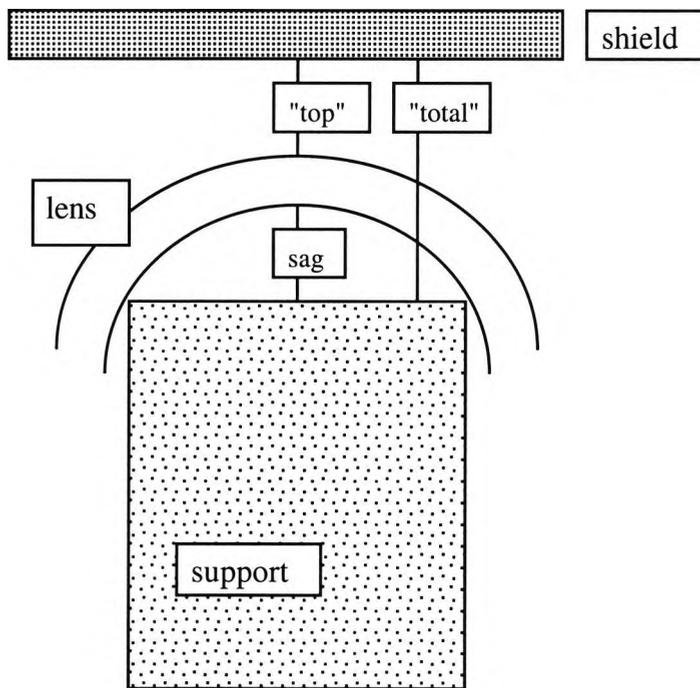
Figure 5.2.6 The three values calculated from the frozen USM image are depicted ie the sag, "top" and "total" values. The thickness of the lens is ('total' - sag - 'top')

The lens and probe were repositioned six times to obtain measurements. The mean and SD were calculated. Real values were obtained by multiplying the mean USM value by the conversion factor.

The centre thickness of the lens was calculated from the three measurement means obtained. The sag of the lens and the distance of the convex surface to the shield were both subtracted from the distance of the lens support to the shield.

Typical frozen images from the USM monitor are shown in Figures 5.2.7 and 5.2.8

The reflections appear to have a finite thickness because the circuitry relates signal strength to brightness. Each echo is composed of several sound cycles and there is an electronic envelope formed around each echo. The peak of this envelope gives the brightest part of the image on the screen. The cursor is traditionally placed at the beginning of the envelope ie the part of the envelope closest to the transducer. In this instrument this is the uppermost part of the reflection image. Where surfaces close together are not fully resolved on the screen it may be necessary to use a peak-to-peak measurement (brightest area -to -brightest area)
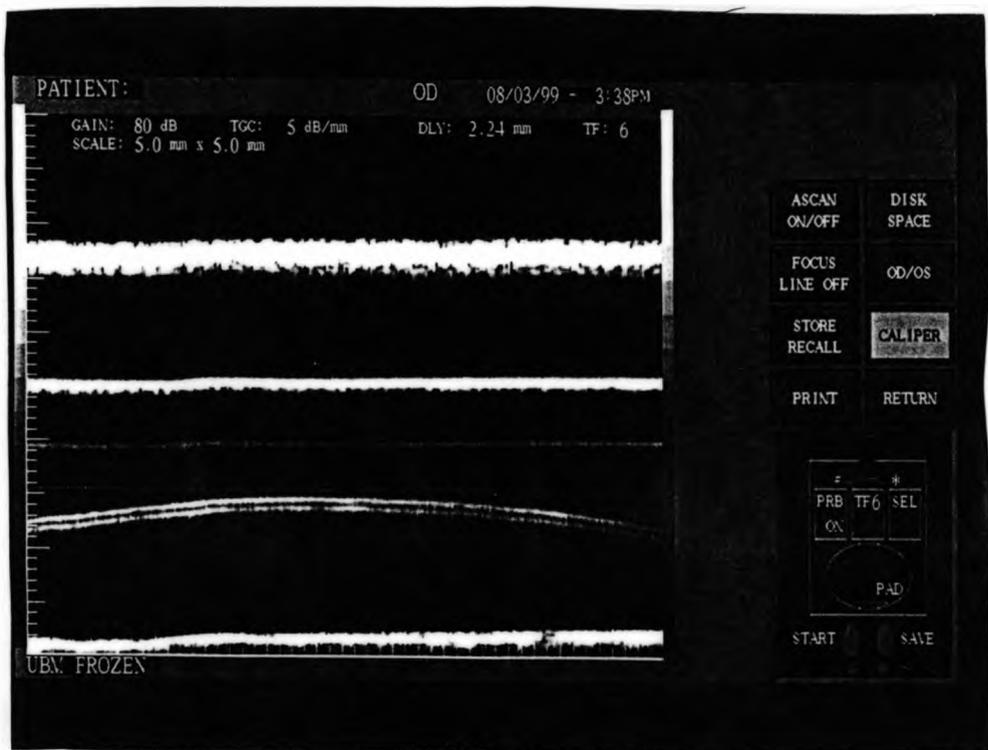
Figure 5.2.7   An image produced from the USM monitor. The thick bright band at the top is the upper surface of the PMMA shield. The next bright band is the lower surface of the shield. Below that band is a dull line (artefact), below that the lens itself can be seen and each surface is visualised. Below the lens, the reflection from the lens support is seen.
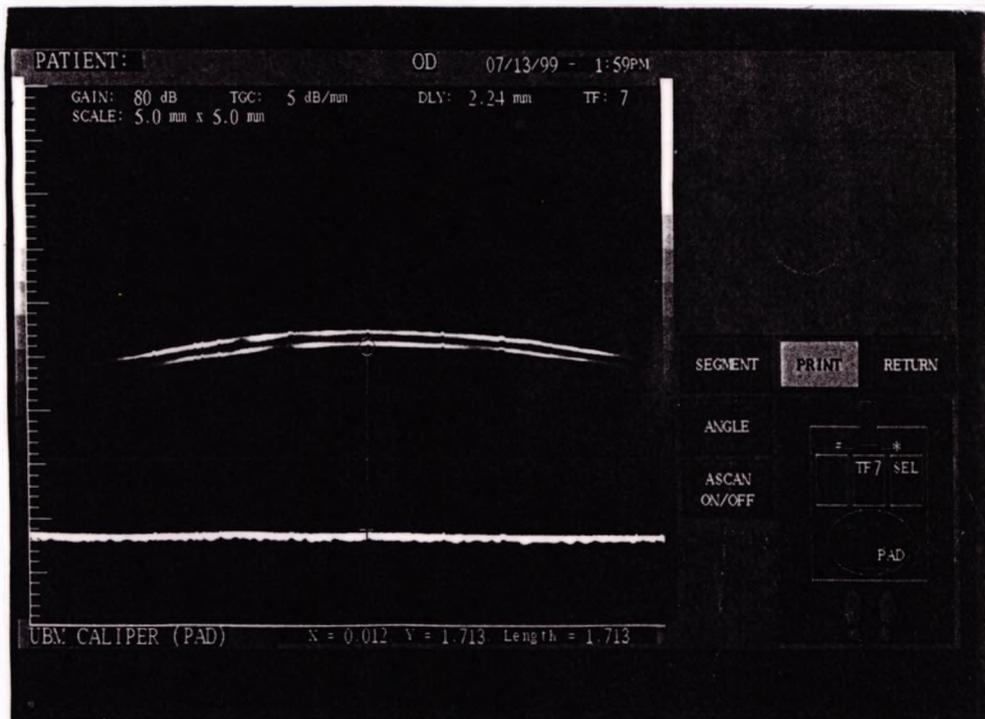
Figure 5.2.8 In this image the lens shield is not in position. Reflections are only shown from the contact lens and the lens support.   The cursor is shown measuring the distance equivalent to the lens back surface sag.   The value 1.713 shown at the bottom of the screen has to multiplied by a conversion factor to give the real distance.

RESULTS

Test lenses

PMMA   --------------------(mean values)-----------------------------

	BOZR(mm)		tc(mm)		BVP(D)	
	spec.	Meas'd	spec.	Meas'd	spec.	meas'd
		(Radiuscope)		(Nissel gauge)		(Focimeter)
1.	8.4	**8.47**	0.10	**0.10**	-3.00	**-3.03**
2.	8.7	**8.75**	0.15	**0.14**	-2.00	**-2.13**
3.	9.0	**9.06**	0.20	**0.21**	-1.00	**-1.06**

USM values

Temperature varied between 26.8°C and 27.5°C. There was no method of stabilising the temperature of the saline within the wet cell. Fortunately, such a small variation does not have a significant effect on the values obtained only that a desired target temperature cannot be obtained. In previous experiments, target temperatures were in the 18-22°C region.

PMMA 8.4 mm BOZR	mean	SD
total distance (shield to lens support)	2.346	0.035
sag (lens support to Cc surface of lens)	1.412	0.061
Shield-> Cx surface of lens	0.872	0.066

PMMA 8.7mm BOZR		
total distance (shield to lens support	2.365	0.031
sag (lens support to Cc surface of lens)	1.280	0.071
Shield-> Cx surface of lens	0.990	0.081

PMMA 9.0mm BOZR		
total distance (shield to lens support	2.376	0.024
sag (lens support to Cc surface of lens)	1.181	0.032
Shield-> Cx surface of lens	1.040	0.037

Real distances (USM values x conversion factor)

PMMA 8.4mm BOZR lens

a.	Lens support to BS of lens	1.959mm
b.	FS of lens to lower surface of shield	1.210mm
c.	Lower surface of shield to lens support	3.254mm
	centre thickness (c-b-a)	**0.086mm**

(0.10mm with conventional gauge)

PMMA 8.7mm BOZR lens

a.	Lens support to BS of lens	1.775mm
b.	FS of lens to lower surface of shield	1.373mm
c.	Lower surface of shield to lens support	3.280mm
	centre thickness	**0.132mm**

(0.14mm with conventional gauge)

PMMA 9.0mm BOZR lens

a.	Lens support to BS of lens	1.638mm
b.	FS of lens to lower surface of shield	1.443mm
c.	Lower surface of shield to lens support	3.296mm
	centre thickness	**0.215mm**

(0.21mm with conventional gauge)

HEMA (38% water content) lenses   (mean values)

	Rs(mm)	BOZR(mm) meas'd (Optimec)	tc(mm) spec.	tc(mm) meas'd (Rehder gauge)	BVP(D) meas'd (Focimeter)
1.	8.3	**8.44**	0.07	**0.067**	**-3.15**
2.	8.5	**8.50**	0.09	**0.095**	**-2.78**
3.	8.7	**8.83**	0.11	**0.117**	**-2.31**
4.	8.9	**8.85**	0.13	**0.121**	**-1.56**
5.	9.1	**9.07**	0.15	**0.120**	**-1.25**

HEMA 8.44 BOZR (Rs 8.30mm)

	USM	Real(mm)
Sag	1.348	1.874
Top	0.932	1.295
Total	2.311	3.212

Centre thickness (ultrasound) 0.04mm   (tc Rehder gauge 0.07mm)

HEMA 8.5 BOZR (Rs 8.50mm)

	USM	Real(mm)
Sag	1.200	1.668
Top	0.972	1.351
Total	2.292	3.185

Centre thickness (ultrasound) 0.17mm   (tc Rehder gauge 0.09mm)

HEMA 8.8 BOZR (Rs 8.70mm)

	USM	Real(mm)
Sag	1.267	1.761
Top	0.914	1.270
Total	2.300	3.197

Centre thickness (ultrasound) 0.16mm   (tc Rehder gauge 0.12mm)

HEMA 8.9 BOZR (Rs 8.9mm)

	USM	Real(mm)
Sag	1.203	1.673
Top	0.053	1.463
Total	2.369	3.292

Centre thickness (ultrasound) 0.16mm   (tc Rehder gauge 0.12mm)

HEMA 9.1 BOZR (Rs 9.10mm)

	USM	Real(mm)
Sag	1.111	1.544
Top	0.110	1.542
Total	2.269	3.153

Centre thickness (ultrasound) 0.07mm   (tc Rehder gauge 0.12mm)

Discussion

The principle of obtaining the thickness of a lens indirectly using ultrasound proved to be correct and practical. Unfortunately, the limitations of the USM apparatus meant that the results obtained were not as accurate as one would need for modern soft lenses. With the PMMA test lenses the thicknesses were within 0.01mm of the values obtained with a conventional thickness gauge. However, with the soft lenses the ultrasound values were only within 0.05mm of the values obtained with the Rehder gauge. Given that many contemporary soft lenses are now <0.1mm in the centre, this level of accuracy is not acceptable. Primarily, the main limitation was the manual holding of the probe in the saline and making a judgement as to when it was correctly centred over the apex of the lens. It was difficult to ensure that the axis of the transducer body remained parallel to the axis of the lens. Thus the two factors of poor centration control and variable obliquity of the axes contributed to the variance in readings and the relatively poor correlation with the Rehder values for thickness. The method used did not employ a temperature control system and if this could be incorporated it would make the whole system more reproducible and repeatable.

If a 50Mz A-scan transducer could be mounted securely as in Figure 5.2.1 then it is envisaged that this indirect method could produce significantly better results than a manually held B-scan transducer. The USM values showed larger SDs for the HEMA lenses than for the PMMA lenses. The signal from the soft lenses would be lower than that from the PMMA and when the shield was lowered into position the soft lens did not always remain as well centred as the rigid lenses. There had to be more movement of the probe to obtain a good signal and image. As the probe was positioned away from the lens apex the 'sag' value shown would become smaller; as a result it was decided to eliminate the the two lowest sag values and their corresponding 'top' values when calculating means above. This brought the SDs down to values between 0.02 and 0.07 for the USM values .

The differences between the different methods are due to two main sources of error. Firstly, the Rehder gauge is a low force gauge and the sensor does slightly indent the lens surface and hence there is a slight tendency for it to underestimate thickness when compared to the

manufacturer's values which are computed from xerogel values and expansion factors. Secondly, it was difficult to control a hand held oscillating probe in a small wet cell to obtain a reasonable image from which measurements could be obtained.

It was quite straightforward to use a conversion equation for a given material at a given temperature in order to determine the centre thickness. The equation enabled a RTT in the centre of the lens to be converted directly to a thickness in mm. The accuracy depended on the initial thickness measurement of the soft lenses and this is open to various random errors as described. The SD of the RTT variance associated with this method was very low (70% had a SD 0.005μs or less when four independent readings were obtained). Although there was statistical difference when the beam was first incident on the back suface and front surface the practical effect was very small (differences in the region of 0.01mm).

Other methods of using ultrasound to measure thickness

It would also be possible to measure the centre thickness directly if the the velocity of sound in the material was known. To achieve this it would be necessary to have xerogel sheets of given thicknesses and knowing the expansion factors of these gels at a given temperature the thickness in saline would be known. With the thickness being known the RTT could be obtained and thence the velocity determined. Thereafter, any lens made from the same material and measured at the same temperature could have its thickness determined.

5.3 Determination of lens power

The thick lens formula (Bennett, 1963) to obtain the BVP of a lens in air can be used for contact lens power determination.

$$BVP = [F_1 + F_2 - (d/n).F_1.F_2] \div [1 - (d/n).F_1] \qquad \text{(equation 1)}$$

where F_1 is the front surface power, F_2 is the back surface power, d is the centre thickness and n is the refractive index.

If the refractive index of the contact lens material is known then it is possible to calculate the power of the lens.

$$F_1 = 1000 (n - 1) / FOZR \text{ where FOZR is in mm} \qquad \text{(equation 2)}$$

$$F_2 = 1000 (1-n) / BOZR \text{ where BOZR is in mm} \qquad \text{(equation 3)}$$

Sections 4.1.1, 4.1.2 and 5.2 have shown that it is possible to measure the BOZR, FOZR and tc with the ultrasonic apparatus described. However, the results with the USM B-scan apparatus showed that the measurement of centre thickness and radii was not accurate enough to make the power measurement feasible (Table 5.3.1)

	--------------------BOZR values (mm) --------------------		
	Rs	Rm(Optimec)	Rm (USM)
HEMA	8.3	8.44	8.71
HEMA	8.5	8.50	9.25
HEMA	8.7	8.83	8.85
HEMA	8.9	8.85	8.92
HEMA	9.1	9.07	9.53

Table 5.3.1   In two cases the USM values are in close agreement with the Optimec values for BOZR but in the other three cases there is a very significant discrepancy from the Optimec values thus making the power calculation inaccurate.

The wet cell developed for use with USM had the potential to measure both BOZR and FOZR (Figures 5.3.2 and 5.3.3) as well as centre thickness. The lack of temperature

control together with the problems of aligning the probe coaxially with the contact lens could not be overcome satisfactorily. A system incorporating a 50Mz A-scan transducer and a temperature control system would be required. This is a fixed transducer and it is relatively simple to arrange alignment of this type of probe with the lens support (see Figure 4.5). However, it was decided to attempt the power measurement despite the shortcomings of the apparatus.

Aim

To measure BOZR, FOZR and tc with the USM device using 5 HEMA lenses and then to compute the lens power assuming the refractive index of HEMA to be 1.43

Apparatus

USM device with custom made wet cell as described in 5.2 (experiment 5)

Glass cover slip (as used in slide preparations for microscopy)

Five HEMA reference lenses with single cut surfaces (see experiment 5 in section 5.2)

Method

- The lens support on the wet cell was adjusted so that the top of the central moveable core was approximately 3mm below the brass rim.
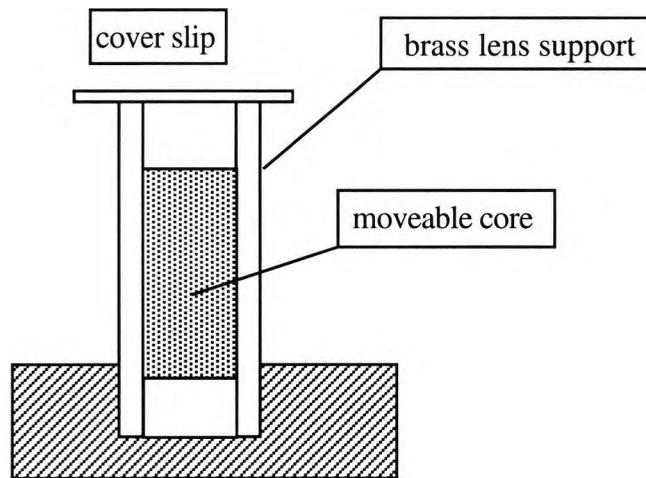
Fig 5.3.1   The brass lens support showing the moveable central core and the cover slip in situ.
To measure the sag of the front surface the cover slip is removed and the lens is placed on the rim with its convex side downwards.   The outer wall of the cell and the saline are omitted for clarity.

NB   All USM values were multiplied by 1.387 . This is the factor previously

referred to where values indicated on the USM monitor are converted to

distance values (mm) in normal saline.

•   A thin flat microscope cover slip was positioned on the brass rim so that the distance

(d1) from the rim to the top of the moveable core could be determined   (Fig 5.3.1) with

the USM.

•   The cover slip was removed.

•   Each lens was placed convex side down on the lens support and centred. This was not

a difficult procedure; in fact it was easier than centring the lens concave side down on

a solid support. A plastic applicator was used to centre the lens once it was on the lens

support. The edge of the lens was moved until it appeared well centred to the eye.

The probe was adjusted in all planes until an 'acceptable' image was obtained. It was

deemed to be acceptable when a good signal strength was obtained and the orientation

of the image was correct. This was quite time consuming especially as the probe was mounted on a cantilever system which made small adjustments difficult at times. The USM probe was used to measure the distance(d2) from the convex surface to the top of the central core. Four independent USM readings relating to d2 were obtained and a mean calculated.

- The sag of the front surface was obtained from d1 - d2.

The formula $FOZR = s/2 + (y^2)/2s$ was used to calculate the surface radius where s is the sag and y is the half chord . The inner diameter of the lens support was taken as 5mm. This was confirmed by measuring the inner moveable core with the Kennedy micrometer. However, there was some slight rounding of the lip and as a result radii of different values would rest on a very slightly different position of the lip. It was not possible to make any allowance for this slight smoothing of the lip.

- The BOZR was similarly calculated from the USM values and subsequent real sag values obtained. The method was described in experiment 5 of section 5.2

- The thicknesses of the 5 HEMA lenses obtained in experiment 5 of section 5.2 were used.

- A refractive index(n) of 1.43 was used for HEMA as this is the value most commonly used within the contact lens industry for this material. The power was calculated from all variables (equation 1 above).
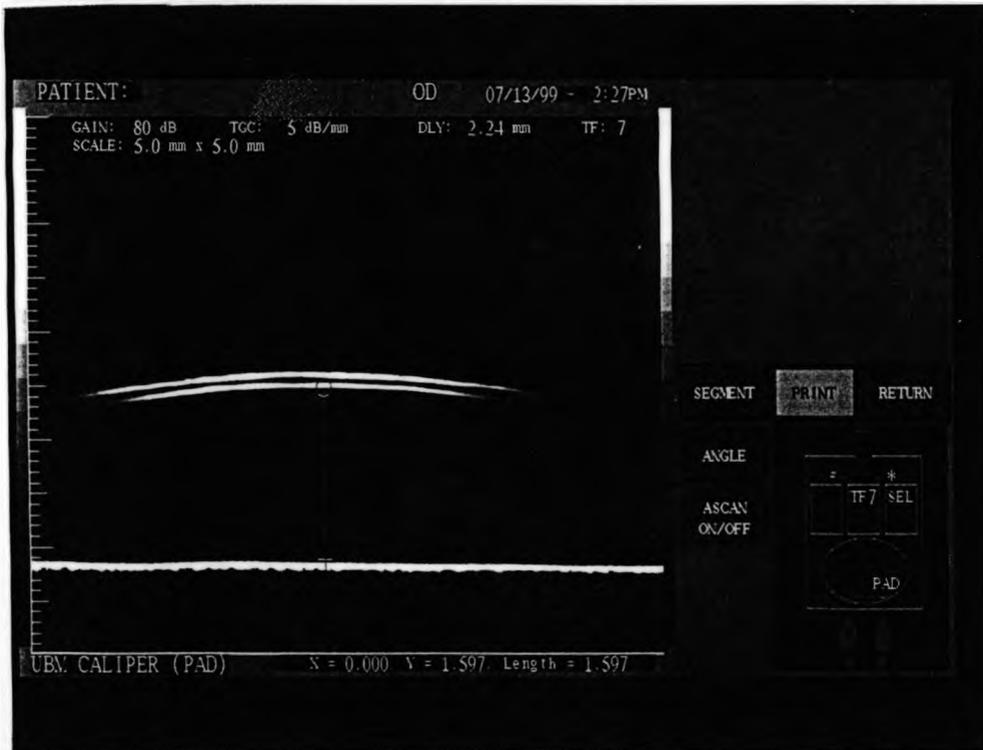
Figure 5.3.2   A USM image used to assess the sagitta of a contact lens back (concave) surface. The cursor used to obtain the raw sag data is shown. The sag value (mm) would be 1.597 multiplied by the conversion factor 1.387 for the example shown in this figure.
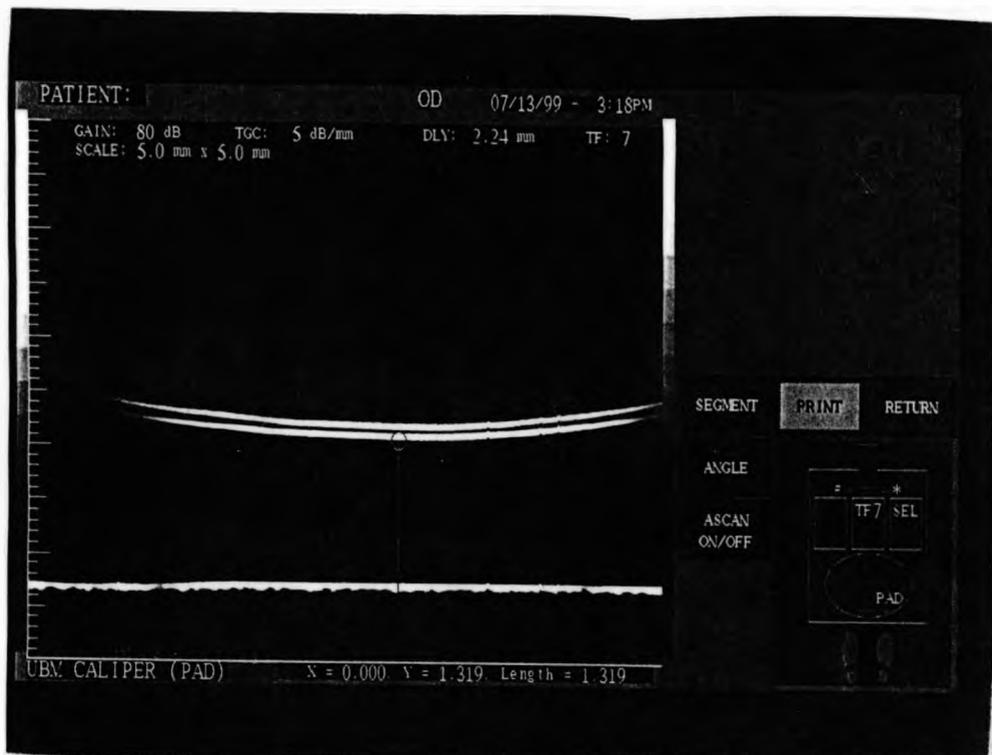
Figure 5.3.3   Assessment of the contact lens front surface.   A USM image showing the ultrasound beam incident on the rear surface of a contact lens. The reference surface is below the level of the lens support. The lens support is a hollow cylinder with a moveable core. The top of this core provides the reference surface for the measurement of front surface radii.

Results

The results are shown in Tables 5.3.2, 5.3.3 , 5.3.4 and 5.3.5

	-------USM values---------				
Rs	d2	d1	d1-d2	sag(mm)	FOZR(mm)
8.3	2.344	1.22	1.124	1.558	8.80
8.5	2.344	1.27	1.074	1.489	9.14
8.7	2.344	1.31	1.034	1.434	9.43
8.9	2.344	1.27	1.074	1.489	9.14
9.1	2.344	1.31	1.034	1.434	9.43

Table 5.3.2 Sag values derived from USM values and the relevant FOZR values obtained from the sag values

Values calculated from Ultrasound measurements

Rs (mm)	BOZR (mm)	FOZR (mm)	tc (mm)	BVP (D)
8.3	8.71	8.80	0.04	-0.38
8.5	9.25	9.14	0.17	+0.73
8.70	8.85	9.43	0.16	-2.83
8.90	8.92	9.14	0.16	-0.95
9.10	9.53	9.43	0.07	+0.64

Table 5.3.3 Computation of BVP from values obtained on the USM apparatus compared to the specified power values of the reference lenses

	BVP (specified)	Measured BVP (focimeter)	Calculated BVP (from USM results)
8.3	-3.00 D	-3.15 D	-0.38 D
8.5	-2.50 D	-2.78 D	+0.73 D
8.7	-2.00 D	-2.31 D	-2.883 D
8.9	-1.50D	-1.25 D	-0.95 D
9.1	-1.00D	-1.75 D	+0.64 D

Table 5.3.4 The BVP values as specified, measured with the focimeter and calculated from the sag values obtained with the USM.

Rs (mm)	USM FOZR (mm)	Predicted FOZR (mm)
8.3	8.80	8.86
8.5	9.14	9.02
8.7	9.43	9.16
8.9	9.14	9.23
9.1	9.43	9.38

Table 5.3.5 Predicted FOZR values using the nominal BOZR values (Rs) and the measured power of the lenses compared to the FOZR values found using the USM. The predicted values would be used by the manufacturer to arrive at the xerogel values when making the lens in the dry state. Even though the nominal values may not be accurate after hydration any change in the front surface would be similarly changed.

Discussion

It can be seen from Table 5.3.4 that the FOZR values found using the USM were, on average, in error by 0.11mm. Whilst this is not significant in terms of measuring radii for fitting purposes, it is significant when considering the power of a surface. The results shown in Table 5.3.2 indicate significant errors in the powers obtained with the

maximum being 3.23D!   The implication is that in its present form the apparatus is not accurate enough to give reliable results for BVP due to the accumulative errors in measuring BOZR, FOZR and tc with the USM equipment. Looking at the results in Table 5.3.3 indicates that in this case, most of the errors occurred in the BOZR measurement rather than the FOZR measurement as the latter tended to be in error by an average 0.11mm. This would be assigned to the errors of beam obliquity and beam centration referred to in section 5.2. It was difficult to obtain consistent centration of the lens when the concave surface was resting on the lens support. Any slight movement of the wet cell could decentre the lens. It was not always possible to position the shield above the lens without disturbing the lens. A beam positioned away from the apex of the lens would show an image with a smaller sag and an oblique beam would increase the apparent sag. However, it is envisaged that a device using a high frequency (50Mz) A-scan transducer as described in 5.2 could produce better BOZR, FOZR and tc values and subsequently more accurate power values. To become a useful instrument, radii would have to be measured to at least ± 0.05mm and this is a high expectation when all the variables such as temperature control, lens distortion, centration and instrument stability are considered. Table 5.3.6 gives and indication of how errors of radius measurement can be compounded to give high errors in power calculation.

	Spec.	A	B	C	D
BOZR (mm)	8.7	9.00	9.00	8.8	8.60
FOZR(mm)	9.3	9.30	9.00	9.4	9.40
BVP (D)	-3.03	-1.38	+0.21	-2.92	-4.05

Table 5.3.6 A lens with a specified BOZR of 8.7mm and a FOZR of 9.3 produces a lens of power -3.03D (assuming a thickness of 0.12mm and a refractive index of 1.43). If the BOZR measurement is in error of 0.3mm flatter, for example, then the power is given as -1.38D (column A). If both front and back radii are measured in error of 0.3mm in opposite directions (B) then the power is given as +0.21.   If the equipment enabled the radii to be measured accurately to ±0.1mm then if both radii errors were in the same direction the power is given as -2.92 (C) but if they were in opposite dierctions (D) an error of -1.05 D is produced from the target value of -3.00 D.

Currently, many contact lenses have lenticular front surfaces. If the size of the lenticular portion is less than inner diameter of the lens support then a further error is introduced. Recently new optical methods have been introduced to the contact lens industry where accurate measurements of lens power can be made in saline eg Rotlex (using a Moiré deflectometer) and Visionix system (using the Hartmann-Schack principle), consequently, the use of an ultrasound system to measure lens power in saline now has reduced application.

5.4   Determination of water content in hydrogel lenses

As stated previously, the amplitude of the reflected ultrasound depends on the difference in acoustic impedance between two materials at a single interface.   In a high water content lens eg 80% water content, the density of the material approaches that of water itself whereas with a low water content material the polymer itself is predominant eg 60% polymer and hence the density is greater.   The low water content lens therefore provides a geater amplitude reflected signal than the high water content lenses.   If a lens had no water content (as in a rigid contact lens) then the amplitude would be even higher than with a low water content lens.

Aim

To assess if the intensity of the reflected signal from materials of different water content provided any correlation with the water content of a hydrogel.

Materials

The Mk II apparatus was used for this study as the lens was placed on a solid support cylinder made of PMMA.   The reflection from this provided a constant reference.

16 Sauflon 85 lenses,

9 lenses of Sauflon 70

10 lenses of Sauflon 55

6 HEMA lenses

Method

The lens was positioned centrally on the lens support.   The attenuator control on the Ultrasonoscope was used to first attenuate the signal from the 'saline/convex surface of the lens' interface until it just dissapeared below the x axis. The dB reading was recorded (dB_1).   With the lens still in position, the attenuator was turned down even further so that the signal from the PMMA base just disappeared below the x axis and

the second reading obtained (dB_2). The value of dB_2 - dB_1 was taken as the measurement associated with the water content of the lens. Each lens was subjected to 4 independent measurements.

Results

Saline temperature 19.6°C - 20.2°C, pH 6.1, 0.9% NaCl

Material	dB2 - dB1	SD
S85	22	4
S70	19	8
S55	17	3
HEMA	15	7

Table 5.4   Results from four different hydrogel materials when assessing the water content using ultrasound reflection from the material/saline interface

Discussion

As expected the overall rationale proved to be correct. However, the variation of radius on the front surface of the lens obviously had some effect on the reflected signal amplitude and this gave rise to the substantial SD obtained . The range of front surface curvatures on lenses from say +35D to -35 D would be considerable and if this affected the outcome the values for water content would be unreliable. An alternative approach would be to use the back surface of the lens. However, the same problem arises as there is variation in the back surface topography in different BOZR configurations.

Although the concept is worthy of development it would probably need a more specialised transducer and the use of small apertures may be beneficial to control the incident and reflected beams. Alternatively, if the lens was made to conform to a more

constant shape the effect of curvature could be significantly reduced. Ideally, only one or two independent trials should be necessary to get a reasonable indication of a material's water content. In the future, lower water content materials with high Dk values may become more prevalent and merely knowing the water content may be of limited significance.

5.5   Evaluation of soft lens topography

Experiments (Port,1979b) on Sauflon 85 material (obtained from rods) showed that the hydrogel lenses although in a spherical state when in the xerogel form did not hydrate into a spherical form. Some degree of asphericity was present as the expansion factors in x,y, and z directions were not equal. It is hypothesised that the anisotropy was caused by

1. Polymerised material not being homogenous (likely to be caused by the conditions of the polymerisation process itself). There is an exothermic reaction followed by shrinkage and the constraint of the tube together with any convection effects tend to reduce homogeneity (Tighe, 1979)

2. Stress induced into the polymer by machining and polishing.

Objectives

To assess the scope of the anisotropy involved with Sauflon 85 and to assess if finished lenses showed the effects of anisometropic expansion. These effects may result in a change in topography of the lens surface away from spherical shape.

5.5.1 Experiments on hydrogel discs

Experiment 1

Materials

Polymerised S85 in polythene tubes.

Travelling microscope to measure dimensions.

Distilled water for the measurement of hydrated samples. Measurements made in liquid were not converted to real in air values as the factor is very small (1.005) and is constant for all hydrated measurements.

Methods

The polythene was removed from the polymer rod. It was then reduced to a nominal 11mm on a standard engineer's lathe. Seven discs of material were cut from the prepared rod using a parting tool. Discs were between 1 and 2mm thick. Lathing marks on the disc faces were removed using fine glasspaper.

The discs were drilled with holes of different diameters (4mm - 9mm).

After measurement in the xerogel state, the lenses were fully hydrated for 24-36 hrs and the hydrogel values obtained. After this stage a single radial cut was made with a sharp scalpel blade in each lens. Each lens was measured as follows :

Mean Outer Diameter (OD) dry ; Mean Internal Diameter (ID) dry

Mean OD (hydrated);   Mean ID (hydrated)

Mean OD (hydrated) with radial cut; Mean ID (hydrated) with radial cut

Each mean was obtained by averaging 5 different diameter values from one specimen

RESULTS

Outer diameter (same nominal value)

Mean dry value (MDV)	11.07 mm	(SD 0.122 mm)
Mean hydrated value (MHV)	20.11mm	(SD 0.203mm)
Mean hydrated value with radial cut (MHVR)	18.89 mm	(SD 0.403mm)
Expansion factor MHV / MDV	1.82	
MHVR / MDV	1.70	

Inner diameter(different values)

Mean dry value (MDV)	7.31mm
Mean hydrated value (MHV)	13.47mm
Mean hydrated value with radial cut (MHVR)	12.42mm
Expansion factor MHV / MDV	1.84
MHVR / MDV	1.70

Discussion

The experiment showed that for S85 material the 'normal' expansion factor was 1.83. However, when stresses were released by the radial cut, the EF reduced to 1.70. As there was some overlap of the two cut edges measurement was unlikely to have been extrememly accurate (relatively large SD noticed in the hydrated cut values). The diameter of the central aperture did not affect the results. Thus finished soft lenses made from this material are likely to produce aspheric surfaces to some degree due to the stresses within the material and by reason of the machining processes involved. Polymer used for contact lenses is more frequently made in button form at the present time and because the moulds often have flexible walls there is a lower degree of induced stress (Dewsbury, 1980). Heat is also dispersed more efficiently during the polymerisation process.

The concept of scanning a soft lens with an ultrasound probe to obtain a cross section of the lens was first mooted by Port (1976) and the experiments below investigate this possibility within the constraints of the apparatus at hand. In order to validate any results obtained in this manner it was decided to photograph cross sections of the same lens and attempt to describe the lens surface in a mathematical way which might then be compared to the results obtained with ultrasound.

5.5.2 Investigation using ultrasonic apparatus.

Experiment 2: Apparatus

The apparatus constructed from PMMA is shown in Figs. 5.5.1 and 5.5.2. This enabled a soft lens to be held in saline while a 20MHz transducer was positioned radially to the surface. Angles of up to 45° to the lens axis (and transducer zero position) could be set (Fig. 5.5.3)

There were two types interchangeable lens holders - one a hemispherical dome of 9mm radius (Fig.5.5.1) and a recessed flat holder (Fig. 5.5.2). The inset flat portion was approximately 0.5mm greater than the total diameter of the lens. A series of four such holders were made to accommodate different lens diameters to ensure that any

soft lens used was well centred with respect to the zero position of the transducer. An additional holder with a deep inset was made to accommodate a steel reference ball. There was no method of controlling the temperature of the saline within the apparatus.

Mk IV ultrasound apparatus. The interval counter was used to measure RTT values.

Steel ball as a reference surface (radius 7.92mm)

Mercury (laboratory grade) theremometer.

Soft contact lenses
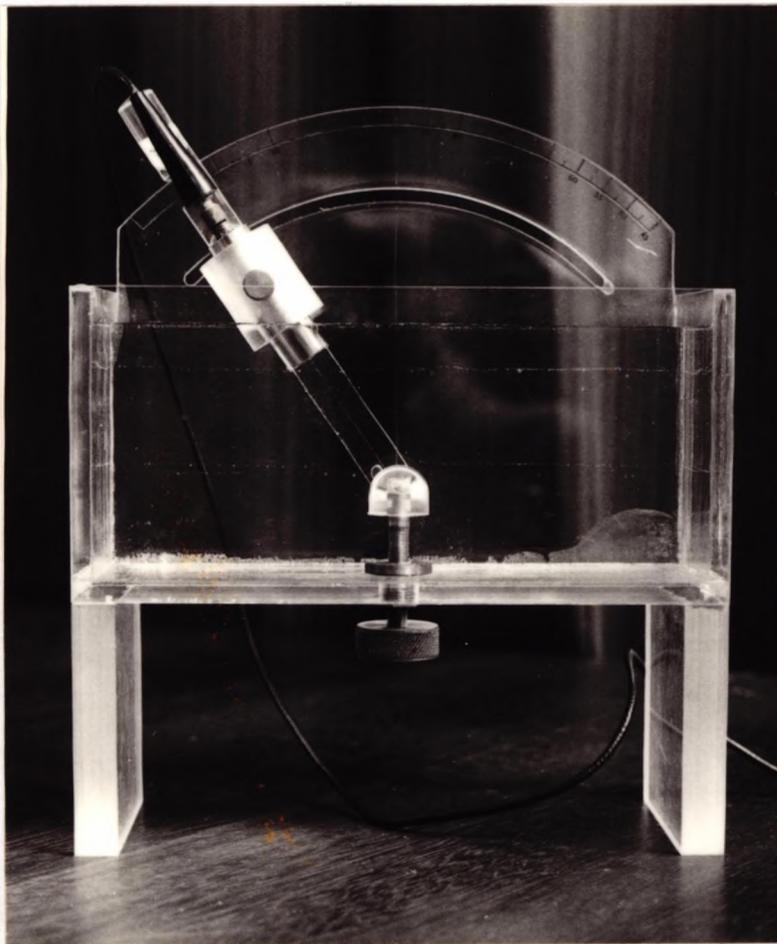
Figure 5.5.1   Front elevation of apparatus used to investigate the topography of lens surfaces. The PMMA hemisphere is shown in position and this is adjusted vertically by the brass knurled knob underneath.
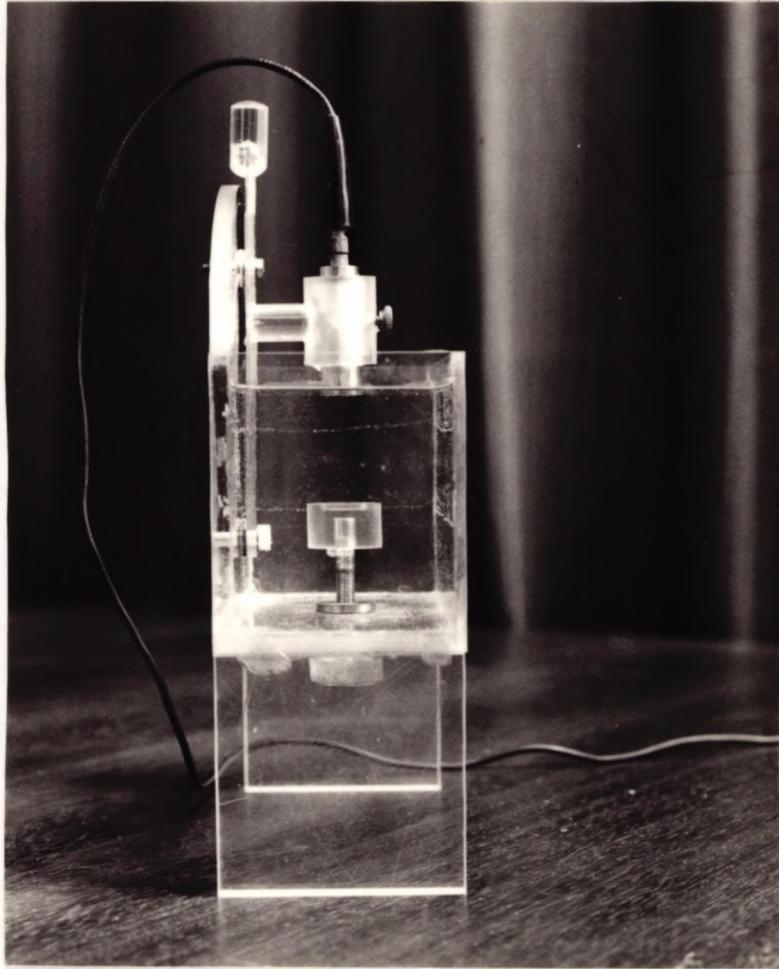
Figure 5.5.2   Side elevation of the apparatus used to investigate the topography of lens surfaces. Note the recessed lens holder in place. This can also be adjusted by the brass knurled knob underneath
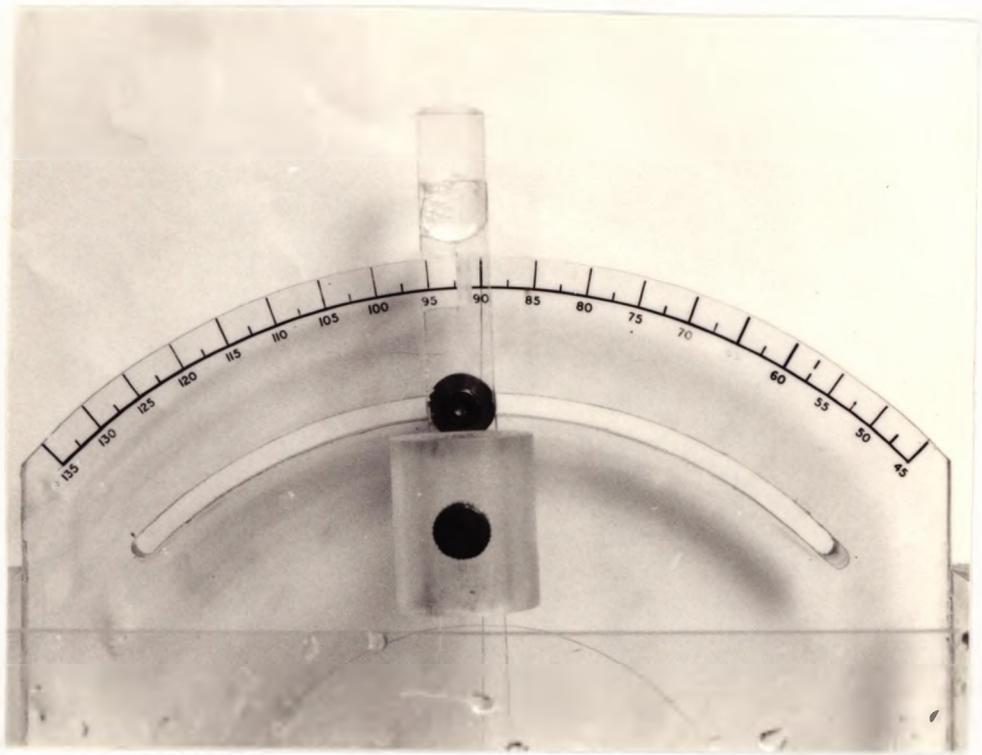
Figure 5.5.3a The protractor scale used to position the transducer at different angles from the vertical
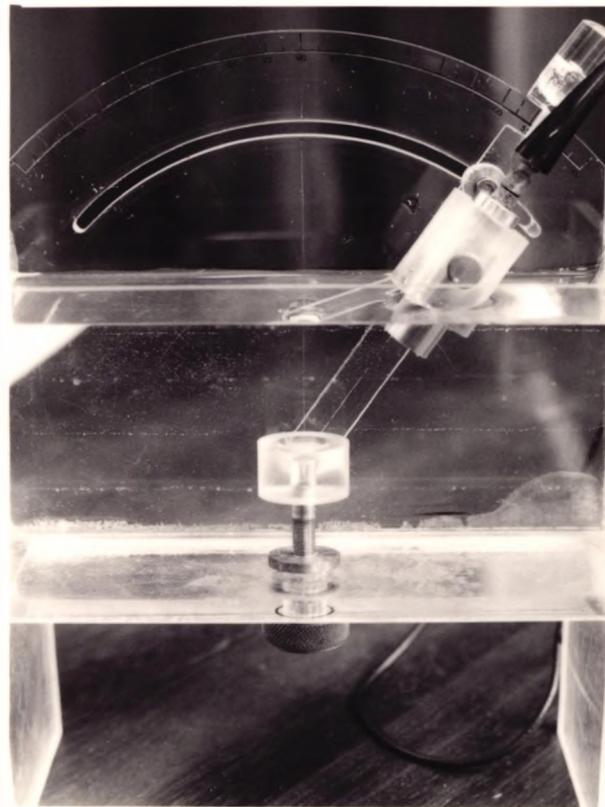
Figure 5.5.3b   The protractor scale with the transducer in situ. The face of the transducer is below the saline surface at all times.

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Principle (Fig. 5.5.4)

The centre of curvature of the hemisphere is also the centre of rotation of the transducer.

The hemisphere is removed and the surface to be evaluated is substituted. The apex of this surface is adjusted so that it is in the same position as the apex of the hemisphere was originally.

Moving the transducer into a different position at a different angle (θ) will give rise to a different RTT_θ value which can be used to calculate the distance Z_θ. Knowing the distance z_θ for different positions of the transducer enables the x and y coordinates of the test surface to be obtained.

$$z_\theta = 0.5 (RTT_1 - RTT_\theta) v$$

where θ is the transducer angle and v is the velocity of sound at the specified temperature.
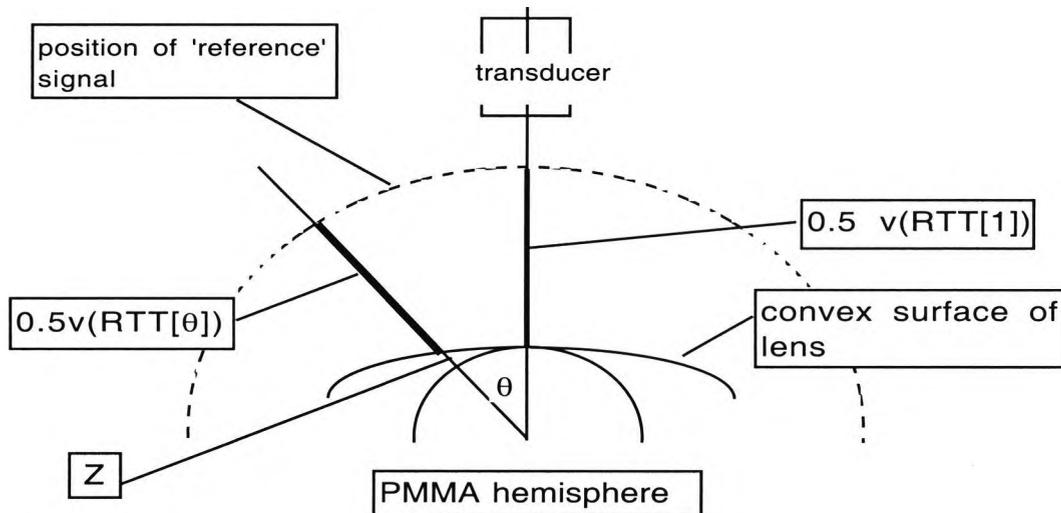
Figure 5.5.4 Principle of obtaining x and y coordinates from a test surface. Note that the hemisphere and test surface are not used at the same time and the apparatus shown would be in saline.

From the z_θ values obtained, the x_θ and y_θ coordinates were obtained from the

expressions:
$$x_\theta = (z_\theta + R)\ Sin\ \theta$$
$$y_\theta = (z_\theta + R)\ Cos\ \theta$$

where R is the radius of curvature of the PMMA dome.

Given the x and y coordinates of the surface several possibilities arise to analyse the shape of the surface.

1.   For each chord (2x) the sagitta of the surface (R-y) could be used in the conventional sag formula to determine the radius of curvature. If the surface was spherical, all radii found in this way would be the same within the limits of experimental error. If the surface was aspheric, the radii would show a trend which was either steeper of flatter from vertex of the lens.

2.   The coordinates could be plotted graphically.

3.   The coordinates could be used in a computer program to find the equation of the surface

4.   Coordinates near the centre of the lens could be used to find a best fit circle and coordinates near the lens periphery could be used to determine if the best fit circle was different.

Method

The apparatus was filled with normal saline so that the transducer face was always submerged.

The hemispherical dome was adjusted vertically so that its centre of curvature was in the same horizontal plane as the transducer's centre of rotation (Fig. 5.5.4). This endpoint was achieved by moving the transducer either side of the zero position and observing the RTT on the interval counter. If the peripheral RTT was shorter than the central value then the hemisphere was too low. When the RTT was constant within experimental limits, for all positions of the transducer, the dome was in the correct position. RTT_1 was recorded

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when the transducer was in the zero position.

The dome was then removed and a test surface holder substituted. The test surface was adjusted vertically until the RTT_1 was obtained indicating that the vertex of the test surface was in the same previous position as the vertex of the PMMA dome.

The transducer was moved in 5° intervals either side of the zero position and the RTT_θ values recorded at each position. From these RTT values the z value and xy coordinates were computed as shown above.

Experiments were designed as follows:

Experiment 2a

AIM. To obtain RTT values for the PMMA dome at different angles either side of the vertical and determine the variance of these values.

METHOD. In this experiment the transducer was positioned at 5° intervals from the zero (vertical) position to a maximum of 40° in each direction. Six independent RTT values were obtained for each transducer position.

RESULTS. The SDs obtained for each position ranged from $0.004\mu s$ to $0.02\mu s$. The largest deviations were seen at the furthest extent of the transducer travel.

The 8 mean values from 95° to 130° gave a mean of $1.992\mu s$ (SD $0.012\mu s$)

The 8 mean values from the 85° to 50° gave a mean of $2.037\mu s$ (SD $0.017\mu s$)

Discussion

It can be seen that there was a degree of asymmetry present in these results and the obvious conclusion was that the PMMA dome had not been positioned accurately enough on the adjustment spindle. The hole for the spindle had been made on an engineer's lathe and the dome had been cut on a contact lens lathe. The assembly

must have given rise to some degree of tilt to produce this discrepancy. The dome was fixed to the spindle and once the height had been adjusted no other alteration was possible.

Experiment 2b(part 1)

AIM. To use a steel ball of known radius and determine the curvature from the ultrasound apparatus.

Method. A steel ball of radius 7.92mm was used as a test surface in the apparatus. The transducer was positioned at 5° intervals from 45° to 135°. Five independent RTT readings were obtained for each position. The x-y coordinates were calculated as described and are given below (Table 5.5.1):

Transducer angle (degrees)	x	y
135	-6.09	6.09
130	-5.60	6.67
125	-5.03	7.19
120	-4.42	7.65
115	-3.76	8.06
110	-3.05	8.39
105	-2.32	8.64
100	-1.56	8.84
95	-0.78	8.96
90		
85	+0.78	8.96
80	+1.56	8.84
75	+2.32	8.66
70	+3.05	8.39
65	+3.76	8.06
60	+4.42	7.65
55	?	?
50	?	?
45	?	?

Table 5.5.1   The transducer angle related to x and y coordinates of a steel ball's surface

$$y = -0.001x^4 - 0.000x^3 - 0.058x^2 + 0.001x + 8.984 \quad r = 1.000$$
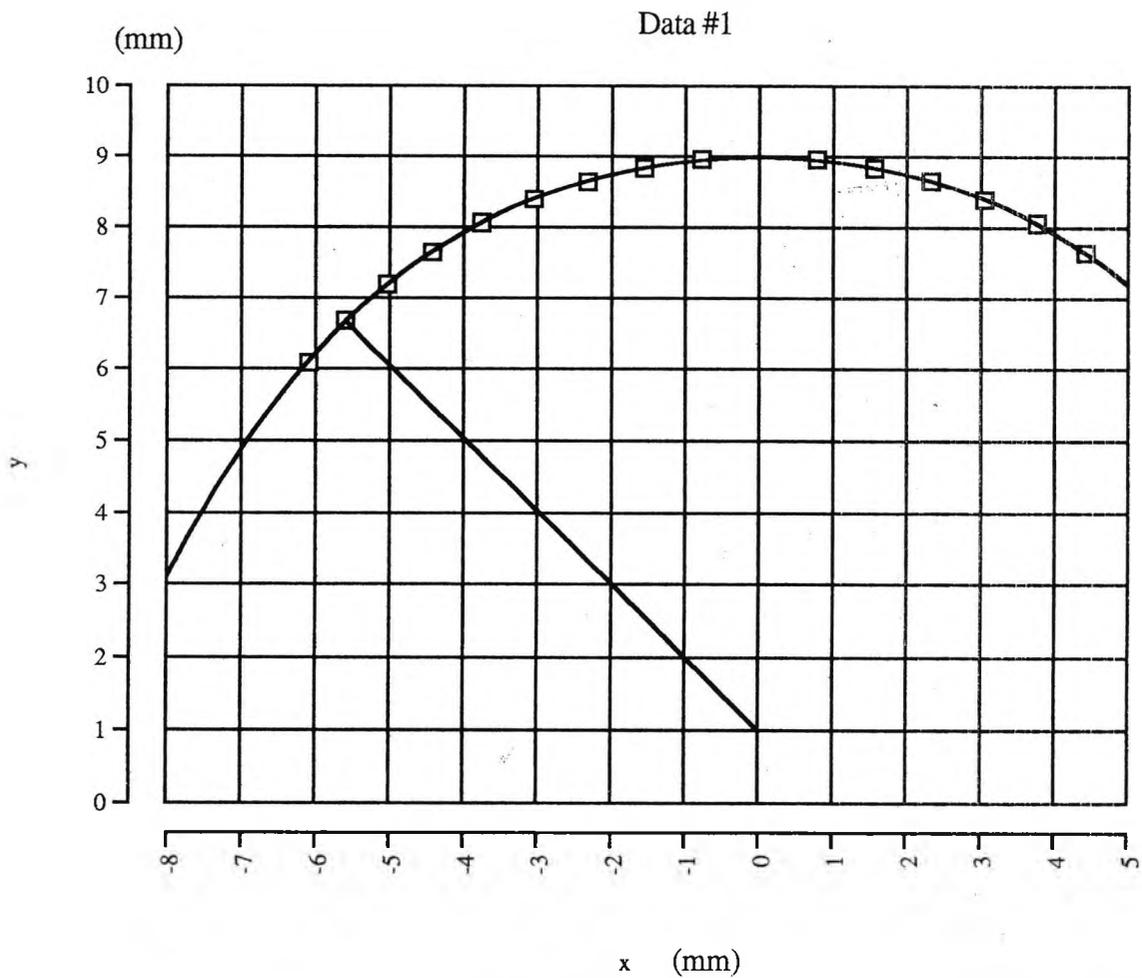
Figure 5.5.5   A plot of the x and y coordinates for the steel ball. Note that less values are plotted on one side of the vertical as the transducer values were unreliable at the larger angles.

Discussion

As the results from experiment 2b(part 1) indicated that the best readings were obtained in the sector 90° to 135° it was conceivable that taking more readings in this sector would give better data.

Experiment 2b(part 2)

Aim. To obtain a more consistent set of results from the steel ball.

Method.   Experiment 2b(part 1) was repeated using transducer positions at 2.5° intervals

only in the 90° to 135° sector rather than 5°. Five independent RTT readings were obtained

for each point. A best fit front surface radius was calculated using a computer spreadsheet

(Clarisworks).

Results. The results are shown in Table 5.5.2

	Trans.	Transducer	Saline	Sound	origin-surface	Coordinates		Radius of		
RTT	angle	angle	Temp.	Velocity	Distance	x	y*	surface		(r-mean)^2
μs	degrees	radians	C	mm/s	mm			r(mm)	0.9	
2.01	95	1.6581	20	1.55567	8.99	-0.784	8.058	8.096		2.57119e-5
2.02	97.5	1.7017	20	1.55567	8.98	-1.173	8.008	8.093		6.56406e-5
2.015	100	1.7453	20	1.55567	8.99	-1.561	7.952	8.104		5.83184e-6
2.04	102.5	1.7890	20	1.55567	8.97	-1.941	7.856	8.093		7.28149e-5
2.045	105	1.8326	20	1.55567	8.96	-2.320	7.760	8.099		4.34246e-6
2.06	107.5	1.8762	20	1.55567	8.95	-2.692	7.639	8.100		2.53293e-6
2.065	110	1.9199	20	1.55567	8.95	-3.061	7.510	8.110		7.16087e-5
2.09	112.5	1.9635	20	1.55567	8.93	-3.417	7.350	8.106		2.23155e-5
2.105	115	2.0071	20	1.55567	8.92	-3.769	7.183	8.112		1.09676e-4
2.14	117.5	2.0508	20	1.55567	8.89	-4.105	6.987	8.103		5.54974e-6
2.165	120	2.0944	20	1.55567	8.87	-4.436	6.783	8.105		1.32177e-5
2.2	122.5	2.1380	20	1.55567	8.84	-4.752	6.559	8.100		1.62088e-6
2.21	125	2.1817	20	1.55567	8.84	-5.068	6.339	8.116		2.17557e-4
2.27	127.5	2.2253	20	1.55567	8.79	-5.351	6.074	8.095		4.32002e-5
2.285	130	2.2689	20	1.55567	8.78	-5.643	5.825	8.110		7.11467e-5
2.35	132.5	2.3126	20	1.55567	8.73	-5.896	5.535	8.087		1.96155e-4
2.38	135	2.3562	20	1.55567	8.70	-6.155	5.255	8.093		6.42772e-5
y* = y value less iterated value				Final	Iterated value =	0.900		8.101		3.15150e-2
								mean radius		variance

Table 5.5.2 Spreadsheet results from the steel ball . Derivation of column values were as follows:

Col.3 = Col. 2 / 57.296   (converting degres to radians)

Col.5 = (-0.0245 * (74 - Col.4) + 1557)/1000   (To otain velocity of sound at 20°C).

Col.6 = (+ (1 - Col.1/2) * Col. 5   (To obtain distance of surface point from origin)

x = Col.6 * Cosine (Col.3)   (x coordinate of surface point)

y = Col.6 * Sine (Col.3) - iterated value

"Iterated value" - a value increased from zero in 0.01mm steps until the spreadsheet produced

a minimal variance (as seen at end of last column)

Variance = Square root (Addition of Col. 11 values)

In this case the iterated final value was 0.90mm and this gave a mean radius value of 8.1mm and this

      agrees with the centre of that circle being 0.9m higher than the origin.

The origin is the centre of rotation of the transducer and the reference surface (radius 9mm)

The SDs of the RTT values were between $0.006\mu s$ and $0.012\mu s$. The best radius estimatewas 8.10mm which was 0.18mm flatter than the value obtained with a micrometer.

Experiment 3

Aims.   To investigate front surface curvatures of soft lenses in various materials for any signs of asphericity.

Materials

Topographical ultrasound apparatus as described above with contact lens supports.

8 hydrogel lenses with the following specification:

Lens	Material	BOZR	TD	BVP
A:	Hydron HEMA ,	7.5mm,	12.5mm.	-3.75D
B	Hydron HEMA,	7.5mm,	12.5mm,	-1.75D
C:	Hydron HEMA,	7.5mm,	12.5mm,	-3.50D
D:	Hydron HEMA,	8.1mm,	13.5mm,	-1.50D
E:	Hydron HEMA,	7.5mm,	12.5mm,	-4.00D
F:	Bionite,	8.7mm,	13.5mm,	-5.00D
G:	Sauflon 55,	8.1mm,	13.0mm,	-1.75D
H:	Sauflon 85,	8.7mm,	13.5mm,	-3.50D

Method

Each lens was positioned on the appropriate recessed lens holder as described above. The transducer was positioned every 5° between 135° and 45°. Where unreliable signals were obtained the value was disregarded. A minimum of 3 independent readings were used for each RTT value. Front surface radii were calculated on a computer spreadsheet on the same basis as that used for the steel ball (experiment 2b above).

RESULTS

The sectors that were usable and the temperature ranges during the experiments are shown in Table 5.5.3

One lens had three indpendent trials, one had four, five had five and one had six.

. Lens	Saline temperature	sector used
A	19.5 ± 0.1° C	60-135°
B	19.3 ± 0.2° C	70-115°
C	20.1 ± 0.3° C	55-130°
D	19.6 ± 0.1° C	45-135°
E	19.2 ± 0.2° C	70-135°
F	19.9 ± 0.2° C	70-120°
G	19.7 ± 0.3° C	65-135°
H	20.0 ± 0.1° C	60-115°

Table 5.5.3a   Saline temperature ranges and transducer sectors used for eight soft lenses.

The SDs obtained were generally in the region of $0.008\mu s$. However, with lens C the values seemed significantly higher ($0.008\mu s$ was the best obtained and $0.09\mu s$ was the worst).

Front surface curvatures

Lens	BOZR (spec) (mm)	Power (spec.) (D)	Measured FOZR (mm)	Iterated value (mm)	No. points used
A	7.50	-3.75	**8.35**	0.65	14
B	7.50	-1.75	**7.42**	1.6	10
C	7.50	-3.50	**8.53**	0.46	12
D	8.10	-1.50	**8.54**	0.46	10
E	7.50	-4.00	**8.54**	0.45	13
F	8.70	-5.00	**9.03**	0.00	10
G	8.10	-1.75	**8.29**	0.70	9
H	8.70	-3.50	Too few useable points	n/a	

Table 5.5.3b   The fourth column shows the FOZR values calculated from a spreadsheet

Discussion

It was apparent that mechanical tolerances and other unknown factors e.g. the exact axis of the transducer beam, resulted in the apparatus being of limited value. The main difficulty was to centre the contact lens accurately and obtain reflections of usable intensity. If the incident beam of the transducer is not perpendicular to the test surface the intensity falls.

The apparatus gave reasonable signal strength when the transducer was in the 90° to 135° sector but generally poorer and less relaible signals in the 90° to 45° sector. If the lens was not centred well, bizarre results were sometimes obtained e.g. the surface appearing flatter than the PMMA dome on one side and steeper than the dome on the other side of the vertical. The results obtained on the steel ball were quite adequate but it was simple to centre the ball on the holder and the material gave good intensity reflections.

For correct assessment by this method the ultrasound beam must pass perpendicularly through the true vertex of the surface. If this condition is not met then spherical surfaces could appear to be aspheric.

The results obtained in the spreadsheet program indicated only small variations from the mean value. For example, with lens C, the central value was 8.54mm with the peripheral values around 8.51 or 8.52mm. Given the variation of readings from one side of the surface to the other such small differences would be accounted for by random errors.

It was felt that the methods used to analyse the data were adequate but the apparatus in its present form was not accurate or sufficiently reliable to produce useful data. Apart from lens B all the FOZR values were flatter than the BOZR values and this is to be expected with negative powered lenses. However the power values, if computed with the specified BOZR values, gave rise to errors of up to 4.00D. The specified values of BOZR were prone to errors. If the BOZR values in the HEMA lenses had been approximately 0.3mm flatter than the specified values then the power values would be close to those specified.

5.5.3 Validation of curvature using a photographic system

If a surface is truly spherical in nature then the general sag formula

$$\text{Radius} = \frac{s^2}{2} + \frac{d^2}{8s} \qquad \text{(where s = sagitta and d = chord)}$$

holds good for any chord chosen. If the the surface is aspheric then the resulting 'radii' from different chords will vary and will get either flatter or steeper from edge to periphery depending on the asphericity.

Objective. To photograph a cross section of each lens and from transparency project this cross section onto a screen so that various chords and sags can be measured. From these two variables, 'radii' can be calculated and compared within the experimental limits of the method.

Materials

A wet cell was constructed from PMMA and is shown in Fig. 5.5.6 The thickness of the shelf "A" was measured with a micrometer before being incorporated permanently into the wet cell.

Normal 0.9% saline was used in the wet cell

A Olympus OM2 single lens reflex 35mm camera was used to record images. A tripod was used to support the camera. The camera platform was adjustable vertically.

Film: Kodachrome 64

Kodak 35mm film Carousel projector.

Graph paper 100cm x 75cm scaled in mm to receive the projected image.

Sauflon 55, Sauflon 70 and Sauflon 85 soft lenses.

Method

A soft lens was removed from its vial and placed on the shelf (A) of the wet cell so that it balanced on the shelf edge. In this situation the shelf edge and a cross section of the lens through the lens apex were in the same vertical plane (see Fig. 5.5.6).

The camera was focussed on the edge of the shelf. The lighting of the cell and the background

pattern were changed experimentally to enhance the cross section profile.   Film exposure was automatic but was approximately 1second at f8.
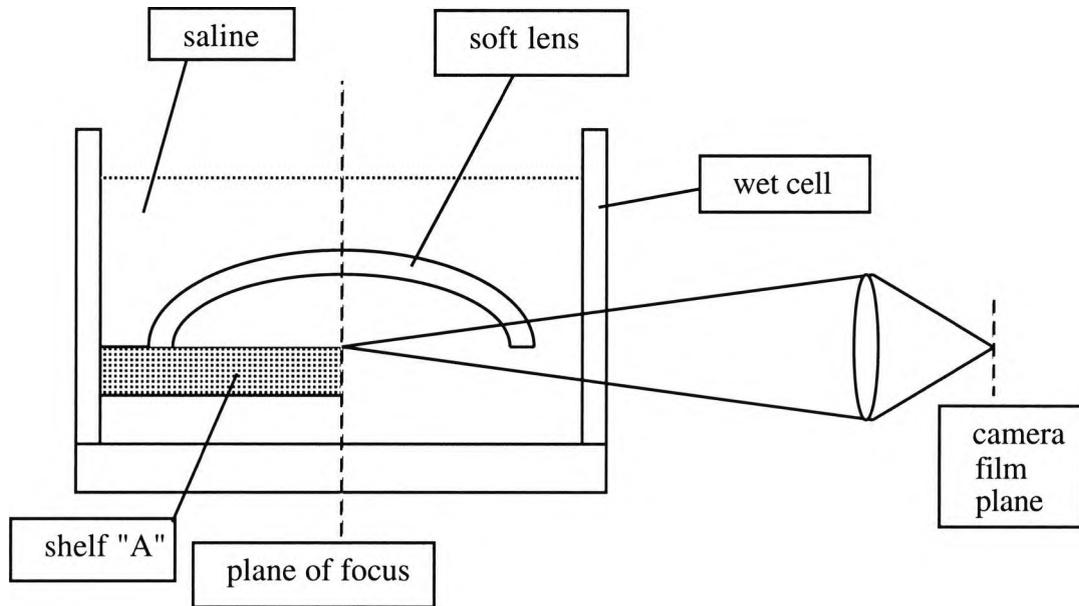
Figure 5.5.6a   Side elevation of the wet cell used to photograph an equatorial cross section of a soft lens.
Shelf A was measured before the cell was constructed in order to calculate the magnification of the projected image.
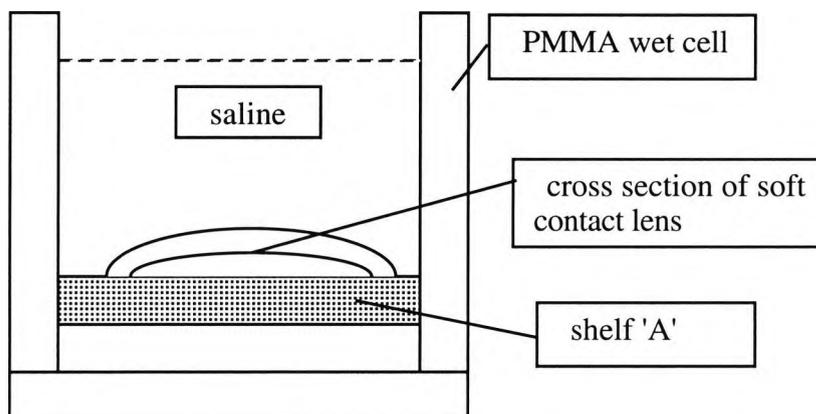
Figure 5.5.6b   Alternate side elevation of the wet cell used to photograph a cross section of a soft lens.
This is the view see from the camera viewfinder.

Knowing the thickness of shelf 'A' the projected image of the shelf could be measured and the actual magnification claculated. The transparencies were were projected onto the graph paper screen with a magnification between 25 and 50 times.

A series of approximately 10 different sag measurement (s') and the associated chords(d') were taken from the image of the front surface. Two independent measurements of each variable were taken and the radii calculated having taken the magnification into account.

RESULTS

Using a magnification above 50X resulted in poorer image quality and measurements became unreliable. Measurements on the graph paper could be taken to the nearest 1mm and on occasions to 0.5mm.

The saline temperature was in the range $19.9°C \pm 0.5°C$

Measurements and values are shown in Tables 5.5.4 to 5.5.8

chord (mm)	sag (mm)	image radius (mm)	real radius (mm)
9.0	5.5	186.84	6.75
11.0	8	193.06	6.97
13.0	11.7	186.40	6.73
15.0	16	183.78	6.64
17.0	20.5	186.46	6.74
19.0	26	186.55	6.74
21.0	32.3	186.81	6.75
23.0	40	185.31	6.69
25.0	48	186.76	6.75
27.0	58	186.11	6.72
magnification = 27.66			mean = 6.75mm SD = 0.086mm

Table 5.5.4   Surface 1 (front surface) . The results indicate a spherical surface with an estimated curvature of 6.75mm

. chord (mm)	sag (mm)	image radius (mm)	real radius (mm)
99	5	247.52	8.93
136	10	236.20	8.52
166	15	237.13	8.56
189	20	233.25	8.42
209	25	230.90	8.33
228	30	231.60	8.36
241	35	224.93	8.12
257	40	226.40	8.17
269	45	223.50	8.06
280	50	221.00	7.97
291	55	219.95	7.94
301	60	218.75	7.89

Table 5.5.5 SURFACE 2(Front surface)   magnification = 27.70
The results show radius values steepening from centre to periphery.

.chord (mm)	sag (mm)	image radius (mm)	real radius (mm)
166	9	387.22	7.58
209	19	401.18	7.86
274	24	403.02	7.89
300	29	402.43	7.88
325	34	405.32	7.94
350	39	412.12	8.07
370	44	410.92	8.05
388	49	408.54	8.00
407	54	410.44	8.04
425	59	412.18	8.07

Table 5.5.6 SURFACE 3 (Front surface)   magnification = 51.030
The surface appears to be either flattening towards the periphery or it may show a
    lenticulated front surface.

.chord (mm)	sag (mm)	image radius (mm)	real radius (mm)
170	8	455.56	**8.91**
214	18	439.5625	**8.60**
278	23	431.52	**8.44**
307	28	434.75	**8.51**
330	33	429.44	**8.39**
353	38	428.89	**8.39**
374	43	428.11	**8.38**

Table 5.5.7   SURFACE 4   (Front surface) ;   magnification = 51.085
The surface appears to be steepening away from the centre and then stays fairly constant in the periphery.

.chord (mm)	sag (mm)	radius of image (mm)	real radius (mm)
181	12	347.26	**6.80**
258	23	373.26	**7.30**
311	33	382.86	**7.49**
354	43	385.79	**7.55**
390	53	385.22	**7.54**
424	63	388.19	**7.60**
453	73	387.88	**7.59**

Table 5.5.8   SURFACE 5   (Front surface)   magnification   = 51.064
The surface appears to be flattening from the centre towards the periphery.

Discussion

The values obtained near the apex of the lens were not as reliable as measurements with a larger sag value. A change of 1mm could have a significant effect on the radius value. However, the surfaces shown above demonstrate that surfaces supposed to be spherical could be either:

    spherical (surface 1)

    steepening towards the periphery (surfaces 2 and 4)

    flattening towards the periphery (surfaces 3 and 5).

Thus, the exercise established that anisometropic expansion had taken place to varying

degrees in the Sauflon materials.

The method proved reasonably satisfactory as a means of assessing the topography of the soft lens surfaces but as the ultrasound results had to be treated with some doubt, it was not a worthwhile exercise to compare the findings of ultrasound values with the photographic values. In retrospect, it would have been preferable to use specially made reference lenses rather than standard production lenses where the use of lenticular front surfaces are often used used even in relatively low powers.

Chapter 6.0　　　DISCUSSION

The original development of an ultrasound based measurement system resulted in a compact piece of equipment that was straightforward to use. Thus, the main objective of the study was completed satisfactorily. Indeed, this method for the measurement of curvature has now been acknowledged in an International Standard (ISO 10338,1996) dealing with the measurement of soft lens radii. Although sagitta measurement has become the most popular method of measuring back surface curvature, ultrasound is the only current method that allows this to be carried out without mechanical interference of the surface. Keratometry has remained an undeveloped method for the measurement of soft lenses curvatures. With the design of better lens supports, centration devices and a temperature control system it still has potential.

Since publication, there have been a number of BOZR measurement sytems devloped utilising ultrasound . The Panametrics device (Patella et al, 1982) uses a 0.75" focus transducer. There is no temperature control and the system is calibrated with only one test piece with a known sagitta. The system only displays a sagitta value - the calculation of radius has to be carried out as a separate procedure. The Optison device (Port, 1982b) also used a short focus transducer . It did have a temperature control system and did have an internal device for computing the RTT to a radius value which was more convenient than the Panametrics system. However, the centration device was not easy to use and the device only measured one parameter. In contrast, the Optimec system (Port, 1981) was a mechanical device but it did enable the practitioner to measure the radius, total diameter, thickness (approximately) and one could also inspect the surface quality. Thus for about the same money, the Optimec was more popular amongst contact lens practitioners. Eventually production of the Optison ceased.

Refinement of the temperature control system was not possible in the original experiments but today there are compact components that can be incorporated in a wet cell to cool and heat the saline to a specified temperature. The current Optimec mechanical measurement system uses Peltier devices to achieve this, for example.

The electronics involved were part of an ophthalmological ultrasound system but again modern components can be small and ultrasound systems developed after the original studies were published achieved this eg the Optison (Port, 1982b). Modern electronic equipment is also likely to be more stable and less prone to electrical drift.

The ultrasound transducer is a critical component. It has to be robust and at the same time have good resolution together with a beam that is not greatly affected by the curvatures used in soft lenses. Although the original transducers were in the region of 20-25MHz and this was the highest frequency generally available at the time, modern transducers are made with a frequency of 50MHz. However, modern soft lenses are getting thinner and thicknesses as low as 0.04mm are not unknown and measurement of thickness using ultrasound would still prove difficult. However, with a well designed 50MHz transducer, the thickness measurement of lenses over 0.1mm could be a real possibility. Other ultrasound systems use a membrane or the transducer face as a reference when measuring sagitta. The developed system used an electronically generated reference(EGR) and it was envisaged that two EGRs would be utilised in a simple thickness measurement system. The other novel feature of such a system was that the speed of sound through the lens material need not be known - only the speed of sound through saline at the specified temperature and this is easily calculated by measuring the RTT across a known distance as described. The principle of measuring the lens thickness indirectly proved to be feasible using the USM 50Mz B-scan probe. However, the problems of holding the probe accurately and a lack of a temperature control system meant that the results were not as repeatable as one would like.

The possibility of using ultrasound to measure lens power and water content were considered. At the time, the limitations of the beam design in relation to the highly curved surfaces of contact lenses meant this was not an immediately practical proposition. The measurement of lens thickness using ultrasound proved to be within ±0.01 mm with special large diameter PMMA reference lenses but only to within ±0.05mm witth HEMA lenses. With transducers specifically

designed and mounted for thickness measurement the possibility of reasonable measurement is still present. The effect of an oscillating transducer was to cause a rippling effect of the lens especially with thin lenses and this in turn gave poorer repeatability.

There was potential in assessing water content using ultrasound. However, with newer materials entering the soft lens arena the water content may be less relevant as the relationship between water content of a soft lens and the gas transmissibility is likely to be less rigid.

The original ultrasound measurement system for BOZR measurement was very acceptable even for the equipment available at the time. Round trip times proved to be very repeatable (SD $0.006\mu s$ or 0.02mm radius) if the environment and equipment remain stable. This variance was achieved with single lenses on one day. This was consistent with the work of Patella et al (1982) who used the Panametrics ultrsound device. Studies involving the Optison device and the Optimec system (Port 1982b) showed that the variability in radius measurement was in the range 0.03 to 0.04mm. The repeatability trials showed that the author's apparatus could measure lenses to 0.12mm on a day to day basis. Quesnel and Simonet (1994), using keratometry, found repeatability coefficients which ranged from ±0.08mm for low water content materials (comparable to the value obtained by Grant[1987]) to ±0.17mm for high water content materials confirming that it is material itself which affects the measurement repeatability (Port, 1981). A repeatability of 0.12mm is seen as quite sufficient for soft lenses especially as today's lenses are thin and are often only available in a limited range of radius values; eg, Acuvue (Vistakon) are only available in two radii and some lenses e.g. Bausch & Lomb O series and U series are only available in one back surface design. Where there is a range of radii available, the fitting steps are normally 0.3mm or 0.4mm and the ultrsound equipment easily distinguished such differences. Manufacture of soft lenses is currently becoming more of a high volume business where there are fewer designs. Manufacture is moving towards moulding procedures rather than lathing and most products are very reproducible in terms of curvatures. To obtain low wastage rates there has been better control of polymers and their components and the anisotropy that was found in the original work is far less likely to be observed in today's materials. However, in a study of

moulded lenses (Port,1992a) it was found that the BOZR of lenses did vary according to the lens power. It is postulated that the polymerisation process may have been affected by the cross section profile and therefore the polymerisation throughout the lens varied for different lens powers. However, as the lenses were thin, this difference in radius did not affect the the actual fit of the lenses on eyes (Port, 1992b).

The use of sagitta methods for the measurement of BOZR has become an industry standard especially as most laboratories use the Optimec system (Port, 1981) and some use the Panasonics system. Indeed in some quality control systems, the operator is only concerned that the sagitta is within a band of tolerance values rather than being concerned with the actual radius measurement. Strachan (1975) considered the sag of the lens to be a more useful dimension that the radius and Wichterle (1981) considered that volume under the posterior surface of the lens might be a more useful way to specify back surface design. If one is concerned with sagitta, then sagitta measurement systems can cope with both aspheric and spherical lenses. If one is concerned with calculating the asphericity or toricity of a surface then the keratometer system is more useful.
In practice, many soft lens designs now incorporate two or three curves of the posterior surface and it is not always easy to know if lens is resting on part of the optic zone or a peripheral zone. Because of this the measurement of lenses using sag over a diameter of 10mm is prone to errors. To make a smaller lens support decreases the difference in sag between two radii and this is more difficult to measure with any equipment.

The scanning system evaluated was partially successful. The concept certainly proved to be feasible but the mechanical constraints of making the apparatus components resulted in values which were not accurate enough to be useful. The photographic system used for checking the topography of soft lens front surfaces was quite adequate but comparisons with the ultrasound values was not feasible especially as the ultrasound results were analysed to give spherical values.

The effects of temperature on hydrogels of various water contents was investigated. Particular attention was given to the change found between 20 and 30°C as this is the average change found

when a soft lens is removed from a vial and placed on the eye to equilbrate. The relationship between water content and change in radius for a temperature change of 10°C was essentially linear. As might be expected the change in this 10°C band was greater with the higher water content materials and the highest water content material tested changed by 0.4mm which is one fitting step (Fig. 5.1)

Future developments

1. Determination of aspheric curvatures

The author has considered a sagitta system which uses, for example, three lens supports of different diameter and a single transducer (see Fig. 6.1). This would enable 3 sag values to be obtained from the same surface and from these values a curve fitting technique can be applied to compute the asphericity of the lens.
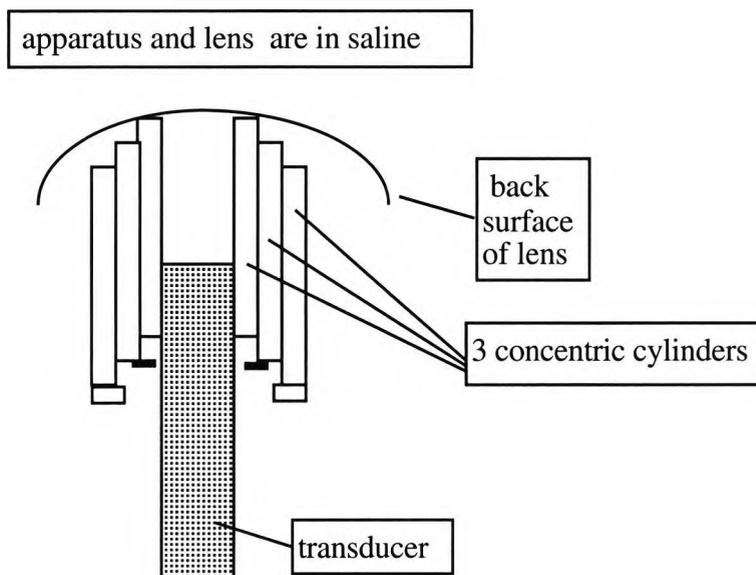
Figure 6.1   A design using ultrasound to measure three sagitta values on the back surface of a soft lens. From these three values a best fit equation could indicate the asphericity of the surface.

2.   Lens thickness determination

The main problem with existing systems for measuring lens thickness is the indentation into the lens surface. Each different material has a different indentation for a given weight and hence the effect is difficult to evaluate. The advantage of the ultrasound system is that any mechanical interference with the lens is avoided. To make a system practical, a long focus transducer of high frequency (approximately 50MHz) and narrow beamwidth would be needed. This would have to differentiate the two surfaces and avoid the effect of the surface curvature.   The indirect method

of measuring thickness could be simply investigated. Not having to measure the speed of sound through a material is a distinct advantage. The efficacy and accuracy of the ultrasound method could be validated using special rigid lenses fabricated using curvatures used in soft lenses and with varying thicknesses.

3. Water content determination.

Again a transducer with a narrow beam to avoid the effects of curvature would be essential but this is a quick method which has some advantages over the convenient and cheap method which utilises a hand held refractometer (Brennan, 1983). With the refractometer the reading is sometimes affected by dyes which may be incorporated and with very thin lenses it is not always easy to prepare the lens properly and get reliable readings.

The ultrasound method provides a stable environment for the material and the effects of temperature change on the material's water content can be easily assessed. In this use of ultrasound the velocity of sound is not so important as a distance is not being measured. It would be worthwhile to investigate the amplitude of reflected signals from materials which do not absorb water in case there was a factor which had to be accounted for.

There is a large range of available hydrogel materials which can be used to standardise the method. The ultrasound method is relatively fast especially when compared to the ISO method of choice (ISO 10339, 1997) which uses a gravimetric method.

4. Total diameter (TD)

The measure of TD by ultrasound has not been investigated to date. There are two approaches which may be applicable. The first is to use a a B-Scan arrangement so that an image of the lens can be 'frozen' on a display screen. Modern software enables a cursor to be superimposed on the image to measure distances. This usually means that the operator views the image and 'clicks' the cursor on two separate points. The distance between the points is then calculated.
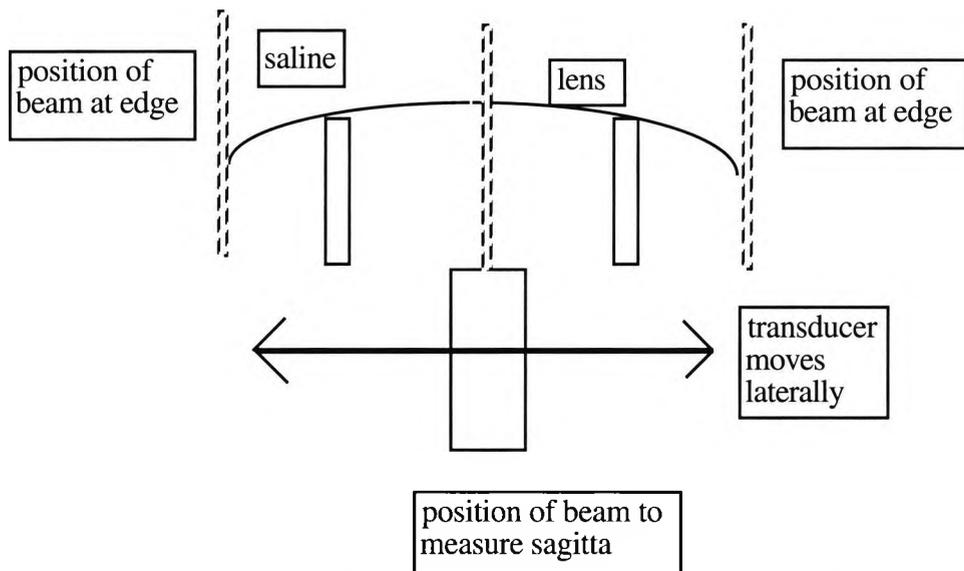
Figure 6.2   An arrangement that could measure both the back surface sagitta above the lens support and also measure the total diameter of the lens by moving the transducer laterally.   The width of the beam would have to be taken into account when the transducer travel was recorded. This could be ascertained with rigid test pieces of known diameter.

The second approach is to use an A-scan transducer and move the transducer laterally so that the beam picks up each edge of the lens in turn as the transducer moved across an equatorial plane. The arrangement could be an extension of the BOZR measurement system (Figs. 6.2 and 6.3)
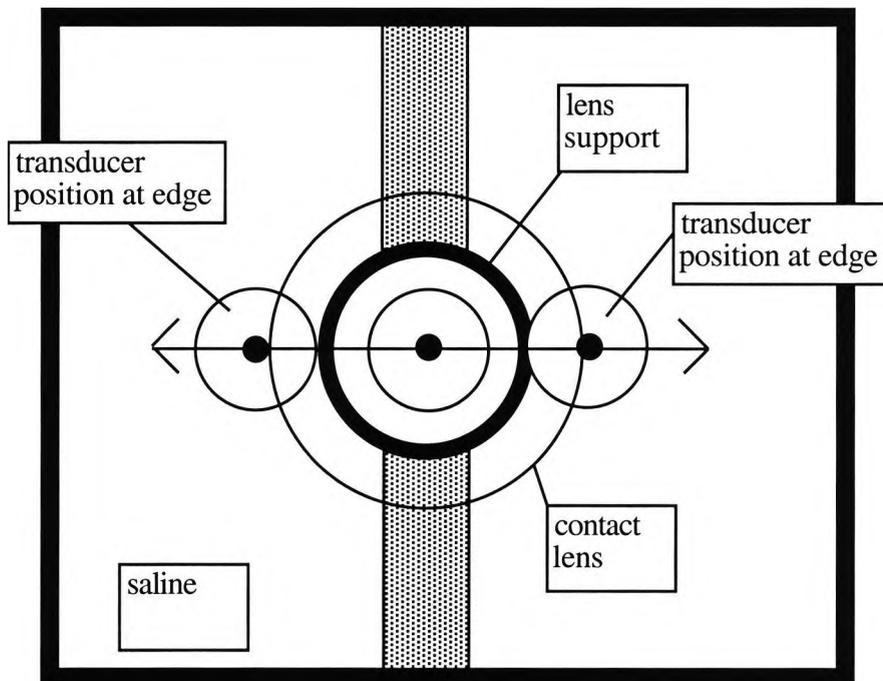
Figure 6.3 Plan view of the arrangement to measure the total diameter of a soft lens. In oder to have the transducer in the correct position to measure the sagitta there could be either a mechanical click-stop or one could simply find the position which gave the greatest sagitta value.

5.   Topography of lens surfaces

The task required by the present study was ambitious. The small changes in distance to be measured could not be accurately determined. The principle worked satisfactorily but the mechanical limitations of the apparatus and the transducer design did not enable good data to be achieved. It is probably not worthwhile to pursue this area of investigation in the future.

A redesigned system could realistically include measurement of:

thickness using a long focus 50Mz A scan transducer,

water content,

BOZR,

Total diameter

total sag of back surface,

aspheric shape of the back surface.

It is probably not worthwhile to include power and FOZR. The latter is rarely needed and for the power calculation one would need to obtain the FOZR and know the refractive index at the measurement temperature. The latter is not difficult to acquire as manufacturers would have this information. The FOZR would not be easy to measure in view of the variable size of lenticulated areas on the front surface.

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Appendix 1

The radius measurement of soft lenses in air

M.J.A.Port

The Radius Measurement of Soft Lenses in Air

Michael Port

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Abstract
The effects of radius, power and material on the in-air measurement of BCOR in soft lenses are examined. Consistency of sagitta measurement is also tested in relation to the same three variables. Seven different materials are used in the trials.

Introduction
Over the last few years a growing number of BCOR measurement systems (e.g. by Medicornea, Neitz, Wohlk, Reid-Prentice) that measure this soft lens parameter in air have been introduced for use by the contact lens practitioner and manufacturer. The author has advocated (1, 2) that soft lens parameters should be measured in normal saline under controlled environmental conditions. The effects of storage solutions on lens parameters are well documented (4, 5, 6, 7, 8, 9, 10, 11). Different measuring systems for BCOR have been compared (12, 13, 14, 15, 21) and the effect of different materials on reliability and specification variance have been discussed (12, 16, 20, 22). Comparison of stated and measured radii has been investigated on various materials (12, 17, 18, 19). The interaction of lens power, radius and material has been noted to some extent in the references above. As a comparison to the author's own ultrasonic apparatus it was decided to utilize a contemporary in-air system to measure the BCOR of soft lenses made from different materials. At the same time consistency of sag measurement could be tested.

Lenses Chosen
The contact lenses were normal finished lenses stored in 0.9% saline solution in conventional glass vials.

The majority of the lenses had a diameter of 14 - 16mm. A few measured 13.5mm. Diameters below 13.5mm were excluded.

a. Materials
The materials chosen were:

	Menicon 30
	Snoflex 38
	Weicon 38
	Duragel 60
	Sauflon 70
	Duragel 75
	Sauflon 85

b. Powers
Four groups were selected viz:

	High plus
	Low plus
	High minus
	Low minus

c. Radius
Lenses of two, three or four radii were used from within the normal radius range. An example is shown in Fig. 1.

SAUFLON 85

Lens no.	Vial Radius (R_S)	BVP
1	8.1	high +
2	"	low +
3	"	high −
4	"	low −
5	8.4	high +
6	"	low +
7	"	high −
8	"	low −

Fig. 1

Apparatus

A Neitz SM100 (Softometer) was used to record the sagitta of the lenses. In this instrument the sag was measured across a chord of 10.99mm. The apparatus was calibrated (zeroed) before the trials began and at intervals during the trials. A Unicam pH meter was used to check the saline pH.

Methodology

Environmental conditions:

Tonicity: 0.9%

pH range: 6.0 to 7.0

Temperature: 22 to 25°C (ambient air and saline in vials). The vials of the first group of four lenses were opened. Lens No. 1 was removed carefully from the saline and placed convex side up on a paper tissue for 5 - 7 seconds in order to let the surplus surface solution drain off the lens. The lens was then transferred to the SM100, the sag was measured and recorded. Removal of surface saline and sag measurement was achieved in approximately 20 seconds (surface drying within this period should be minimal). After sag measurement the lens was returned to the vial. The procedure was repeated for lenses 2, 3 and 4. The measurement of four lenses as described comprised one trial. Five similar but independent trials were completed for each group of lenses. From each sag measurement a radius was obtained from the conversion table accompanying the instrument. Thus from the five independent results from each lens a mean and standard deviation (SD) were obtained for sag and radius.

Results

1. Consistency of measurement.

The SD obtained above gives a measure of consistency. This was tested against power (BVP), radius, and material. Figs. 2, 3, 4 and 5 show that there was no significant correlation between the SD (using the radius values) and power, radius or material. Taking all the lenses the SD_{rad} follows a
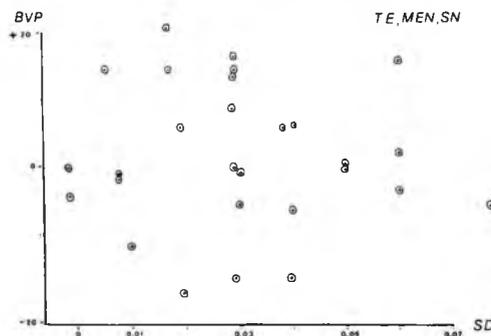
Fig. 2
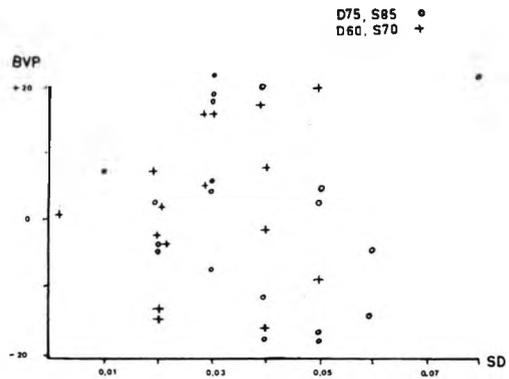
Fig. 3
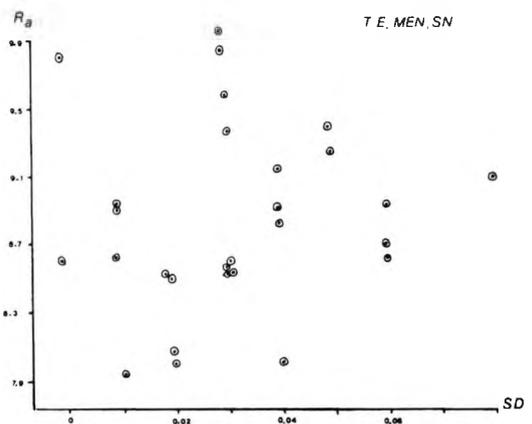
Fig. 4
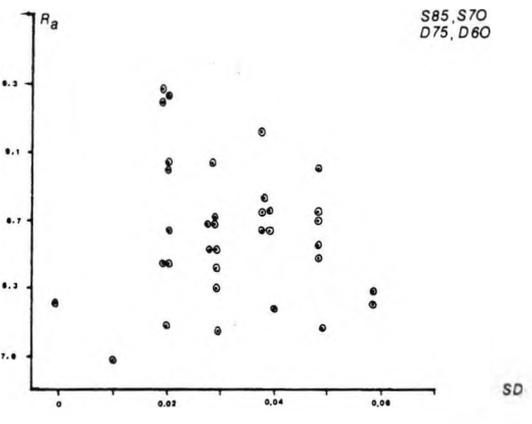
Fig. 5

fairly normal distribution with a modal and mean value of ±0.03mm (see Fig. 6). This value is virtually identical to that obtained by Hamano & Kawabe (1978) with a very similar instrument.

It can be concluded that all *sags* of soft lenses made from the materials tested can be measured with the same consistency irrespective of power and radius.

Fig. 6

Frequency

N = 64

SD
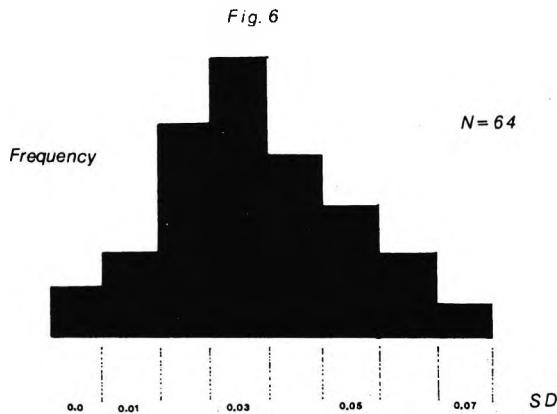
One SD for sag values was 0.01mm (mean value). To account for measurement errors inherent in the instrument two SDs would be more appropriate. Hence we can realistically say that the instrument used can measure *sags* to ±0.02mm.

Having found that the sagitta can be measured consistently, can one rightly transpose this to a radius value from the conversion table. For the conversion to be accurate, the lens, as it rests on the measuring instrument must present a truly spherical back surface. If this is not the case the radius value obtained is inaccurate. For the sake of comparison and presentation of the data the author has assumed a spherical surface to be present.

2. Radius estimation

The radius marked on the storage vial(R_S) is compared with the radius measured in air experimentally(R_a).

Figs. 7 and 8 show the relationship of (R_S-R_a) and power for the different materials. It can be easily seen that no special relationship exists.

Figs. 9 to 15 illustrate the values of R_a for all the lenses. The overall pattern is one of lenses flatter than their specification with (R_S-R_a) tending to decrease as the water content of the material decreases.

Figs. 16, 17 and 18 show R_S related to R_S-R_a. For the whole low water content group (R_S-R_a) tend to

R_S - R_a

BVP

Fig. 8

S85, D75 ⊙
S70, D60 +

MEN.

R

R_S

R_S

BVP

Fig. 9

R

SN38

R_S

R_S

BVP

Fig. 10
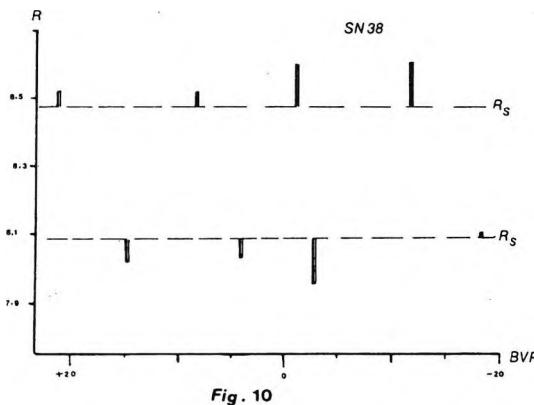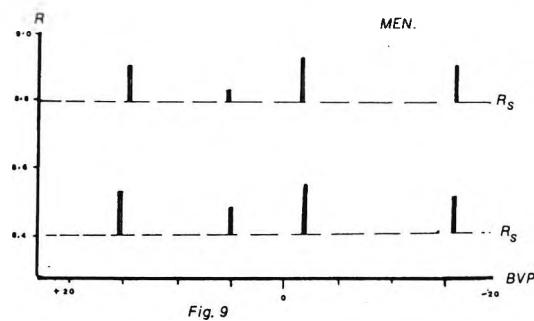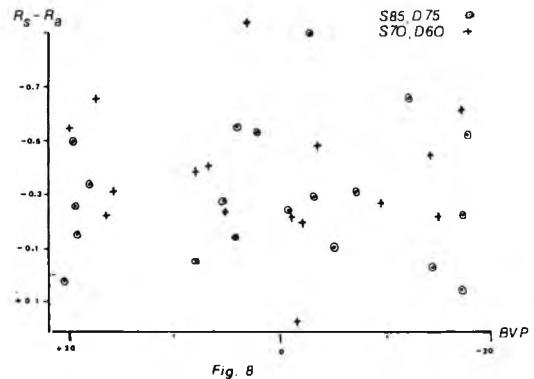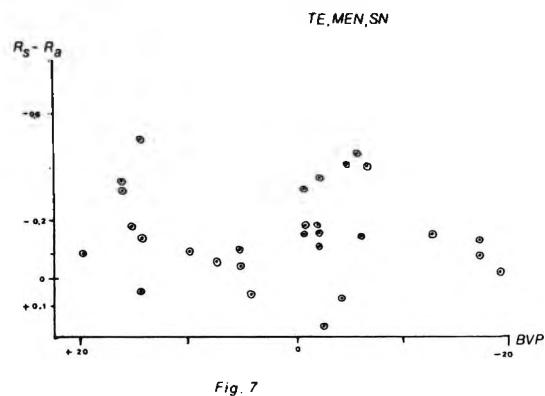
increase in the direction of flatness as the value of $\bar{R}_S$ lengthens.

The Duragel materials show a different relationship. With these the (R_S-R_a) value is minimal for R_S values in the 8.4/8.5mm area. For lenses flatter or steeper (R_S-R_a) tends to increase. Suaflon 70 shows the opposite effect to the Hema group. R_S-R_a is maximal at the steeper end of the radius range and decreases as R_S lengthens. Sauflon 85 showed a similar relationship to Duragel 75 but more exaggerated. Ideally more values of R_S should be used so that more points on the graph may be plotted.

Note. To obtain Figs. 16, 17 and 18 the radii of 16 additional lenses were measured in order to give a spread of radii better than the original 64 lenses provided.

TE, MEN, SN

R_S - R_a

BVP

Fig. 7

170

R

WEICON

R_S

R_S

R_S

BVP

+20   0   -20

Fig.11

R_a

S 85

R_S

c

R_S

+10   0   -10   BVP

Fig.14

R

D 60

R_S

c

R_S

BVP

+20   0   -20

Fig.12

R

D75

c

R_S

R_S

R_S

BVP

+20   0   -20

Fig.15

R

S 70

R_S

R_S

BVP

+20   0   -20

Fig.13

Mean
$R_S - R_a$

p. Hema

-0.4

-0.2

0.0

+0.2

8.0   9.0 R_S

Fig. 16.

Fig.17

Fig.18

Fig.19

the degree of distortion. Lenticular front surfaces by virtue of their size and design coupled with the carrier design will also affect distortion.

b.   Calculations for determining the hydrated BCOR do not take account of all factors (e.g. the difference between the longitudinal and transverse swell factors). Because of this lenses tend to hydrate to a value flatter than that predicted (Bussacker, 1978).

c.   The rear surface of the lens is aspheric with a peripheral portion flatter than the central part thus giving a sag value smaller than that predicted (Port, 1979b).

d.   In some cases where the overall diameter is small a peripheral curve on the back surface could influence readings as the annulus of the measurement instrument is not on the optic portion of the lens (see Fig. 20). This condition will obviously produce a sag value lower than that expected and the conversion to radius will give a flat value for the BCOr.

Discussion and Conclusions

The experiment showed that the apparatus used could measure the *sagitta* of a soft lens consistently to ±0.02mm irrespective of the lens power and radius for the materials tested. However, it is very doubtful if the same accuracy level can be applied to the *radius* estimation. One may expect from a random selection of lenses that approximately half might be flatter than R_S and half steeper than R_S if the basic calculations for determining the hydrated radius are correct. In this experiment 90% of the lenses tested were flatter than their specification. Some of the reasons for this may be hypothesised as follows:

a.   The actual mass of the lens in air is affected by gravity and this coupled with the dynamic properties of the lens material leads to a distortion of the lens. This distortion effectively flattens the BCOR (see Fig. 19). Due to shape and weight distribution one may expect a flat plus lens to distort more than a steep minus lens when the lens is placed on an annulus such as used in the experiment. Looking at the results obtained this is not borne out. Additionally, the elasticity of the lens material will have a bearing on

Fig 20

Summary
See Fig. 21.

The method enabled a lens sagitta to be measured quickly and accurately. *If* the lens presents a spherical surface to the measuring instrument then radii can be measured to an accuracy of ±0.05mm. However, due to the complexity of factors mentioned above no single figure can be given for the accuracy of radius

SUMMARY

Lens	N	$\Sigma(R_s - R_a)/N$	Range		
Weicon	12	−0.27..	+0.04	to	−0.52..
S N	8	−0.01	+0.14	to	−0.13
Menicon	8	−0.10	+0.02	to	−0.17
D 60	8	−0.28	+0.18	to	−0.44
S 70	8	−0.40	+0.28	to	−0.96
D 75	12	−0.20	−0.00	to	−0.52
S 85	8	−0.40	+0.10	to	−0.89
Mean		−0.24..			

Fig. 21

measurement as this appears to be related to the properties of a particular material in air. The Menicon and Snoflex materials gave the smallest variations from R_S and for these materials a tentative value of ±0.1mm may be appropriate for radius accuracy.

The Duragel materials gave less variation from R_S than the Sauflon materials. This may be due to the latter having

a. greater elasticity
b. greater response to environmental variations
c. a less homogeneous polymer

Anyone measuring soft lens parameters will enhance the accuracy, reliability and repeatability by controlling the environment. The temperature band should be as small as possible. A single storage solution of buffered normal saline (Kemp, 1979) is very worthwhile. Paper indicator strips can be of use in assessing the pH of storage solutions.

The disadvantage of an in-air measurement system compared with an in-saline system is that the lens/air interface tends to accentuate the · inter-material properties compared with the lens/saline interface.

Speed of operation gained by measuring soft lenses in air is generally nullified if the accuracy is lowered by the variability of dynamic properties in the wide range of contact lens materials available today.

Acknowledgements

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Appendix 2

The hydration geometry of hydrophilic materials

M.J.A.Port

The Hydration Geometry of Hydrophilic Materials

Michael Port, M. Sc., F.B.O.A., F.S.M.C., D.C.L.P.

Consideration of surface geometry with soft lenses involves looking at curvatures and trying to measure them. Three methods are currently in use.

1. *Keratometry.* Two reflected points some 3mm apart are used for the measurement. It is important to remember that when we use the keratometer to measure the corneal radius it is not assumed that one reading is valid for the whole corneal surface, but we do tend to assume that the central reading from a contact lens surface represents the curvature value across the entire surface.

2. *Projection techniques.* A projected image of the lens surface is matched to a known spherical curve on the projection screen. On occasions one can measure the center or the periphery of the lens but not match both at the same time. A compromise result may have to be accepted.

3. *Sagitta determination.* A formula based on spherical geometry is applied to obtain a radius. False readings are obtained if this formula is applied to aspheric surfaces.

Figures 1 and 2 summarize the above points.

Mr. Port is a member of the department of ophthalmic optics at The University of Aston in Birmingham, England. He gave this paper to the International Contact Lens Congress in Scandinavia, which was co-sponsored by NERF and Scandinavian contact lens societies. The congress was conducted in Gothenburg, Sweden, September 14-17, 1978.

Given the assumption that all three methods have the same accuracy of measurement, then with a truly spherical surface each method will give very comparable results. If the differences are significantly greater than the accuracy limits, then aspherical surfaces are being measured. For example, given a truly spherical surface of 8.0mm radius and a measurement accuracy of ± 0.1mm, then results in the 7.9 to 8.1mm range are the norm. With the ellipse one might expect: Keratometry, 8.0mm; Projection, 7.7mm; Sagitta, 7.75mm. With a parabola/hyperbola: Keratometry, 8.0mm; Projection & Sagitta, 8.3mm. Reference to Figure 1 will clarify these points.

Figure 3 shows a section of a dehydrated lens with its surfaces expanded to complete spheres. Conventionally, when a section is hydrated, linear factors are applied to obtain the hydrated diameters and radii (see Figure 4).

The dehydrated section in Figure 4 shows that there are only two places where the inner and outer surfaces are truly parallel. It seems logical that only in these places can linear factors be applied with complete accuracy. In the contact lens situation there are two "separate" surfaces and these are rarely parallel. In solid forms such as a sphere there is only one simple curved surface.

To test the theory, thin discs of high water content hydrophilic material were produced (see
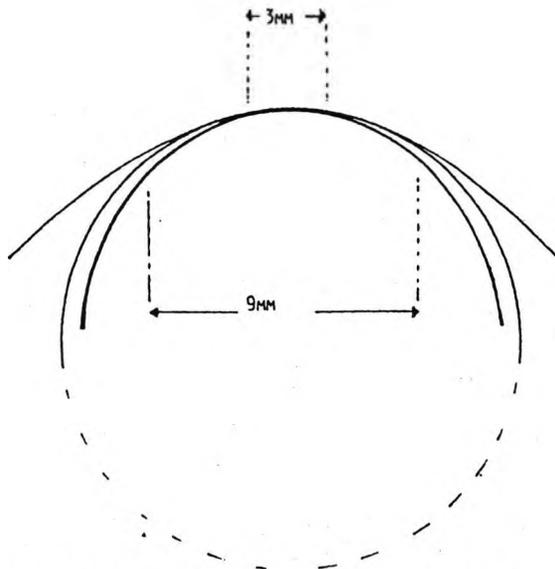
Figure 1. The spherical curve "matches" the parabola and ellipse centrally but not peripherally.
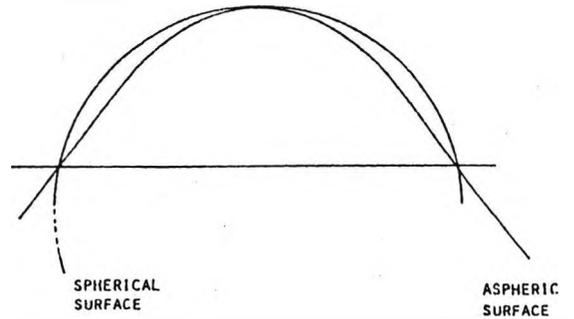
Figure 2. Sagitta measurements are the same for both curves but there are different central curvatures.
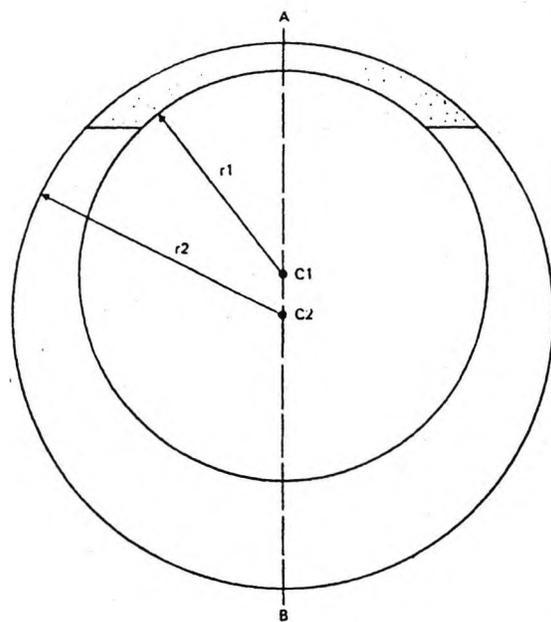
Figure 3.
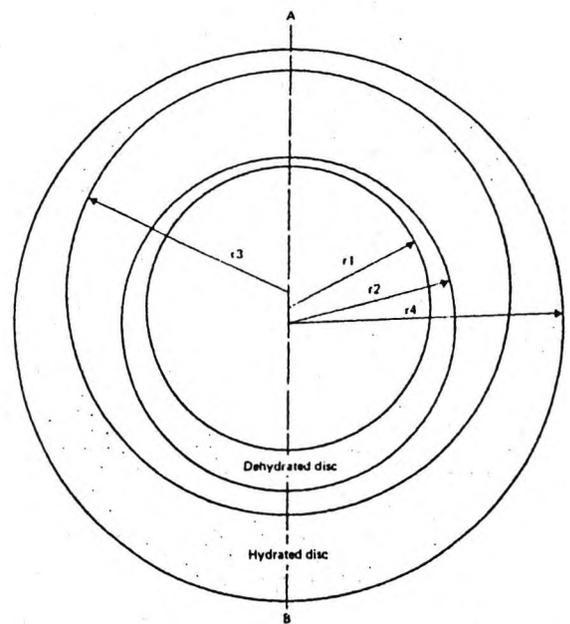
Figure 4.

Figure 6) and the curves measured in the dry state. The discs were hydrated and the shape forecast did actually materialize (Figure 7). The important result from the experiment was to show that rather than there being a single expansion factor, a series or gradient of expansion factors had been responsible for the hydrated shape. To release the stress within the hydrated disc, it was cut at the widest part. The result is shown in Figure 8.

A disc with a concentric hole rather than an offset hole gives a different situation. When hydrated the annulus was still circular but on cutting the disc there was still some stress and a smaller radius resulted.

From these two examples one may envisage a contact lens in a normal unstressed condition with which one would get a steeper BCOR (base
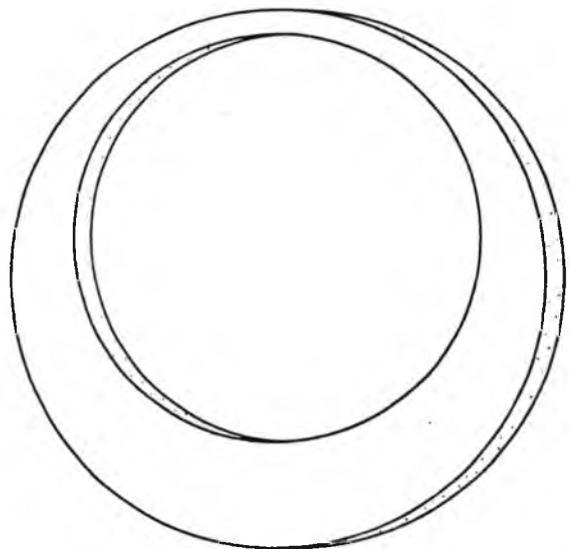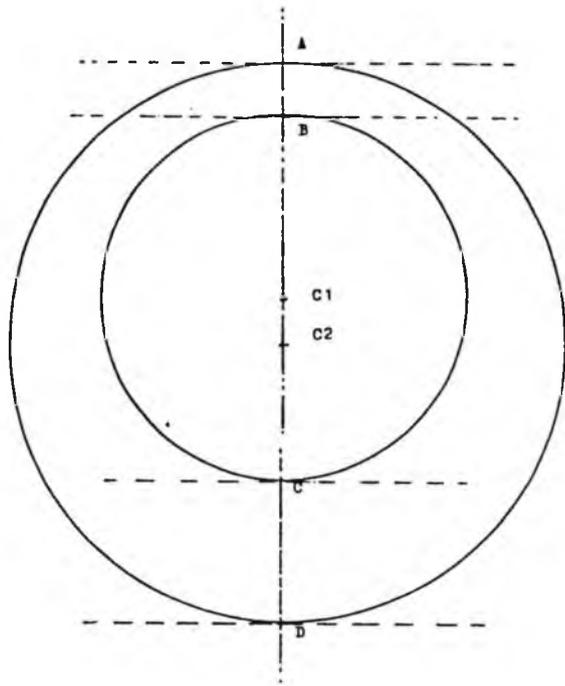
Figure 6. Thin dehydrated disc of hyrophilic material.

Figure 5. Tangents to the curved surfaces are parallel at points A, B, C, and D.
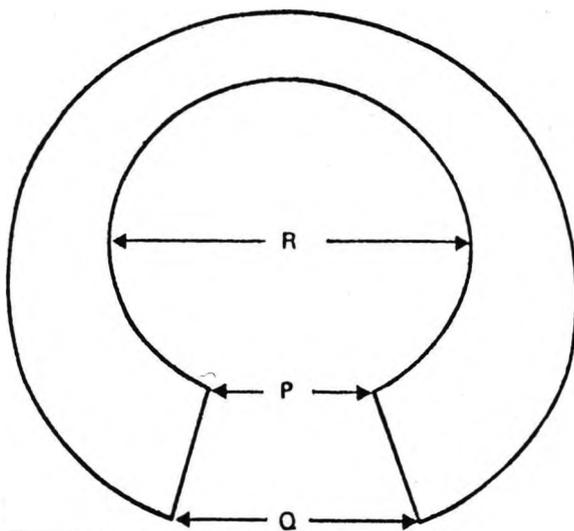
Figure 8 (above). Unstressed hydrated disc.
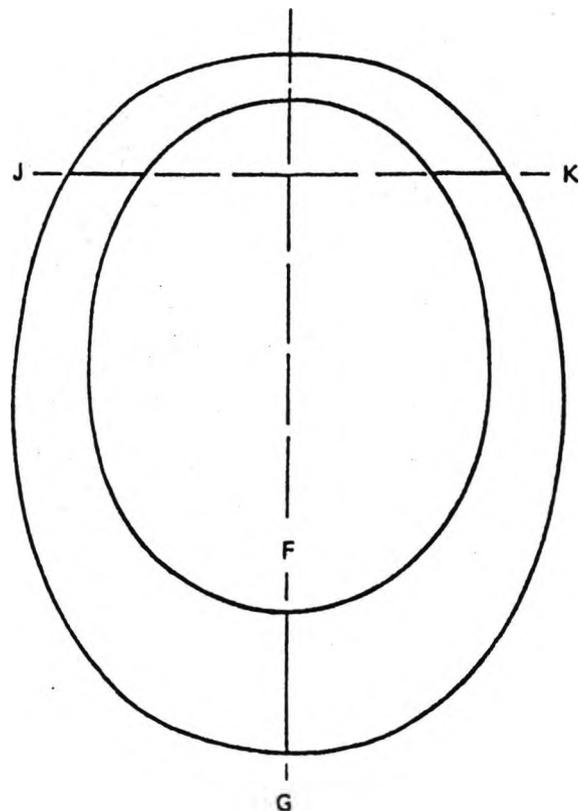
Figure 7 (right). Stressed hydrated disc.

curve) or flatter BCOR than that predicted from the linear swell.

It was natural to turn to material properties for an exploration of these phenomena. The material was from polymer rods. Polymerization involves the production of heat, and the expansion/contraction effects coupled with convection effects during polymerization must produce some internal stress. Single button production must produce a better product, but as long as rigid containers are used for polymerization there will probably be some minimal stress in the material.

The major factors thought to affect the hydrated lens form are as follows.

Hydrated lens form dependent on: (1) The material, its water content and linear swell. (2) The method of polymerization. (3) The combination of posterior and anterior curves. (4) The center thickness. (5) The overall diameter.

Other possible factors: (6) Prism. (7) Front surface lenticulation. (8) Edge curves.

The combination
of anterior and posterior curves.

If five lenses all have the same BCOR, diameter, material and mean thickness but powers of +10, +5, Plano, -5, -10D, will they all fit in the same way? By conventional theory they should but many practitioners choose a lens close to the spectacle prescription to ensure that the patient's final lens is the same fit as the trial lens. This would indicate that the effects of the different front curves can affect the fit of the posterior curve on the eye.

Evidence from the measuring and fitting of soft lenses suggests that many lenses become aspheric in the hydrated state, as compared to a spherical dehydrated state. As lenses become smaller and thinner this may be of little importance. At the moment one cannot simply apply linear factors to dehydrated, curved, three dimensional surfaces and forecast the hydrated specification accurately.

Referring again to Figure 1 and considering the three curves to represent the base curves of three lenses, it can be seen that when measured centrally all will give approximately the same radius. Looking at the surfaces as a whole, one can see there will be significant differences from the fitting aspect because of the peripheral differences.

Where curvature has to be taken into account with soft lens fitting, it may be more useful to specify sagitta only and not convert it to a radius. The sagitta could be measured a. across a standard chord, b. across a chord 3mm less than the overall diameter, or c. across a chord equal to the lens diameter. This system could make fitting sets from different manufacturers more compatible. □

Discussion

The author offers succinct explanations for the possibility of error in the laboratory measurement of hydrogel lens parameters. He clearly illustrates the possibility of discrepancies using the same methods of measurement for aspheric (as found in spin-cast lenses) and spherical (as found in most lathe-cut lenses). The difference in fitting characteristics and the lack of interchangeability are emphasized.

Moreover, the use of markedly different sagittal and reflex measurements to determine whether a lens is aspheric is a novel and useful approach even though most clinicians are unlikely to make use of both methods. The author's experiments hydrating discs made of hydrogel materials graphically explain many of the clinical observations that seem to emphasize the undependable nature of manufacturers' published standards.

The paper offers much food for thought, and its concepts should be better understood by every practitioner. This is especially true if one is tempted to reach any conclusions about the base curve radius of any lens based upon a single method of measurement.

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Appendix 3

New methods of measuring hydrophilic lenses

M.J.A.Port

New methods of measuring hydrophilic lenses

Michael Port*

To date, measurement of the back central optic radius (BCOR) of soft contact lenses has been carried out in five different ways, *viz*

1. Sagitta measurement using mechanical methods;
2. Keratometry in conjunction with wet cells;
3. Projection methods;
4. Template matching;
5. Special radiuscopes.

The first method suffers from the disadvantage that even if the lens is measured in saline there is mechanical disturbance of the lens, and this disturbance will vary with the lens thickness and the dynamic properties of the lens material.

The keratometry methods generally suffer from a lack of reflected light from the lens surfaces and often special light sources have to be used in the keratometer. Holden (1975) describes a method using a Zeiss ophthalmometer and he has good results with the standard light sources enabling him to measure back and front curvatures of spherical and toric soft lenses, including high-water content lenses.

Template matching is a poor method as the lens is in air. There will be stretching and drying of the lens according to its individual characteristics. An accuracy of 0.3mm is difficult to better.

The main problem of all methods where the lens is measured in a saline medium is the control of that medium. Wet cells that hold the contact lens are necessarily small and it is difficult to control the tempera-

ture of the saline environment. Loran (1974) noted this difficulty when testing the Söhnges projection apparatus.

With an ever-increasing number of different lens materials appearing it is now relevant that the measurement of soft lens parameters should be done under standard environmental conditions. Temperature, tonicity and pH should be specified, as all these can alter the lens para-

meters. At present virtually all soft lenses are stored in 0.9 per cent saline. The pH of storage solutions is normally on the acidic side (in a band 5.5 to 7.00). Soft lenses are probably measured at temperatures between 15 and 30°C.

My own method of radius measurement (Port, 1976) is based on sagitta measurement except that there is no mechanical interference with the lens (except for positioning the lens before measurement which is common to all methods, of course). The sagitta is measured using high frequency sound: the depth-gauging principle being basically the same as, for example, the measurement of the anterior chamber in ocular ultrasonography. The apparatus is shown in Figs 1 and 2.

One can determine the radius of curvature in two ways. Either the time measurement is converted to a distance (knowing
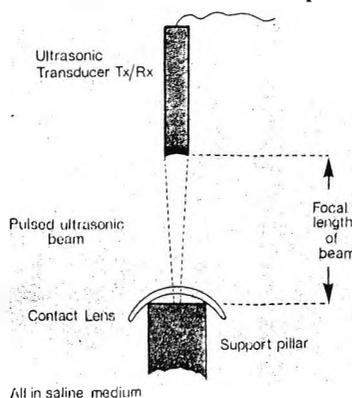
Figs 1 & 2: Apparatus for measuring anterior chamber in ocular ultrasonography
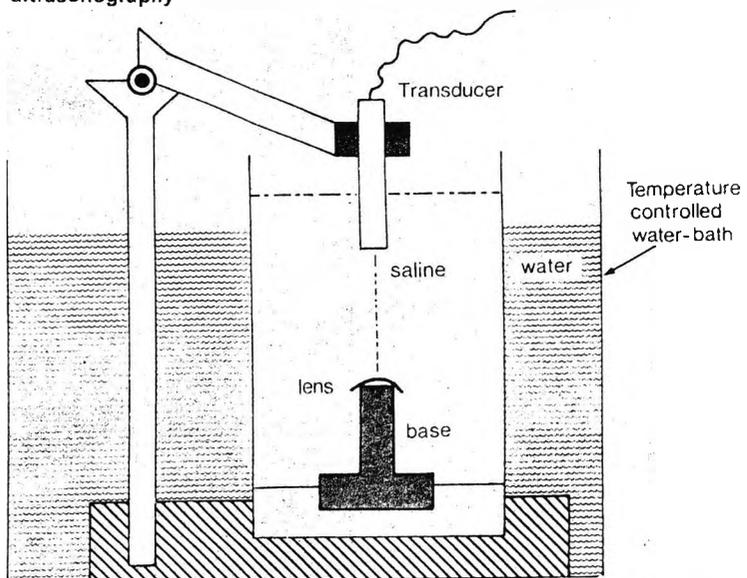
CT = 4mm

Sagitta

Support pillar

← 10mm →

BCOR accurate to 1-2 Newton rings
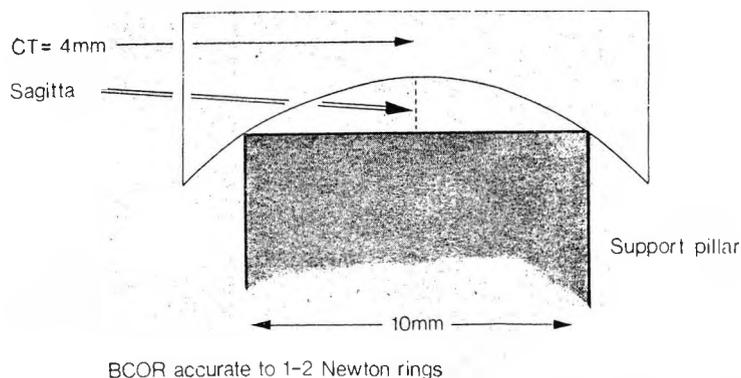
Fig 3: Calibration template, made from Perspex

RTT
(micro-
secs)

7.0   BCOR (mm)   12.0
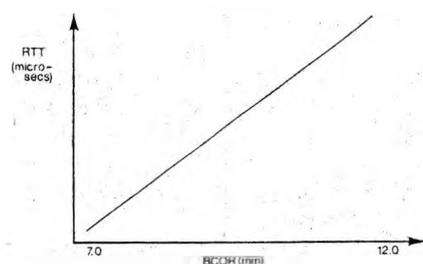
Fig 4: Graph for plotting 'round trip time' against radius

the velocity of sound in saline at the specified temperature) and then this distance (the sagitta) can be converted to a radius by established formulae, or one can use a series of templates (see Fig 3) made of a rigid material to obtain time measurements for a range of radii — a graph can then be plotted with 'round trip time' (RTT) against radius (see Fig 4).

An ultrasonic beam is reflected when there is a change in acoustic impedance (akin to a change in density). In the method described this will occur three times (see Fig 5). These reflections are visualised on an oscilloscope screen (Fig 6). By superimposing a time marker trace the time between each reflection can be measured. These round trip times relate to lens centre thickness and sagitta; the lens is supported on a rigid pillar of known diameter. The apparatus as shown in Fig 2 is placed inside a thermostatically controlled water-bath. The temperature of measurement can thus be controlled very accurately. It can either be kept at a constant temperature or varied if one is looking at the

effect of temperature on the lens radii. Thus, if the temperature is known, and the pH and tonicity are specified, the measurements obtained have a little more meaning.

It was found (Port 1975) that accuracy of measurement of the BCOR (soft lenses) was not dependent on lens thickness or radius to any significant extent. It varied with the individual dynamic properties of the lens material. Hence when specifying the accuracy of any soft lens radius measurement system the accuracy needs to be qualified for particular materials. If there is very minimal mechanical disturbance to the lens when it is positioned for measurement and the lens has time to recover its 'natural' form then this factor is less relevant. The basic accuracy of the system can be determined by using rigid materials. This can be quite different from that obtained when using hydrophilic/flexible materials whose dynamic properties will vary with the material.

Exactly the same principle can be used to measure the front surface curvature (Fig 7). The

lens positioned as in Fig 8 shows the effect of temperature on the FCOR. Hydron lenses steepened by 0.45mm when the temperature was raised from 20 to 30°C. Sauflon 70 lenses steepened by 0.8mm for the same temperature rise. Further results showing the effect of temperature on FCOR and BCOR will be published in the future. Initial results show that radius affects the amount of change to a small degree but the main differences are related to actual material. These changes occurring with temperature have relevance to soft lens fitting principles.

Assessing water content of soft lenses

The water content of the lens material will affect the amplitude of the reflected pulses visualised on the oscilloscope screen. The density will determine how much energy is reflected from the interfaces and how much is transmitted. By comparing the amplitudes of the first and third reflections (Fig 9) an assessment of water content is possible. The actual lens curvatures will also affect the energy reflected and transmitted as the ultrasonic beam is not infinitely thin. It may well be possible to introduce a factor relating to lens power to make the assessment more accurate. More complete results will be published in the future.

Centre thickness

The radiuscope method of measuring the centre thickness of soft lenses described by Sarver is perfectly adequate for most purposes. The problem of using ultrasound is to determine the sound velocity in the particular lens material and without this information one cannot convert the time measurement between the first two reflections to a distance. However, given a range of lenses of the same material, it is easy to determine the percentage differences in thickness. The thickness is proportional to the time
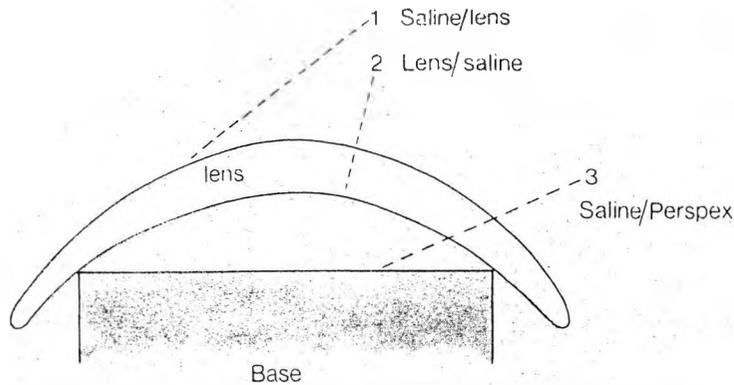
Fig 5: Interfaces 'detected' by ultrasonic beam

Fig 6: Visual detection of interfaces

Oscilloscope screen
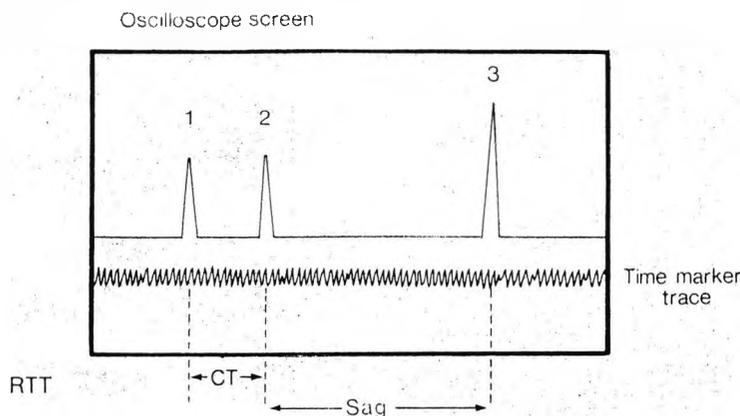
measurement if the velocity is constant. It is also straightforward to establish a linear regression equation so that thickness can be found using ultrasound for a particular material: one determines the thickness with a radiuscope for say 10 lenses of the same material and take 10 time measurements on the same lenses. Thus, for each lens one has a thickness measurement in mm and time (microseconds). With this data a linear regression expression can be obtained so that a time measurement of lens thickness for that particular material can be converted to mm

eg $CT(mm) = [RTT (\mu secs) \times 1.032] - 0.120$

Soft lens tomograms
To obtain a cross-section of a lens, a transducer can be scanned

across the lens (see Fig 10). The reflections at the lens interfaces can be converted to points of light rather than be displayed as the normal pulse envelopes. By using a storage oscilloscope the points of light can be dis-

played to form a tomogram. The composite display can then be photographed or written out on an X-Y plotter.

Lens diameter
It would be quite simple to move an ultrasound transducer across the 'diameter' of a soft lens in saline to measure the diameter, but, again, conventional methods using graticules in conjunction with magnifiers or projectors seem perfectly adequate.

Refractive index
Having measured the FCOR, BCOR and centre thickness under the same conditions it is possible to deduce the refractive index if the power of the lens can be measured accurately. The author has used a computer to explore this method.

Present research
Currently a digital read-out of the time measurement is being employed. This is very much quicker than using the calibration trace on the oscilloscope screen. Fig 11 shows that the counter can be switched to measure the time relating to sagitta or thickness. With very thin soft lenses the second reflection peak is not well separated from the first and thus the counter will not trigger correctly. The resolution of the system needs to be improved so that the thinner lenses now

Fig 7: Measurement of convex surfaces

Sagitta of surface is x-y

FCOR
mm

Change in radius

13   20   30   37   Temp °C

FCOR temperature coefficient $\uparrow^{30}_{20}$ = −0.08mm/°C (Sauflon 70)

−0.045mm/°C (Hydron)
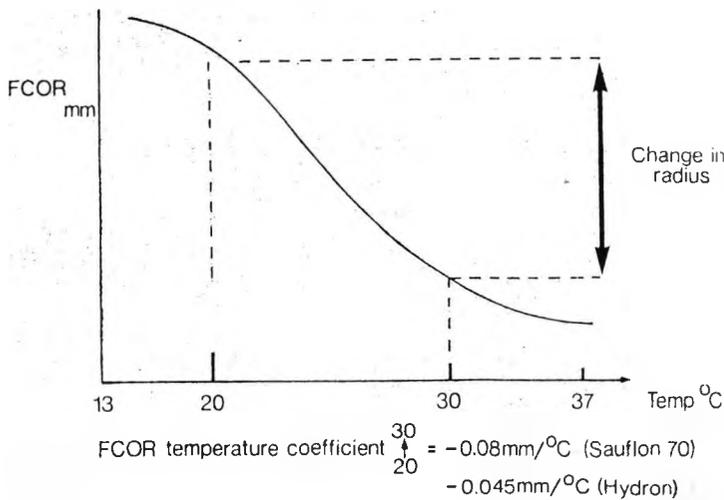
Fig 8: Effect of temperature on the FCOR

Fig 9: Assessment of water content is possible by comparing amplitudes of first and third reflections

High water contact lens

Low water content lens

R.1 low as material density approaches that of water

R.1 higher as lens material density approaches that of Perspex
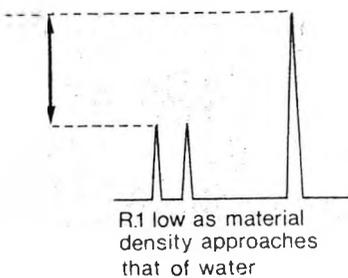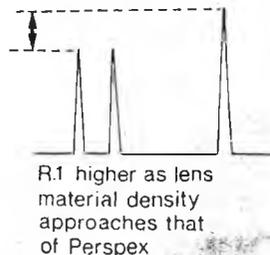
Fig 10: To obtain cross-section of a lens, transducer can be scanned across the lens

Transducer

D
C
B
A
Lens

CC

A
B
C
D

Lens tomogram
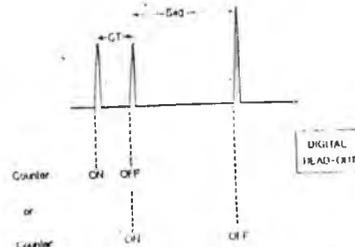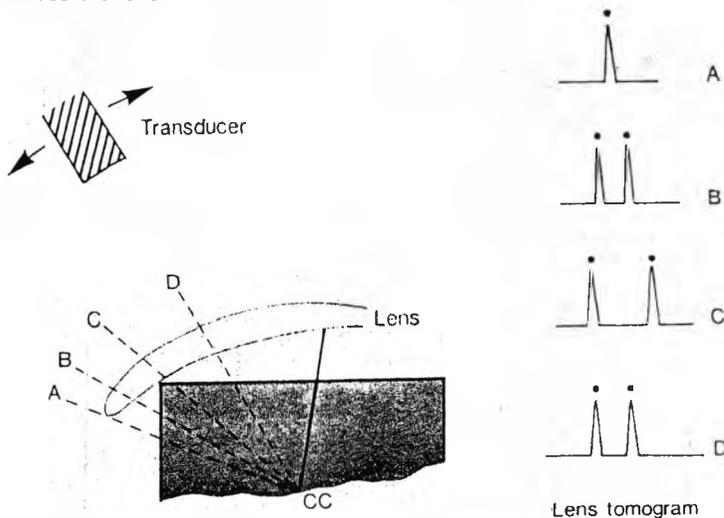
Fig 11: Counter can be switched to measure time relating to sagitta or thickness

being made can be measured. Various avenues are being explored with a view to increasing the resolution.

Mark III and Mk IV models are in the design stage. These, hopefully, will give a more compact and cheaper model. It is possible that models for practitioners and manufacturers will be available in the future.

Examining and measuring soft lenses by ultrasound enables us to monitor lens changes when environmental factors are altered. Changes occurring in hydration can also be investigated: it may well be that there are factors in lens hydration that are unknown or at least ignored by manufacturers at the present time.

With the present system aspheric surfaces cannot be measured. Toric surfaces cannot be measured with the present apparatus. The author feels at this stage that to measure spherical surfaces under standard conditions may be more useful. With aspheric surfaces sagitta measurements can be obtained and this is quite useful as far as fitting lenses is concerned if one has an aspheric back surface.

Ultrasound holography could well be a useful tool in looking at aspheric and toric surfaces if one is looking for a measurement system that is not dependent on light.

REFERENCES
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Loran, D. F. C., (1974) Ophthal Optic, 14, 980.
Port, M. J. A. (1975) MSc Dissertation, University of Aston in Birmingham.
Port, (1976) In preparation.

Appendix 4

The measurement of soft lenses using ultrasound

M.J.A.Port

The Measurement of Soft Lens Surfaces Using Ultrasound

M.J.A. Port, M.Sc., F.B.O.A., F.S.M.C., D.C.L.P.

Abstract

Latest developments in a measurement system that utilizes ultrasound (ultrasonics) to ascertain the sagitta of convex and concave surfaces on soft lenses in a controlled environment are described. The problem of measuring and comparing spherical and aspheric surfaces is discussed. The question is raised as to whether radius measurement is the best way to compare soft lenses of the same diameter.

At present there are six main methods of measuring the curvatures of soft lens surfaces. Most of these are concerned with the measurement of the back central optic radius (BCOR). The methods are as follows: (1) Radiuscope (adapted). (2) Keratometry (ophthalmometry). (3) Projection technique (Sohnges). (4) Hemispherical template matching. (5) Interference methods. (6) Sagitta determinations by mechanical means (a) in air and (b) in saline.

The author has used the sagitta method of determining the radius but has used very high frequency sound (ultrasound or ultrasonics) rather than a mechanical method to find the sagitta. The relationship between sagitta and radius is shown in Figure 1.

Figure 2 shows how an ultrasonic transducer is mounted concentrically with the lens to be measured. Both are immersed in a common saline solution at a known temperature. The characteristics of the transducer are as follows: The pulsed beam is focused at 50mm, the beam width at the focus or waist of the beam is 1 to 1½mm and the frequency is 30MHz.

Sound reflections from interfaces of different acoustic density can be visualized on an oscilloscope. Figure 3 shows three interfaces, and Figure 4 shows the reflection as seen on the oscilloscope screen. It is very simple to measure the "round trip time" (RTT) between these reflections, either with a calibration time trace on the screen or with an interval counter. The latter is very quick and provides "averaging" facilities. Knowing the velocity of sound in saline at a given temperature, the time measurement can easily be converted to a distance (the sagitta) and the radius determined.

The latest form of the apparatus is shown in Figure 5. The lens is inserted just below the surface of the saline onto a perspex cylinder with

Figure 6. The time locked artificial reflection (3a) is shown. Amplitude Y opens the counter gate. Amplitude Z closes the counter gate. Position of peak 2 varies with BCOR.

Figure 5. Latest design of measurement cell and temperature control system.

Figure 7. Arrangement of apparatus to measure the anterior radius of a soft lens.
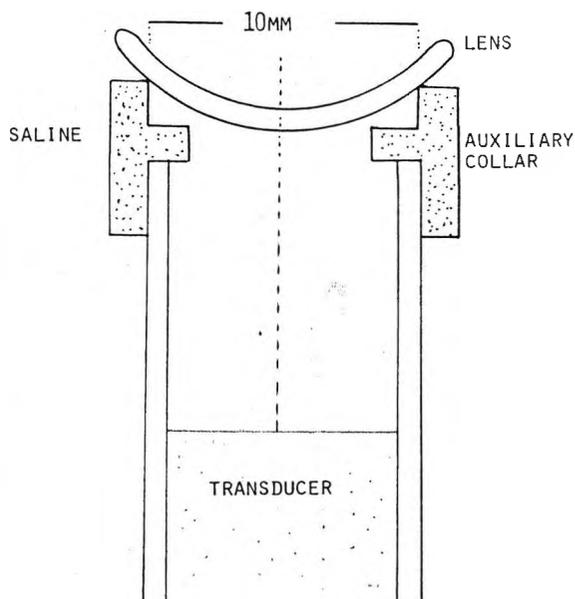
	Round Trip Times (μsecs) *Independent Trial No.*						
Lens	*1.*	*2.*	*3.*	*4.*	*Mean*	*SD*	*Radius*
5.00	3.13	3.15	3.14	3.14	3.14	0.007	7.38mm
-7.25	3.17	3.18	3.18	3.18	3.18	0.004	7.12
-9.00	3.23	3.22	3.21	3.23	3.22	0.008	7.00
-7.50	3.12	3.10	3.09	3.11	3.105	0.01	7.32
-8.75	3.14	3.14	3.12	3.12	3.13	0.01	7.25

Table I. Results of five HEMA lenses.

(CENTER OF CURVATURE)
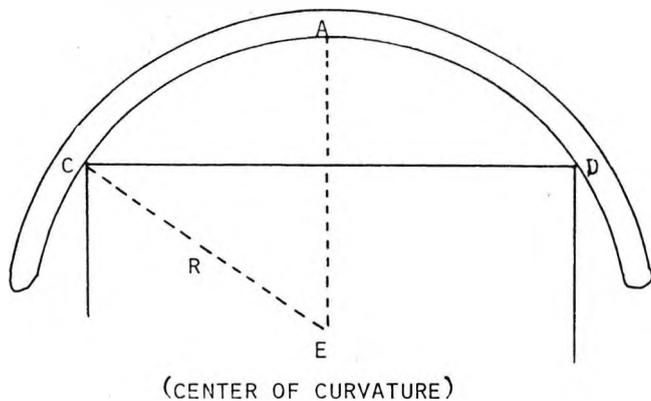
Figure 1. $(CE)^2 = (CB)^2 + (BE)^2$.
$R^2 = (CD/2)^2 + (R - AB)^2$.
AB = sagitta.
CD = outside diameter of cylinder.
R = radius to be measured.
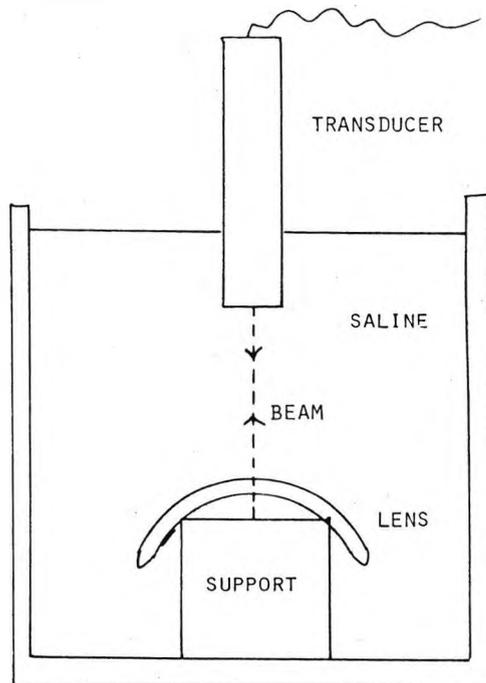
Figure 2.
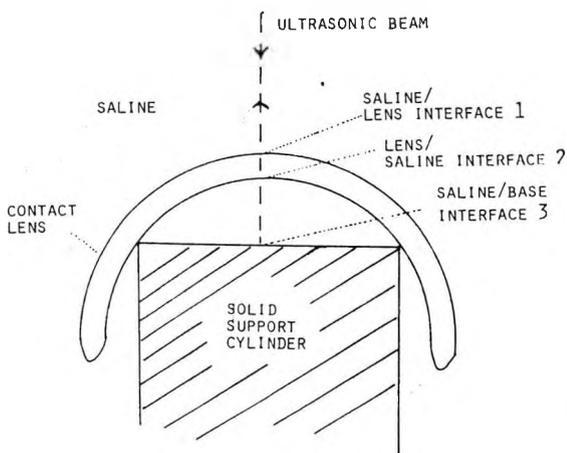
Figure 3. Reflections of the ultrasonic beam occur at the three interfaces shown.

Figure 4. The three interface reflections shown in Figure 3, as displayed on the oscilloscope screen. Below the three peaks trace is a calibration time marker trace.
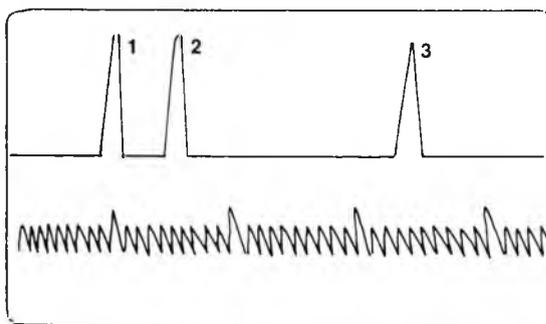
an outside diameter of 10mm. The temperature of the saline is controlled. Reflections of the ultrasound beam are only produced from two interfaces, i.e., the back and front surfaces of the lens. To produce a reference point for measurement, an artificial reflection is generated electronically and displayed on the oscilloscope screen (Figure 6).

To measure the front curvature of the lens, an auxiliary collar with an inside diameter of 10mm is attached to the top of the cylinder (Figure 7).

Table I shows results from a series of five polyHEMA lenses. Each lens is subjected to four independent trials. The RTT variance can be seen; the means, standard deviations and BCORs are shown. A change in RTT of 0.02μsecs is equivalent to a radius change of approximately 0.02mm. Taking all sources of error into account, the accuracy of the whole system is on the order of 0.05 mm.

The RTT can be converted to a radius on theoretical grounds using a series of mathematical formulas. Because of small variations in sound

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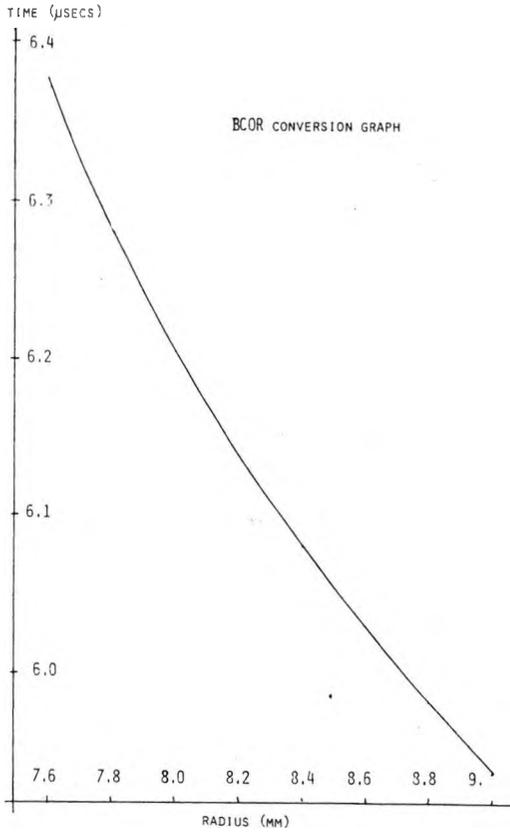
Figure 8. BCOR conversion graph.
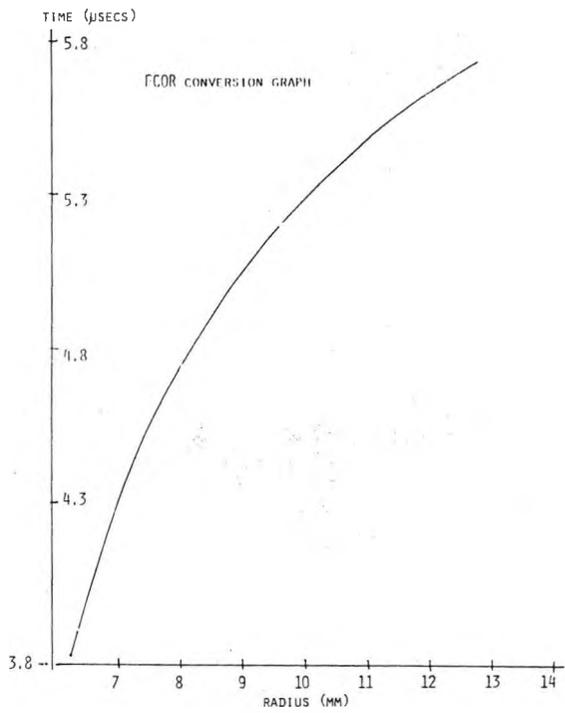
Figure 9. FCOR conversion graph.
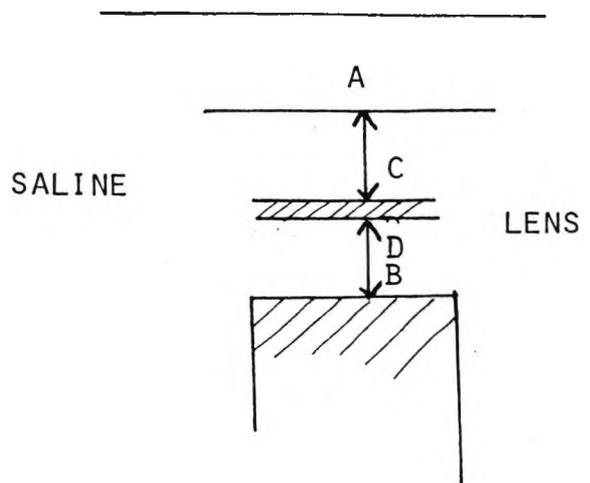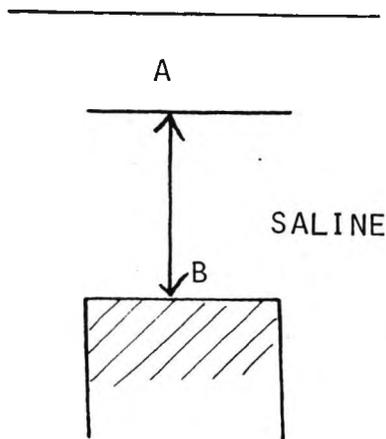
Figure 10. CD = AB — (AC + BD). AB = RTT_1 x V/2. Ac = RTT_2 x V/2. BD = RTT_3 x V/2. CD (lens thickness) = V/2. [RTT_1 — (RTT_2 + RTT_3)] . V = velocity of sound in saline at known temperature. A and B are reference surfaces or points. C and D are the contact lens surfaces.

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characteristics, the radius will vary from that determined from a calibration curve; for this reason, we prefer to use a graph to obtain radius measurements. For convex surfaces, a series of precision steel balls can be used to obtain time measurements for the conversion graph. For concave surfaces, a series of very accurate perspex plane concave test plates was used. Figures 8 and 9 show typical calibration curves for concave and convex surfaces, and from these it is very simple to convert RTT to a radius. Knowing the equation of the calibration would make it possible to use a programmed calculator or computer. One would only need to input the RTT value from digital counter to obtain the radius, assuming that the temperature of the saline was always the same.

Environmental Effects. The biggest failing of most measuring systems occurs because the contact lens environment is not constant. Methods involving measurement in air are particularly poor in this respect as one is bound to get large differences in surface deformation and drying of the lens surfaces with various materials and lens thicknesses.

Lenses should be placed in a cell which should have a standard and known temperature, tonicity and pH. When this is achieved, we are halfway towards measuring lenses accurately. Considering the rapidly expanding range of materials and water contents, only a system that does control the lens environment can have any real claim to accuracy. With ultrasound, the environment has to be constant, as the velocity of sound varies with temperature and the composition of the medium.

Advantages. Besides the above advantage of having a very controlled environment for measurement, the method makes it possible for the sagitta to be measured without any mechanical interference with the lens, and this makes an important contribution to accuracy.

The surface of the lens does not have to be polished. The curvature of purely lathe-cut surfaces can be measured just as accurately, as the method is not dependent on light reflection for measurement.

Disadvantages. This method, like all other methods of measurement, relies on the belief that one is looking at a truly spherical surface, and all assumptions and calculations are based on that premise. That we get disparate results from different methods when measuring the same lenses would lead to the conclusion that soft lens surfaces are not always spherical.[1] It is not possible to measure toric lens surfaces with the present apparatus, but it is possible with the radiuscope and keratometer.

Lens Thickness. If the velocity of sound within a particular material is known, then it is simple to obtain the thickness. This data is not normally available. One can obtain the thickness without knowing the velocity within the material as long as there are two surfaces of reference points either side of the lens within the saline (Figure 10).
□

Reference
1. **Port, Michael**: "The Hydration Geometry of Hydrophilic Materials," *Contacto*, 23(5), 10-13, 1979.

Discussion

It is unfortunately still an uncommon experience in contact lens practice to find that two lathe-cut soft lenses of the same nominal specifications perform quite differently when placed on an eye. This problem will only be eliminated when both laboratories and practitioners are able to measure lenses with sufficient reliability and confidence that agreed standards and tolerances can be rigorously observed.

The present availability of several different methods for measurement of the back central optic radius illustrates a variety of approaches to an elusive problem. A complication is the fact that the dimensions of a soft lens are influenced by the nature of its surroundings. It is so much easier to tackle the problem of measuring the length of a piece of plastic! Michael Port's novel use of ultrasound is an attractive proposition because it permits accurate measurements of several parameters with the lens in a controlled environment. Apart from the question of cost, the factor most likely to detract from the popular use of ultrasound is the fact, duly acknowledged by Mr. Port, that toric lenses cannot be measured

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Appendix 5

The measurement of soft lens radii by proximity gauging

M.J.A.Port

THE MEASUREMENT OF SOFT LENS RADII BY PROXIMITY GAUGING

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Abstract—Thirty hydrogel lenses with a water content of 60% were examined in the Kelvin Soft Lens Measurement Gauge in order to assess their back central optic radii (BCOR). The accuracy, repeatability and limitations of the equipment were considered. The proximity gauging principle avoids central touch of the lens by a probe at the time of measurement. This factor almost certainly contributed to the good measurement consistency obtained (a modal SD of 0.02 mm for four radius measurements).

INTRODUCTION

The principle of proximity gauging (Smith, 1966) has been used in the contact lens industry to determine the back optic central radius (BCOR) of semi-finished hard lens and xerogel blanks. The sagitta or sag, s, is measured for a chord equal to the diameter of the blank support, d. The radius, r, is then given by:

$$r = \frac{d^2}{8s} + \frac{s}{2}.$$

The sag is found by means of a pneumatically-controlled central probe which approaches the vertex of the concave lens surface. The apparatus is designed so that the probe stops at a pre-set distance from the surface to be measured. The true sag is then the distance travelled from the plane of the lens support plus the pre-set distance. The method is quick and simple and has the advantage that there is physical contact only where the lens is supported, no contact being made between the probe and the vertex of the surface during the measurement.

Sagitta determination has frequently been used in equipment for BCOR determination. Manufacturers using a central probe for radius measurement in air include Medicornea, Neitz, Reid Prentice, Rehder Development and Wohlk, while equipment for similar measurements in saline has been produced by Contact Lens Manufacturing, Optimec and Titmus Eurocon.

The application of proximity gauging to soft lens measurement was pioneered in the U.K. by Kelvin Lenses Ltd. The lens is measured in saline rather than in air, so that it remains in equilibrium with its environment (Port, 1980). The motorized probe of the instrument is made of glass and has two electrodes flush with its polished convex surface. An electrical field is created between the electrodes when the probe is in saline and the properties of this field change as the probe approaches the lens surface. Unfortunately, it was found that the water content of the lens material also affected the field when the probe was in close proximity to the lens surface. The radius indication occurred at different distances from the lens surface according to the water content of the lens material. A control was incorporated into the equipment so that the user could

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*Fellow of the British College of Ophthalmic Opticians (Optometrists).

compensate for this effect but, because this compensation is not precise and the instrument cannot be calibrated with a rigid surface of known curvature, the system cannot give direct radius estimates but only radius comparisons.

The aims of the present study were to investigate results obtained with medium water-content hydrogels in the Kelvin apparatus. In particular, measurement consistency was assessed in relation to the SD of the radius measurements. It was also considered to be important to evaluate the repeatability of the results if the equipment settings were changed and then readjusted for a known material.

EQUIPMENT AND TECHNIQUES

The Kelvin Soft Lens Measuring Gauge

The apparatus consists of three separate parts:

(1) The wet cell for lens measurement which contains the lens support and a centration device. Beneath the wet cell is the motorized probe unit (Fig. 1).
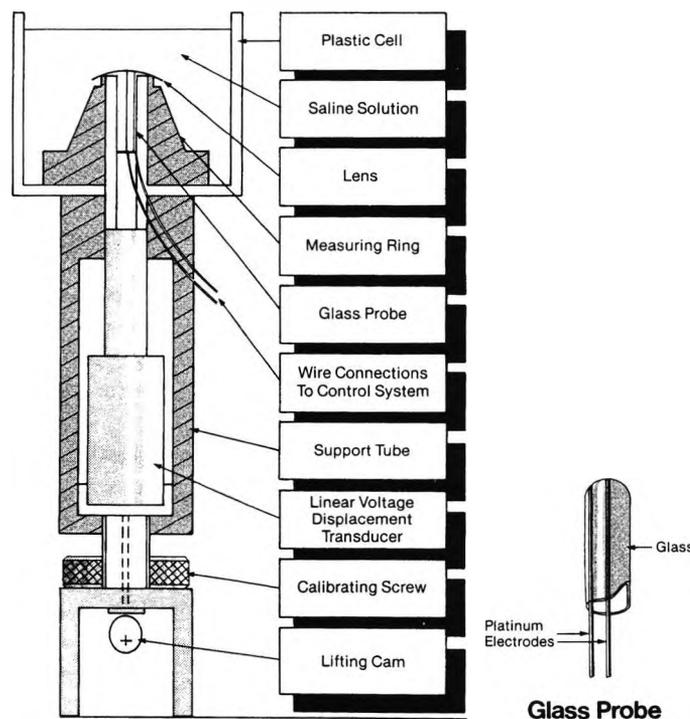
Fig. 1. A cross-section of the Kelvin Soft Lens Measuring Gauge showing the essential components.

(2) A unit to display the BCOR in digital form. A microprocessor converts the sagitta to a radius value. This unit incorporates the water-content control (Fig. 2).

(3) A foot-operated electrical switch. This cancels the previously displayed radius and starts the probe motor.
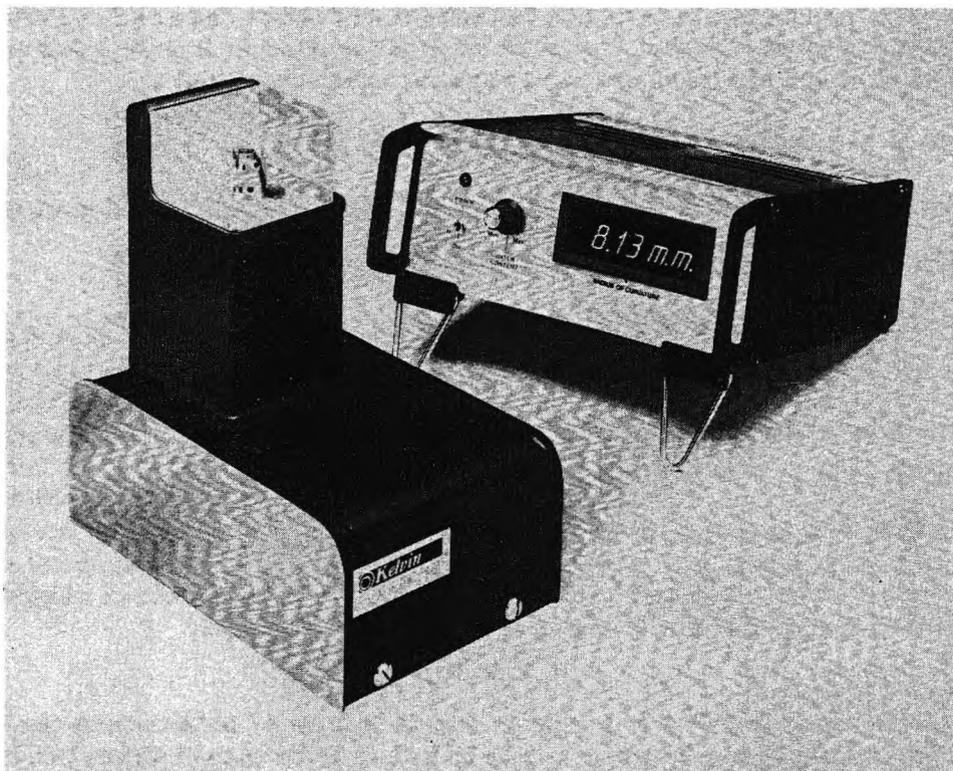
Fig. 2. The two main units of the Kelvin measurement system. On the left is the wet cell together with the motorized probe mechanism and on the right the unit housing the control system and digital read-out.

Operating the system

A soft lens to be measured is positioned on a stainless steel annulus in the wet cell. The support annulus is 10 mm in diameter. The operator initiates the system by operating the footswitch after which the motorized probe rises vertically and concentrically through the support annulus. The radius is shown on the LED display before the probe touches the concave lens surface. The probe always then continues until it reaches its full travel, where it reverses and returns to its start position. During this travel the lens is lifted slightly off the support cylinder. As the probe descends the lens is deposited back on the support. Normally the lens is recentred quite adequately but occasionally there is some greater displacement and in some instances a lens will fall off the support.

The manually-operated centration device provided with the equipment was not used. It was found to work reasonably well with some lenses and badly with others. The operator had to hold the device below the surface of the saline and visability of the lens was hindered when the centration device was *in situ*. Centration devices in other soft lens measuring equipment have proved to be very effective (Port, 1981).

Lens selection

In a larger study, lenses of different powers and radii were manufactured from six different materials. In this report, 30 lenses of one material were used. The lenses were manufactured by Cantor & Silver Ltd. out of their 60% water-content material (CS 60).

Four radius groups were examined, viz. 8.2, 8.4, 8.6 and 8.8 mm, and an 8.2-mm radius lens with a power of $+9$ D was used as the "control" or reference lens. All lenses were 13.5 mm in overall size and powers were within the range $+9 - +15$ D.

Environmental conditions

The saline wet cell of the apparatus was not temperature-controlled. The saline temperature throughout the study was $19.8 \pm 0.8°C$: pH was 5.7 ± 1.4. The saline was 0.9% sodium chloride solution without preservative.

Experimental plan

The aims of the experiments were three-fold. First, to obtain a mean radius estimate $(\bar{R}_m)$ from four independent measurements on each lens, where the mean radius value was related to the stated radius (R_s) of the control lens rather than to that of a rigid calibration surface. Second, to calculate an SD for each set of four trials to obtain an indication of measurement consistency. Third, to investigate the apparatus repeatability (see later). Ideally, the test procedures would subject each lens to four completely independent trials, where each trial comprised lens removal from its vial, transferrence to the wet cell, centration on the lens support, equilibration in the wet cell saline, radius measurement and return of the lens to the storage vial. In practice, a less time-consuming procedure which still preserved a high degree of independence in each trial was employed.

Experimental procedure

The control lens, of nominal 8.2 mm radius, was placed in the wet cell and equilibriated in the saline for 5 min. It was then positioned and centred on the lens support with a nylon lens lift. The water-content control of the Gauge was altered from the "High" towards the "Low" position until the indicated radius measurement (R_m) was close to 8.2 mm. The water-content control was left in this position for the first 156 measurements, to obtain the radius means which were designated $1 - 39$.

The first three lenses to be measured were added to the wet cell with one lens in each corner for identification purposes; these lenses were also equilibriated for 5 min. The control lens and the three other lenses were measured once in turn. This cyclical measurement process was repeated until each lens had been measured four times. The means $(\bar{R}_m)$ and SDs were calculated for each lens and recorded, the mean for the control lens being designated mean 1 and those for the other lenses means $2 - 4$. The latter three lenses were then returned to their storage vials. The next three lenses to be measured were positioned in the saline and equilibriated and measured as before, to give control mean 5 and lens means $6 - 8$, and so on. The control lens remained in the wet cell throughout. All lenses were subjected to the same treatment. Thirty-nine means were obtained, 10 of which related to the control lens.

Repeatability tests

In normal contact lens practice the apparatus would be used to measure lenses of different materials. In order to obtain meaningful results the apparatus has to be readjusted for different materials. It is essential that adjustment for a previously used material will give repeatable measurements for that material. In order to find the optimum method for adjusting the equipment two experiments were performed.

Experiment 1. After means $1 - 39$ had been obtained the water-content control (Fig. 2) was altered and then repositioned visually to be as close as possible to the original setting.

Experiment 2. The water-content control was altered. Before the control was repositioned the control lens was centred on the support. The water-content control was then carefully adjusted so that the lens radius came as close as possible to 8.2 mm. The first three lenses to be measured together with the control lens were again subjected to the aforementioned procedure to obtain means 44 – 47.

RESULTS AND DISCUSSION

The control lens

A mean BCOR $(\bar{R}_m)$ for this lens was obtained 10 times among the first 39 means. The mean of the 10 $\bar{R}_m$ values was 8.24 mm (SD 0.01 mm). Thus, if four trials are used to obtain a mean value, this mean will have a stable value. The range of raw score measurements for the control lens was $8.16 - 8.28$ mm. The average SD was 0.02 mm (range zero $- 0.04$ mm).
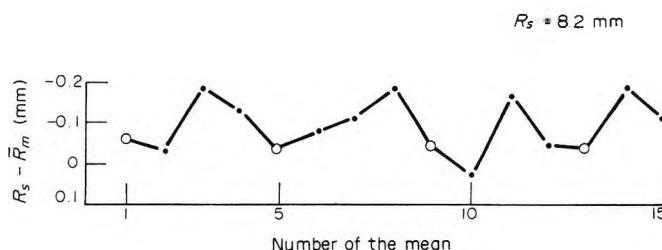
Fig. 3. Results for 12 lenses, one of which was the control lens, all having a nominal specified radius, R_s, of 8.2 mm. The difference between the R_s and the mean experimental radius, $\bar{R}_m$, is plotted against the number of the mean. ⊙ denotes the results for the control lens, which was remeasured with each group of three lenses.
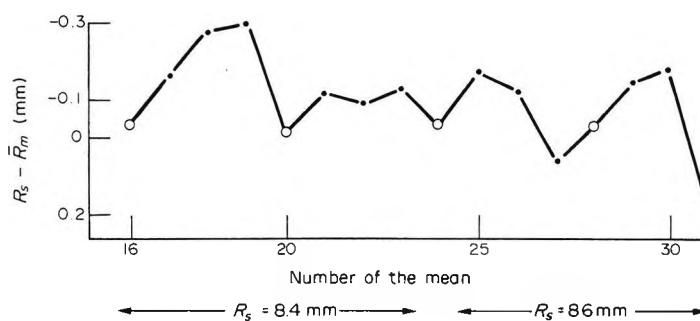
Fig. 4. Results for lenses having different specified radii. The difference between the specified radius and the experimental mean radius is plotted for each lens against the number of the mean. Six lenses have a specified radius of 8.4 mm and six a specified radius of 8.6 mm. ⊙ denotes results for the control lens which was remeasured with each group of three test lenses.
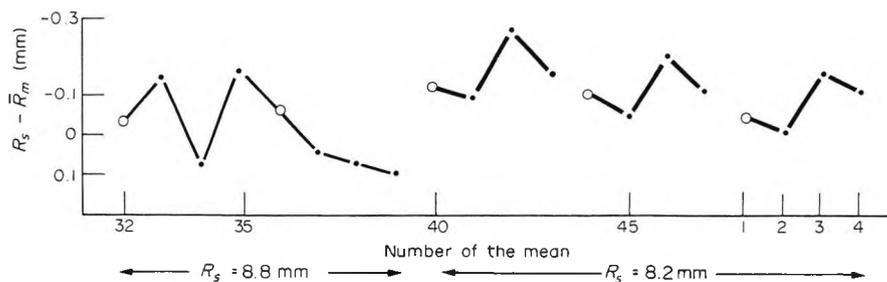
Fig. 5. The difference between the specified radius and the experimental mean radius plotted against the number of the mean. Means 33 – 35 and 37 – 39 refer to lenses with a specified radius of 8.8 mm. Means 40 – 43 show the results obtained in experiment 1 of the repeatability test. Means 44 – 47 are those obtained in experiment 2 of the repeatability test. Means 1 – 4 are included for comparison. ⊙ denotes results for the control lens.
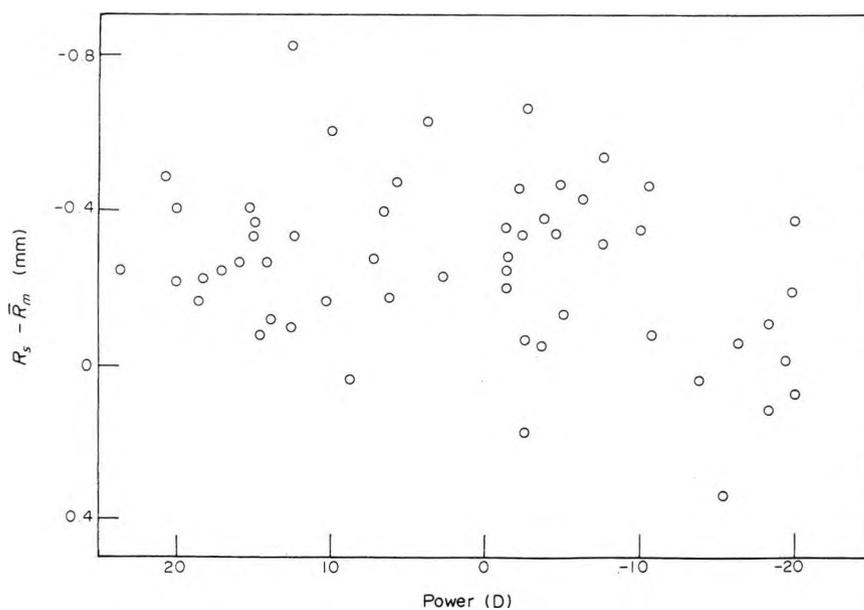
Fig. 6. A scattergram of the difference between the specified radius and the experimental mean radius as a function of the lens power.

The radii groups

The difference between the specified radius (R_s) and the experimental mean $(\bar{R}_m)$ is shown graphically in Figs 3 – 5. The lenses are not designated by their power. Results from the larger study showed that there was no predictable trend when $R_s - \bar{R}_m$ values were plotted against power (Fig. 6).

The British Standard Institution's tolerance for the radius of hydrated soft contact lenses is ± 0.2 mm (British Standards Institution, 1978). In the present study, 17, 40, 60, 93 and 100% of the values of $\bar{R}_m$ lay respectively within 0.05, 0.1, 0.15, 0.2 and 0.3 mm of the corresponding value of R_s.

The difference between the radii groups was 0.2 mm in specification. Measured values gave inter-group differences of 0.27, 0.08 and 0.14 mm. The range of SD values is shown in Fig. 7. The range of all SD values found in the larger study, involving six different types of material, is shown in Fig. 8 for comparison.
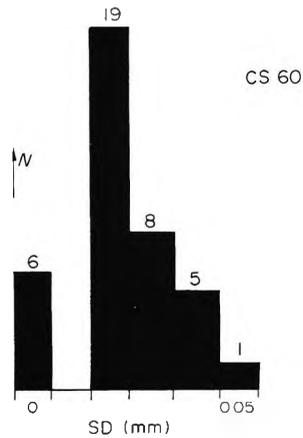
Fig. 7. The distribution of SD values found for means 1 – 39. The modal value is 0.02 mm.
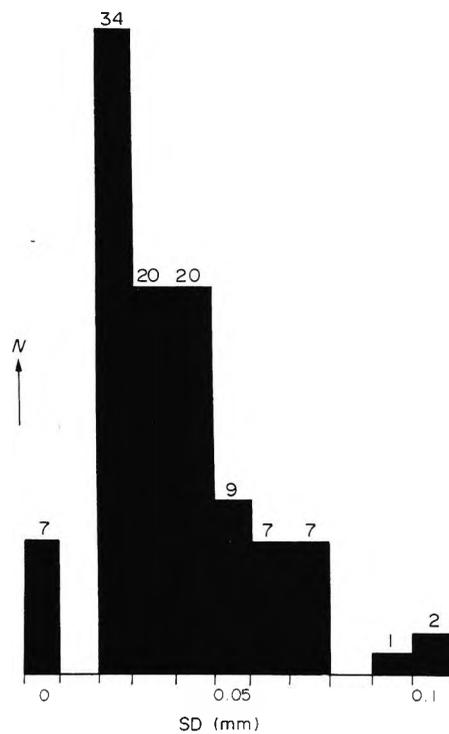
Fig. 8. The distribution of SD values of the 107 means obtained in the complete study. Lenses were made of Sauflon 85, Sauflon 70, Duragel 75, Duragel 60, CS 60 and Weicon. The modal value is 0.02 mm.

The repeat tests

Means 40 – 43 were approximately 0.06 mm flatter than means 1 – 4. Means 44 – 47 were on average only 0.01 mm flatter than means 1 – 4. In both repeat tests the four lenses involved were placed in the same order of steepness and flatness (Fig. 5).

CONCLUSIONS

For good repeatability it was essential to rely on a control lens and a stable environment. If the operator relied on setting the water-content control to a value previously used for the same or a similar material then the variation in mean value could be up to 0.1 mm. Due to the electrical characteristics of different materials it is not possible to have a single calibration surface. Therefore calibration prior to use is required using a lens of the same material and of known radius.

If it were possible to nullify these different material characteristics and a single calibration surface could be included in the system, the apparatus would be transformed from a comparative to a true measurement system.

At present, assuming a constant environment, there is a 98% certainty that any single reading is within 0.07 mm of the mean value (of four trials) with the material being tested. The maker's claim of 0.04 mm for consistency appears to be well substantiated (approximately 2 SDs in this study). The instrument is designed to be a comparator and it fulfils this role very well. It is possible to grade in terms of radius a range of lenses of a particular material if its characteristics are known by a relationship to the known BCOR of the control lens of the same material. The user needs to have a range of control lenses made from materials that are likely to be encountered in contact lens practice. If the material of any lens is not known, the apparatus is of little value. The user has also to assume the accuracy of control lenses, unless he has some other apparatus with which this can be verified.

From the results of this particular study and considering the errors found, it would seem more appropriate for the manufacturer of the series of lenses tested to market this particular design and material in 0.4 mm steps rather than the present 0.2 mm steps.

The apparatus provided measurements in some 20 s and this compared favourably with other apparatus tested (Port, 1982). If the apparatus was to be developed further it would seem important to consider an alternative centration method and the option to incorporate a temperature control system into the wet cell.

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Appendix 6

The Optimec contact lens analyser

M.J.A.Port

contact lenʃ monthly

The Optimec contact lens analyser

Michael Port

THE instrument was designed to measure the three essential soft contact lens parameters these being the BCOR, CT, and OD in saline. There are two forms of this particular apparatus and these only differ in the nature of the wet cell that holds the lens. One model has a temperature controlled wet cell so that the saline can be held at a pre-selected temperature and the other model has no such control facility so that the temperature of the saline in the wet cell will be controlled by the ambient air temperature. If the later model is used in a controlled environment there is little problem, but where such an environment does not exist the model with the temperature controlled wet cell is to be recommended.

Instrument principles. The soft lens was supported convex side up on a vertical cylinder 8.50mm in diameter and a cross section of the lens projected on to a translucent screen viewed by the operator. The magnification was 15 times.

Diameter measurement. A calibrated movable scale was moved horizontally across the screen to measure the lens diameter. Diameters between 8 and 17mm can be measured to 0.1mm.

Radius measurement. The radius was measured by manually raising a probe in the centre of the support cylinder until its upper surface touches the concave side of the soft lens. This was best done by detecting a small degree of lift of the lens centre and lowering the probe by the same amount. Repeating this process two or three times enabled a good end point to be achieved. The probe adjusting knob has a scale attached so that radii between 6.5 and 9.5mm can be recorded to 0.01mm. The radius measurement depends on measuring the sagitta of the surface above an 8.5mm chord and converting the sag directly to a radius.

Thickness measurement. This was measured by lifting the lens slightly off the support cylinder by means of the central probe, aligning the zero mark of the thickness scale with the apex of the lens front surface, and then completely lifting the lens up by means of the centring device so that the lens does not obscure the image of the probe tip. The point where the

uppermost part of the probe tip intersects the thickness scale gave the lens centre thickness. Thicknesses up to 1.4mm can be measured to 0.02mm intervals.

Method of measurement. The wet cell was filled to within 5-8mm of the top with fresh unpreserved 0.9 per cent saline and the temperature and pH recorded at the beginning of each measurement session.

A soft lens was removed from its vial (also at the same ambient temperature as the wet cell) with a plastics ointment applicator and placed concave side down on the lens support pillar. The centring device within the wet cell was used to centre the lens prior to measurement. The lens was left for 30 seconds then the diameter, thickness and radius were measured in that order. The lens was then returned to its own vial and the next lens in a series was then measured in the same way. When the last lens in a series had been measured, lens number one was then measured again. The process was continued until each lens in a series had been measured four or five times independently. The means and standard deviations were then computed. With lenses over 60 per cent water content it was advantageous to leave the lens for about two minutes before recording any measurements.

Measurement of hard lenses. In order to ascertain the system's accuracy and consistency in measuring radius, six hard lenses were measured. Lenses 4, 5 and 6 had a BCOD of greater than 9.5mm. Each lens was measured independently five times.

Results

Lens no	Rm(mm)	SD	R(Radius-cope)	Rm—R
1	7.11	0.006	—	
2	7.65	0.009	—	
3	8.13	0.017	—	
4	8.58	0.018	8.57mm	+0.01mm
5	9.01	0.013	9.00mm	+0.01mm
6	9.54	0.030	9.52mm	+0.02mm

Results

Lens no	Rm(mm)	SD	Dm(mm)	SD	CT(mm)
1	8.35	0.006	12.96	0.05	0.42
2	7.63	0.017	12.75	0.03	0.45
3	7.88	0.020	12.85	0.03	0.42
4	7.96	0.018	12.84	0.04	0.45

The mean SD for radius measurement was 0.015mm and for diameter 0.04mm.

The generally higher value of SD with the flatter radii was not unexpected for two reasons. Firstly, a given probe movement will produce a wider change in radius at the flat end of the scale than at the steep end and secondly, a radius estimate from the instrument scale will be more difficult at the flatter radius section as the divisions are closer together.

The mean SD for the hard lenses tested was 0.015mm.

Measurement of soft lenses. Four poly HEMA Hydron Europe lenses of the same specification were used, this specification being: BCOR 8.3mm; diameter 13.0mm; power +14.50D.

Radius and diameter were measured independently five times but the thickness was only measured once.

The vials were then mixed and randomly designated w, x, y, z so that the operator did not know which of the four lenses was being measured. Each lens was then tested once.

Results

Lens	Rm	Assigned lens no.
w	7.95	4
x	8.35	1
y	7.62	2
z	7.89	3

The results only differed by ±0.01mm from the mean values obtained previously. Thus lenses of this material could be identified if mixed up inadvertently.

Following the above preliminary experiments it was decided to test other materials in a similar fashion to a previous study (Port, 1980). The materials chosen were: Menicon 30; Duragel 60; Sauflon 70; Duragel 75 and Sauflon 85.

Menicon

Lens no	Specification	$\overline{Rm}$(mm)	$\overline{Dm}$(mm)
1	8.2/13.0/ + 16.00	8.10	12.4
2	8.2/13.0/ + 5.00	8.06	12.9
3	8.2/13.0/ − 3.25	8.28	12.9
4	8.2/13.0/ − 18.00	8.06	12.6
5	8.6/13.0/ + 14.00	8.57	12.9
6	8.6/13.0/ + 5.00	8.60	12.75
7	8.6/13.0/ − 3.00	8.59	12.95
8	8.6/13.0/ − 18.00	8.73	13.05
9	9.0/13.5/ + 13.0	9.08	13.85
10	8.8/13.0/ + 5.00	8.58	12.8
11	8.8/13.0/ − 4.00	8.83	12.9
12	9.0/13.0/ − 18.00	9.01	13.1

Temperature range: 25.7 ±0.7°C
pH range: 7.0 ±0.2
SE(rad): 0.008mm

Duragel 60

Lens no	Specification	$\overline{Rm}$(mm)	$\overline{Dm}$(mm)
1	8.0/14.0/ + 14.00	7.89	14.6
2	8.0/14.0/ + 9.5	7.86	14.2
3	8.00/13.5/ − 3.25	8.01	13.7
4	8.0/14.0/ − 16.50	7.88	14.1
5	8.2/14.0/ + 18.00	8.08	14.3
6	8.2/13.5/ + 11.00	8.11	14.1
7	8.20/14.5/ − 5.50	8.27	14.8
8	8.2/14.1/ − 16.00	8.33	14.1
9	8.4/14.5/ + 16.00	8.45	14.6
10	8.40/14.0/ + 12.0	8.26	14.3
11	8.4/14.5/ − 4.50	8.44	14.6
12	8.4/15.0/ − 11.0	8.37	15.35

Temperature range: 27.1 ±0.1°C
pH range: 6.7 ±0.5
SE(rad): 0.011mm

Sauflon 70

Lens no	Specification	$\overline{Rm}$(mm)	$\overline{Dm}$(mm)
1	8.0/14.0/ + 18.00	8.05	14.18
2	8.00/14.0/ + 7.00	8.54	14.63
3	8.00/14.5/ − 1.00	8.49	14.22
4	8.0/15.0/ − 19.50	7.79	14.63
5	8.2/14.5/ + 15.00	8.27	14.3
6	8.8/14.2/ + 6.5	9.40	14.28
7	8.2/13.5/ − 1.00	7.68	13.5
8	8.2/15.5/ − 19.5	8.07	14.37

Temperature range: 27.1 ±0.5°C
pH range: 5.8 ±0.2
SE(rad): 0.014mm

Duragel 75

Lens no	Specification	$\overline{Rm}$(mm)	$\overline{Dm}$(mm)
1	7.8/14.0/ + 24.00	7.88	13.8
2	7.8/14.5/ + 7.00	7.88	14.7
3	7.8/14.0/ − 10.00	7.98	14.4
4	7.8/15.0/ − 19.00	7.83	15.2
5	8.2/14.0/ + 17.00	8.24	15.07
6	8.2/14.0/ + 7.00	8.34	14.10
7	8.2/13.5/ − 7.00	8.12	13.72
8	8.2/13.5/ − 18.00	8.25	13.25
9	8.6/14.0/ + 20.00	8.47	13.8
10	8.6/14.0/ + 3.00	8.40	14.3
11	8.6/14.5/ − 11.00	8.29	14.4
12	8.6/14.0/ − 20.00	8.14	13.8

Temperature range: 26.5 ±0.4°C
pH range: 6.7 ±0.3
SE(rad): 0.020

The lenses of each material were chosen to give a wide range of powers and a realistic range of radii. Each lens was measured independently three times and a mean obtained for the BCOR and diameter.

Discussion. Unfortunately the temperature controlled model was not available for testing. The author would have preferred to have the saline in the wet cell at 20°C rather than have the saline temperature governed purely by the ambient air temperature.

For the period of lens measurements the apparatus proved to be well manufactured and reliable.

The lens profile on the viewing screen enabled the operator to inspect the lens edge form adequately if this was required and diameters of front surface lenticulations could also be measured.

The centring device worked particularly well and is the best of its type amongst the centring devices encountered by the author.

The measurement time per lens was in the order of two minutes which allowed for equilibration and measurement of BCOR, OD, and CT. The obvious advantage of this instrument is that all three basic measurements can be obtained by one instrument in a temperature controlled wet cell while not many other commercially available systems offer this facility. Once the lens has been centred in the optimec wet cell there is little disturbance to the lens itself.

BCOR measurement of high minus lenses made from high water content material was the most difficult measurement to make as only a very small change in the lens surface was apparent when the probe just touched the posterior lens surface. (The auxillary magnifier helped somewhat in this respect). A few of the high water content lenses slipped off the lens support after having been centred but this was not a serious problem.

The instrument measured the hard lens BCORs very accurately compared with the radiuscope results.

The 8.5mm diameter support was seen as a useful size to prevent any gravitational sagging of the lens towards the probe. However, one has to balance this against the greater variance of radius measurements at the flat end of the scale.

It is noteworthy to consider that the low

Sauflon 85

Lens no	Specification	Rm(mm)	Dm(mm)
1	7.8/13.5/ + 14.00	7.64	13.4
2	7.8/14.5/ + 11.50	7.87	14.8
3	7.8/14.9/ − 1.00	7.85	14.7
4	7.8/13.5/ − 8.00	8.20	13.9
5	8.10/14.0/ + 21.50	7.95	14.3
6	8.1/14.0/ + 6.00	8.04	14.5
7	8.1/13.0/ − 2.50	8.33	13.1
8	8.1/14.0/ − 8.00	8.38	14.3
9	8.4/13.5/ + 20.00	8.15	13.5
10	8.4/14.0/ + 7.50	9.11	13.9
11	8.7/14.0/ − 8.00	8.07	14.0
12	8.6/14.0/ − 18.00	8.01	14.2

Temperature range: 26.8 ±1.2°C
pH range: 6.7 ±0.4
SE(rad): 0.027mm

Material	Rs-Rm range	Ds-Dm range
Menicon	+ 0.22 to − 0.13mm	+ 0.6 to − 0.35mm
D60	+ 0.14 to − 0.13mm	− 0.1 to − 0.6mm
S70	+ 0.52 to − 0.60mm	+ 0.37 to − 1.13mm
D75	+ 0.46 to − 0.14mm	+ 0.25 to − 1.07mm
S85	+ 0.63 to − 0.71mm	+ 0.20 to − 0.50mm

Abbreviations

BCOR —Back central optic radius

BCOD —Back central optic diameter

CT —Centre thickness

OD —Overall diameter

Rm —A single radius measurement with the Optimec apparatus

Dm —A single diameter measurement with the Optimec apparatus

$\overline{Rm}$ —The mean of N independent Rm values

$\overline{Dm}$ —The mean of N independent Dm values

R —radius

Rs —The BCOR specified on the lens vial

Ds —The OD specified on the lens vial

Spec —Specification of the lens given as BCOR/OD/POWER

SD —Standard deviation

SE —Standard Error

D60 —Duragel 60, D75—Duragel 75

S70 —Sauflon 70, S85—Sauflon 85

water content lenses were measured with the same consistency as the hard lens surfaces. It was found that above a water content of 40 per cent the consistency of measurement became poorer as the water content of the material increased. Thus the dynamic properties of materials which caused measurement variance were chiefly ascribed to water content value.

The Menicon and D60 lenses were quite accurate in terms of BCOR but there were quite large excursions from the specified diameters (see tables). The D75 lenses in the Rs 7.8 group and the Rs 8.2 group showed good accuracy in BCOR measurement but the Rs 8.6 group showed $\overline{Rm}$ values all steeper than Rs. Again there were some large diameter errors. Overall the Sauflon materials showed the largest range of errors and consistency of measurement was the poorest.

It was interesting to note that if the BCOR measured was steeper than the Rs the diameter was not always smaller than Ds. Thus in some cases either the tolerances on the xerogel lenses were not good enough or the correct transverse and longitudinal expansion factors had not been correctly used to calculate the hydrated dimensions.

Conclusions

The instrument enabled soft lenses to be measured accurately in terms of BCOR, OD, and CT and edge form inspection and lenticular measurements were possible.

On the BCOR measurements, two SDs

gave an accuracy of ±0.03mm for hard and soft lenses of water content 40 per cent or less. The SE increased as the water content increased.

From the manufacturers' and practitioners' view the system was easy to use and enabled all measurements to be carried out in saline at a fixed temperature if required. One instrument for all measurements was obviously convenient.

All BCOR measurement systems have their limitations. The sagitta principle depends on the posterior lens surface being spherical. Any asphericity affects the accuracy of measurement. Sag systems, at present, cannot measure the curvatures of toric lenses.

The design and construction of the Optimec instrument is excellent. It is relatively expensive, but considering its versatility and accuracy it is probably the most useful soft lens measurement system available at the present time.

Acknowledgments

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In the May issue of *Manufacturing Optics International*: Contact lens polishing time reduced by half by Stan Herbert, press officer for DeBeers. He describes the first contact lens lathe to be built by a diamond tool maker to cope with the challenge the new co-polymer materials present to the contact lens manufacturer.

Appendix 7

Curvature changes in dehydrating soft lenses

M.J.A.Port

Note.   Not all graphs are included
- only one representative one.

Curvature Changes in Dehydrating Soft Lenses (Part I)

Michael Port, MSc, FBCO, DCLP

Joint Winner of the 1981 B.C.L.A. Dallos Award, Michael Port is Senior Ophthalmic Optician at Moorfields Eye Hospital Contact Lens Dept.

Introduction

Most practitioners have seen soft lenses tightening on an eye from an initially good fitting. Some contact lens materials may be susceptible to variations in pH and tonicity and may produce parameter changes when placed on the eye. If the storage solution pH in particular is markedly different from the eye pH this phenomenon may be encountered. However, the most probable cause of lens tightening is that of water loss from the hydrogel. This may be caused by evaporation from the lens surface and/or a heating up of the lens when placed on the eye. The problems of dehydrating lenses or lens surfaces is obviously greater in higher water content lenses where there is potentially more water to be lost. Many patients' eyes react adversely when wearing soft lenses in dry and warm environments where the lens dehydration is accelerated. The lenses may not feel comfortable, vision may be poorer (Fatt and Chaston, 1981) and less stable; there may also be some physiological embarrassment to the cornea. Coupled with a patient's blinking pattern, crystallization of tear components on to the lens front surface may be accelerated by increased evaporation from the lens front surface (Hathaway and Lowther, 1978). This is particularly so if the individual's tear film by its nature is going to encourage evaporation. The tear film over the lens front surface may be quite different from the tear film over the wearer's naked cornea. Hamano *et al*, 1981 found that the rate of evaporation from a low water content gel lens could be up to 2.5X that of the naked eye.

The changes in soft lens properties and parameters when the lens starts drying out on the eye have received scant attention by researchers and the literature is bereft of data on the subject. For this reason the author embarked on the present investigation.

Selection of Lenses and Materials

It was thought important to investigate the dehydrating properties of various soft lens materials. To this end six different water content materials were tested. A high plus (HP) lens and a high minus (HM) lens of five materials were used to examine the extremes of the power range. With the sixth material only a low minus (LM) lens was tested.

Lens	Water content	Power	BCOR	OS
1.	29%	−3.00 D	8.2mm	13.0mm
2.	38	−19.00	8.1	15.5
3.	38	+17.00	8.2	13.0
4.	60	−16.25	8.2	14.0
5.	60	+18.25	8.2	14.0
6.	70	−19.50	8.2	15.5
7.	70	+18.00	8.0	14.0
8.	75	−18.75	7.8	15.0
9.	75	+17.00	8.2	14.0
10.	85	−14.00	8.0	13.0
11.	85	+20.00	8.4	13.5

Mean minus power	−17.5D	(SD 2.1)
Mean plus power	+18.0D	(SD 1.1)
Mean BCOR	8.13mm	(SD 0.16)
Mean OS	14.1mm	(SD 0.87)

The experimental model

On the eye a soft lens has a fairly constant interface with the cornea but the front surface of the lens has more variable interface due to the blinking action and the direct exposure to the air. Thus one is likely to find water loss from the lens front surface of the lens

but the water content of the posterior surface is likely to be static. To manufacture a model to match the in vivo situation would be difficult and costly. The author used a conventional in-air soft lens BCOR measurement device. This was a motorised version with digital readout of sagitta. The contact lens was supported on a small hollow cylinder (see Fig. 1); in this way the front surface of the lens is directly exposed to the air whilst the posterior surface is more isolated and evaporation will be slower than from the front surface.
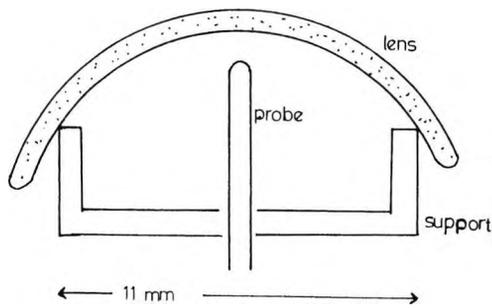
Fig. 1

Over a given period the sag of the lens can be measured many times. It was shown (Port, 1980) that this type of measuring instrument was very accurate for measuring sagitta but there were limitations in obtaining radius measurements from the sagitta. In this study only the change in sagitta was used.

Methodology

The lenses were stored in 0.9% normal saline at room temperature (22°C ±0.9°C), pH 5.9 ±0.5. Lens measurement was carried out in still air (21.6°C ±1.3°C); hygrometry 50-60%.

Prior to measurement it was necessary to remove all the surface saline from the lens front surface. The lens was removed from its storage vial and placed convex side up on a paper tissue. Most surface saline ran off quickly and was absorbed in the tissue. Thereafter the lens was turned over so that the convex surface was on the tissue. A nylon lens lift was used to gently move the lens on the tissue so that the front surface was further "dried". A compromise was reached between drying the front surface slowly and efficiently and obtaining a sag reading as soon as possible. The first sag reading was used as the baseline measurement for the particular trial. Sag
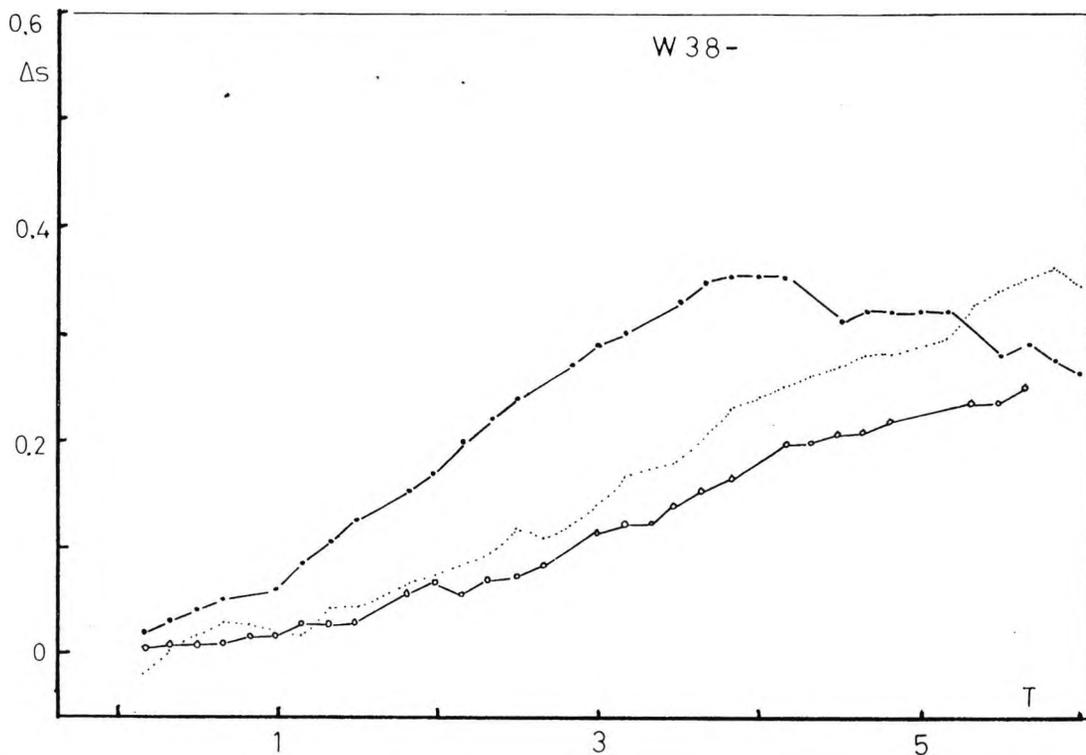
Fig. 2

measurements were taken every 10 seconds over a period of six minutes. It was found expedient to miss a measurement after five or six measurements in order to quickly but gently move the lens on its support and re-centre it. This could be done within ten seconds and it minimized any "sticking" of the lens back surface to the support. Occasionally the measuring instrument would give a faulty reading necessitating a quick re-calibration or finishing the trial short of six minutes.

With one trial completed the lens was returned to its vial of saline. The remaining lenses were treated in the same way. After each trial the lens was rehydrated for at least a day. A second trial on each lens was made after this complete rehydration and subsequently a third trial after a second complete rehydration. The change of sag from the baseline reading was recorded against time.

Results and Discussion
38% water content (Fig. 2 and Fig. 3).

With the high minus lens a rate of sag change of 0.1mm/minute was seen and this was fairly linear for some three minutes. The difference between the three curves was almost certainly due to the varying amounts of saline left on the lens surface prior to

dehydration commencing, i.e. if there was a relatively large amount of saline on the front surface then there was a smaller change due to very little water loss from the lens itself. Thus for the "wettest" surface a sag change rate of 0.07mm/min. was observed. In the case of the high plus lens there was a much more rapid change in sag (0.35mm/min) in the first 45 seconds.

In both plus and minus lenses the driest surfaces showed an increase in sag initially and then a decrease. This could be explained by the lens dehydrating in a regular way at first and then the periphery of the lens tending to turn up — with a corresponding decrease in sag. Certainly this peripheral shape change was observed in a number of lenses (see Fig. 4).

60% water content (Fig. 5 and Fig. 6)

The minus lens showed a fairly linear rate of change (0.07mm/min) over the first three minutes and then the rate increased. The plus lens showed a greater range (0.275mm/min) for the first 45 seconds on the driest surface and 0.10mm/min for the wettest surface.

70% water content (Fig. 7 and Fig. 8)

Over three minutes both the plus and minus lenses performed in almost the same manner. All trial results were consistent in morphology and rate of sag change (0.07mm/min for plus and 0.08mm/min for minus).
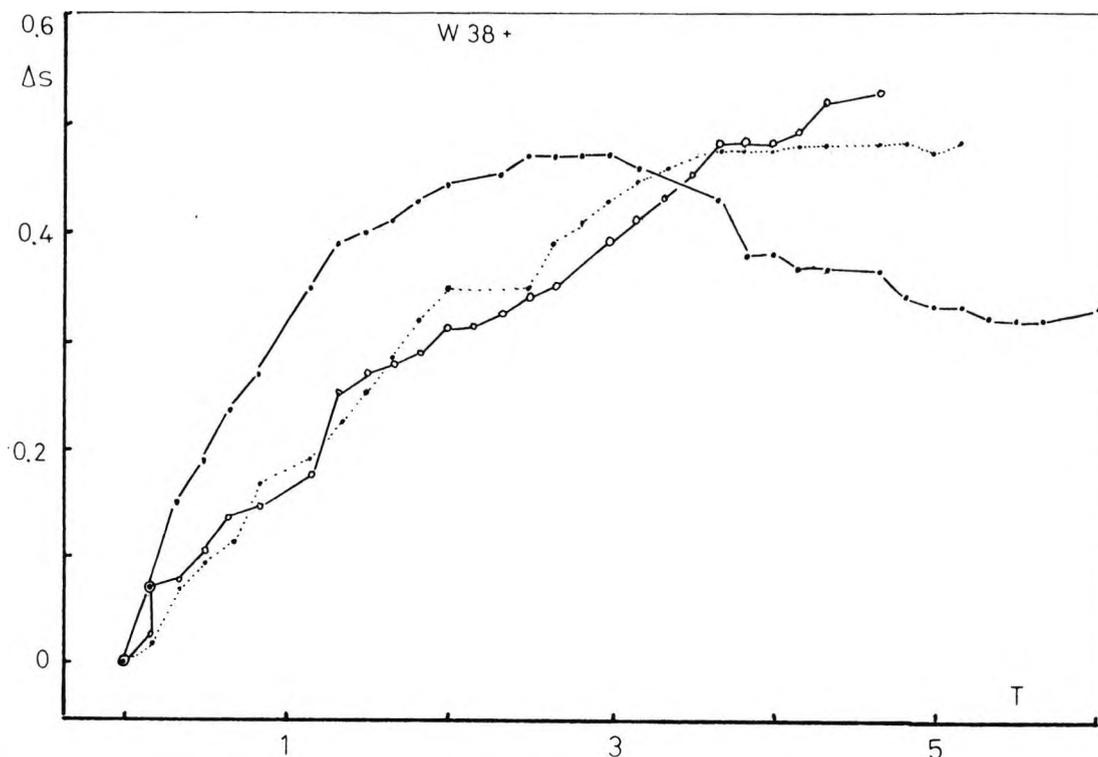
Fig. 3
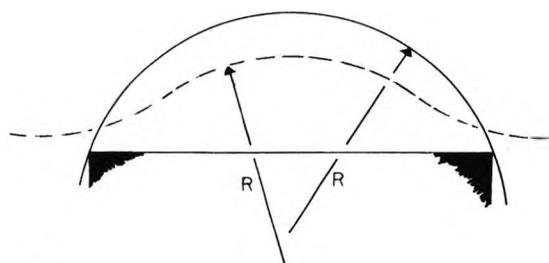
Fig. 4

75% water content (Fig. 9 and Fig. 10)

The minus lens showed a change of 0.12mm/min from the driest state compared with 0.04mm/min in the wettest state during the first three minutes. The plus lens showed a faster rate (0.30mm/min for the driest surface and 0.1mm/min for the wettest surface).

85% water content (Fig. 11 and Fig. 12)

The minus lens showed a maximum rate of change of 0.09mm/min and a minimum of 0.05mm/min. The plus lens showed a rate of change of 0.20mm/min to 0.06mm/min.

The actual sag change over three minutes for the driest surfaces is shown in Fig. 13.

Fig. 14. The single 29% LP lens was tested in the same way as described above. This showed a sag change of 0.35mm in three minutes. The change in the first minute was 0.2mm. If lenses had been changing spherically a sag change of 0.2mm would be equivalent to a radius change of 8.5 to 8.0mm for an 11.0mm chord.

Conclusions

The general pattern of results was as expected. Lenses were steepening with dehydration. Some lenses showed peripheral distortion or deformation (see Fig. 4) which precipitated a decrease in sag after an initial increase. Plus lenses showed a faster rate of sag change than minus lenses (Fig. 13). There was no correlation between rate of sag change and water content of the lens material under the conditions of the test (Fig. 13).

Further work

To ensure better control of variables a series of lenses should be specially made such that there is less variance in BCOR, OS and power. Ideally each material selected could be used to make four lenses (−15.00D, −5.00D, +5.00D, +15.00D) and all of these would have the same BCOR and OS e.g. 8.5mm and 15.5mm respectively.
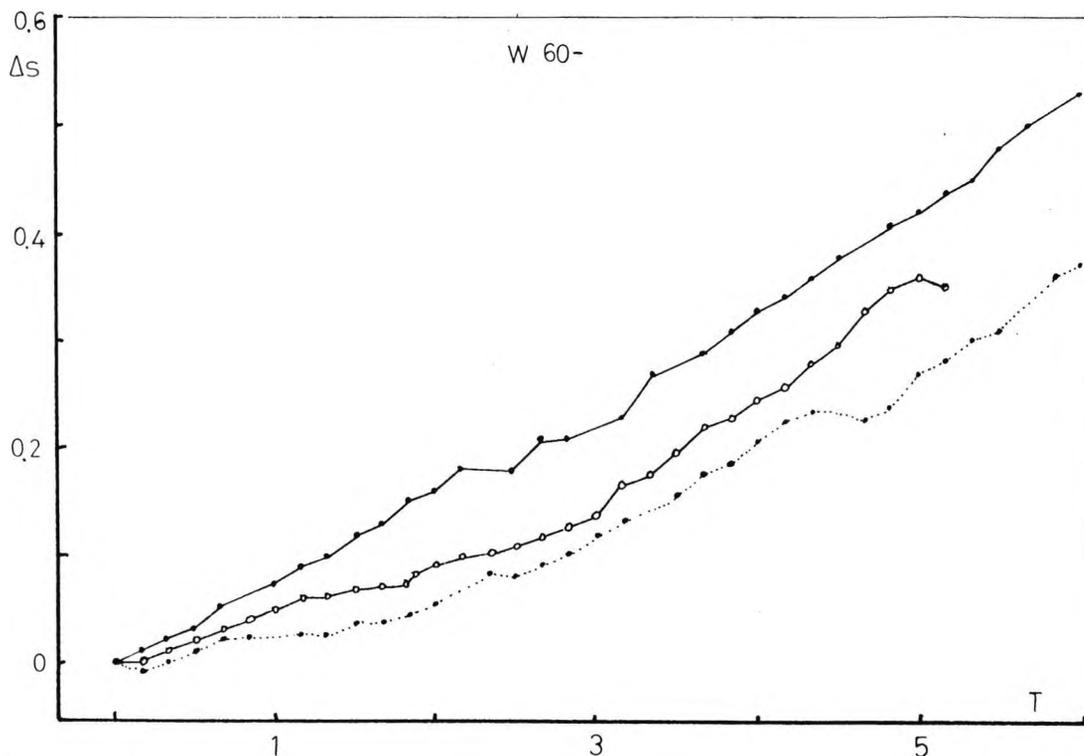
Fig. 5
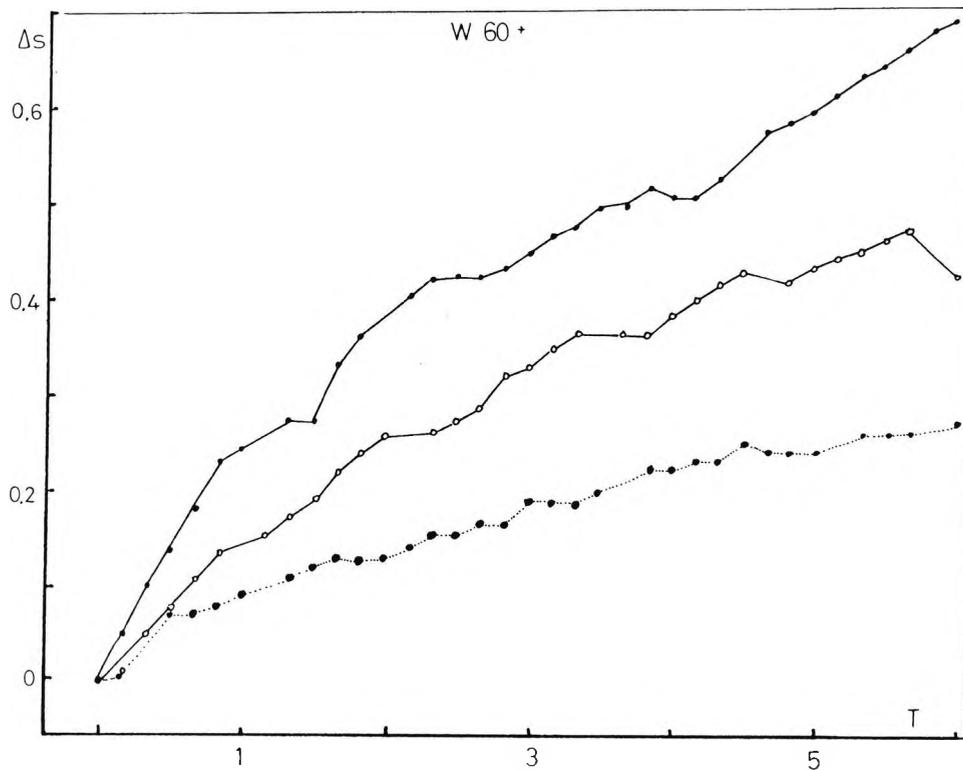
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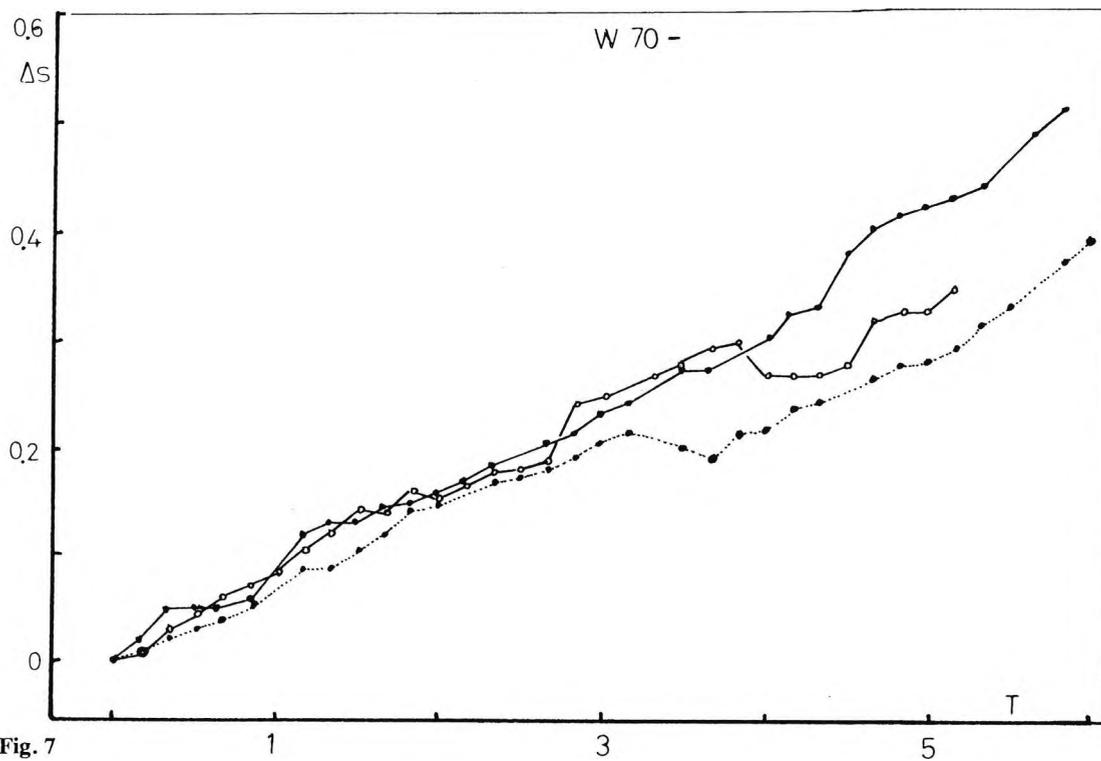
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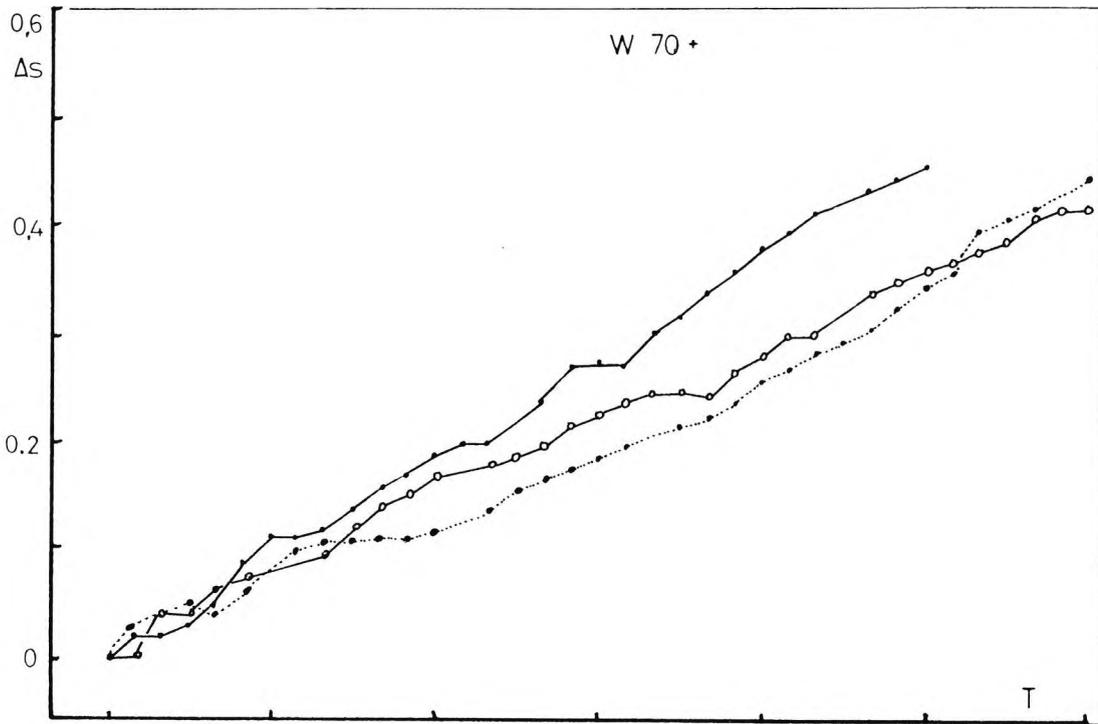
Fig. 8
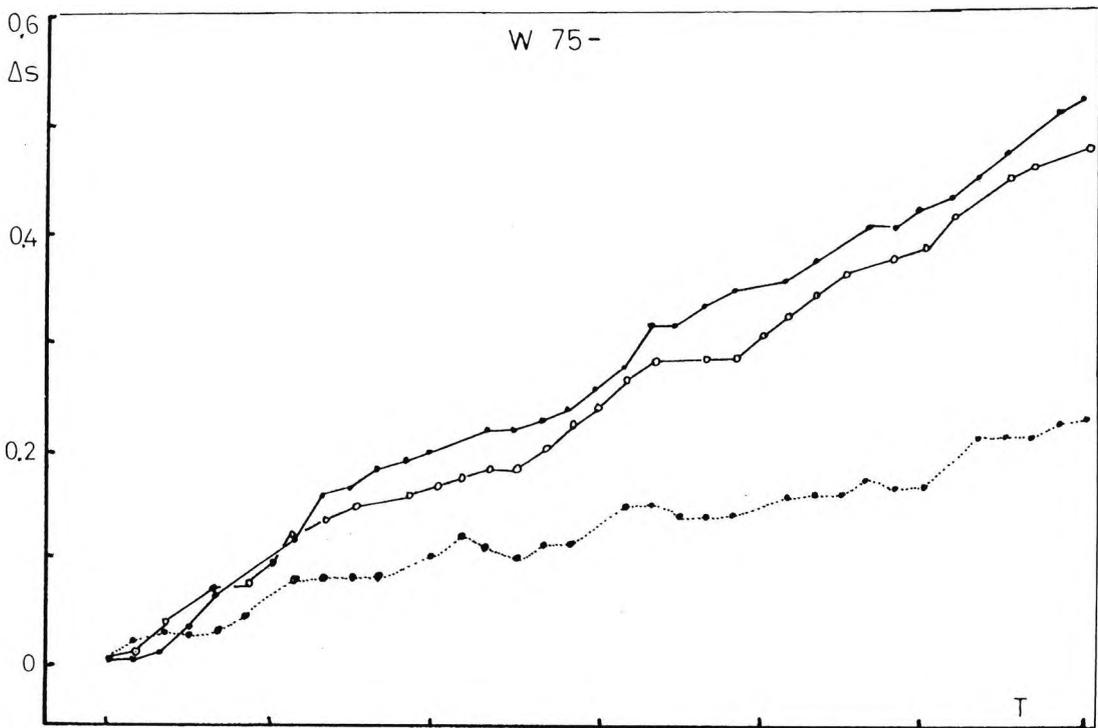
Fig. 9
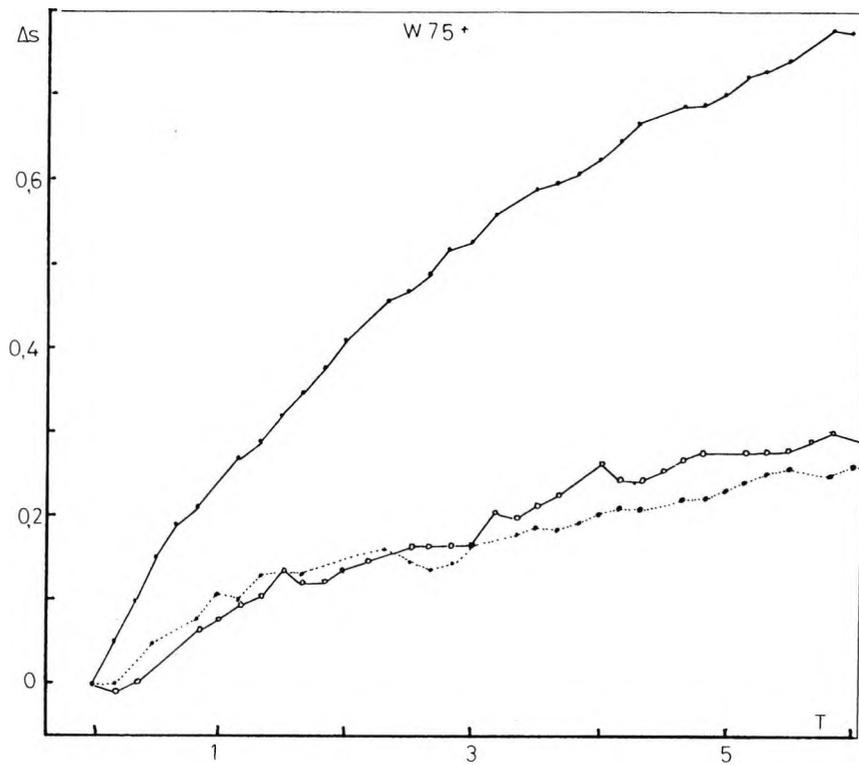
Fig. 10
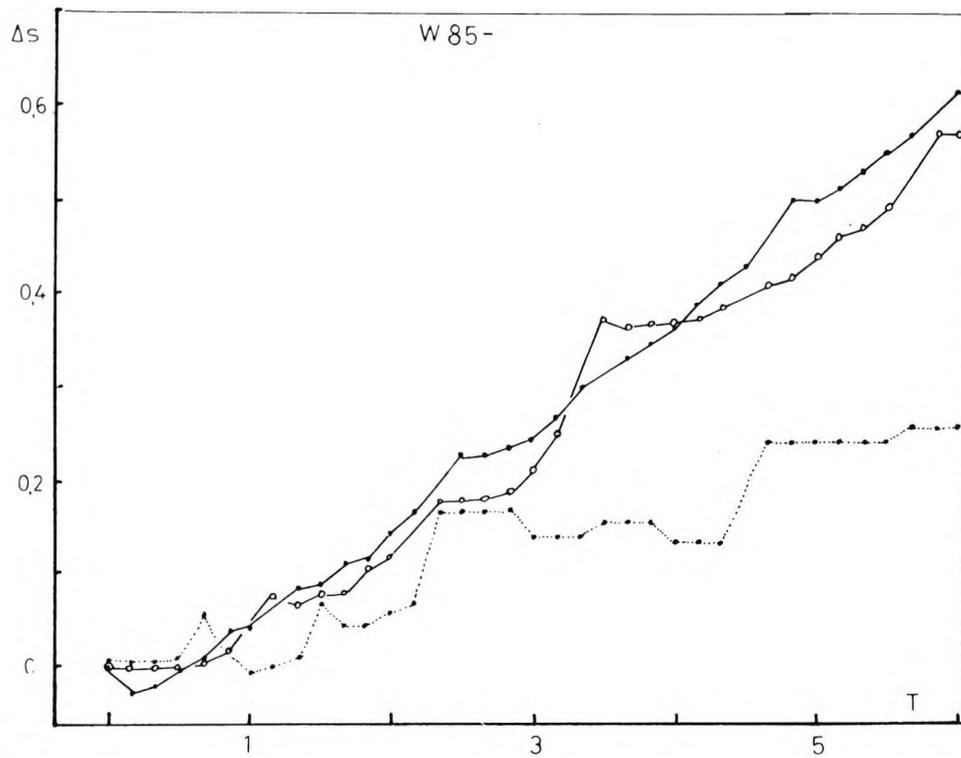
Fig. 11
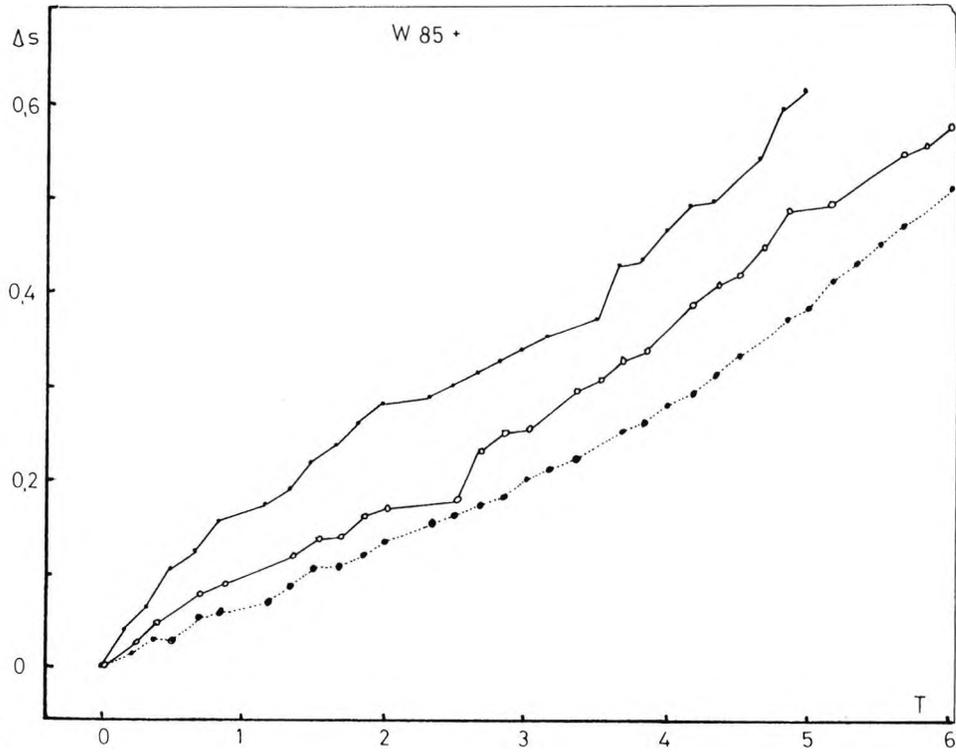
Fig. 12
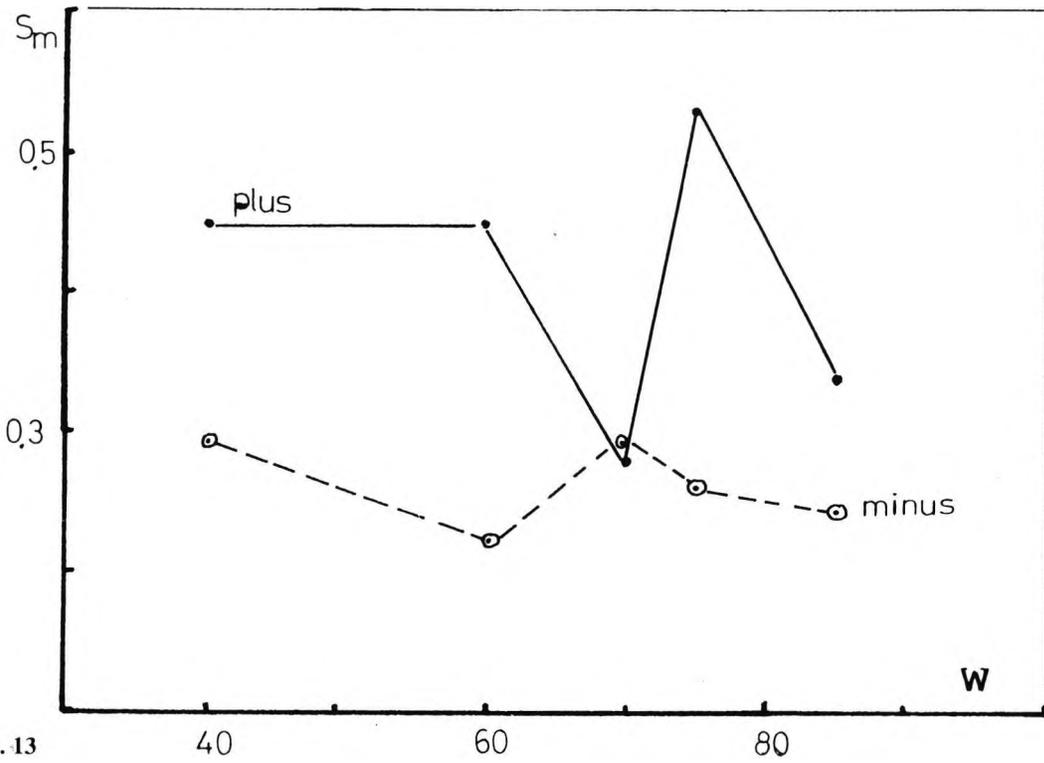
Fig. 13
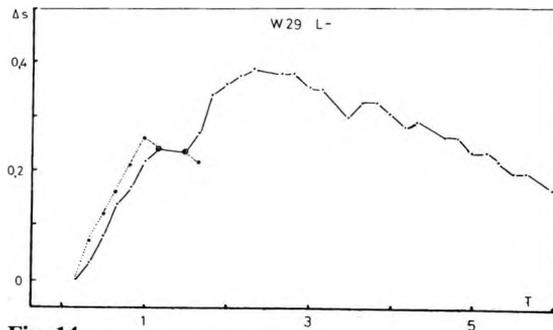
Fig. 14

Weighing the lenses before and after the sag measurements would be useful. The lens design and front surface area should be analysed in conjunction with the results.

In part 2 of the study the results of lenses dehydrating under different conditions will be presented.

Abbreviations

Δs	Change of sag from the baseline measurement
T	Time (minutes)
W	Water content (%)
SD	Standard deviation
R	Radius
S_m	Sag change measured over three minutes
BCOR	Back central optic radius
OS	Overall size

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Appendix 8

Soft lens verification

M.J.A.Port

Textbook chapter,

Ruben & Guillon, Chapman & Hall, London , 1994

Note. Only pages 171 -176 relating to curvature measurement are reproduced.

polynomial expression can be found to fit the data. This is done very simply if a computerized curve-fitting program is used. The author uses Cricketgraph™ very successfully for this purpose.

10.4 MEASUREMENT TECHNIQUES FOR CURVATURE DETERMINATION

10.4.1 THE BACK SURFACE SHAPE

Variation in back surface shape is necessary to fit different shaped eyes. Most eyes tend to flatten from the centre of the cornea towards the limbus and sclera. Soft lenses may have aspheric back surfaces or they may have a series of concentric spherical curves which flatten in radius from centre to edge. In the case of a multicurve back surface the back optic zone radius (BOZR) is specified and a given lens series may have anything from one to six different BOZR values; the BOZD is usually 10 or 11 mm. The verification of the BOZR is carried out using one of two broad principles – one mechanical and one optical.

There are two traditional arguments regarding radius determination. First, measurement in air or in saline, and second, sagitta determination versus ophthalmometry.

The reason for in-air measurement is speed. The disadvantage is that soft lenses in air dehydrate quickly (Port, 1980a) and lose their shape. The use of optical methods means that toroidal surfaces can be measured and this is impossible with sagitta methods. However, the reflection from the hydrogel lens/saline interface is very small and this coupled with reflections from the front surface of the lens, can make the method difficult at times. There are two other techniques which have been reported, but are not in widespread use. One is the Drysdale principle (Chamarro, 1974; Steel & Noack, 1977; Drysdale, 1900) and the other is a template
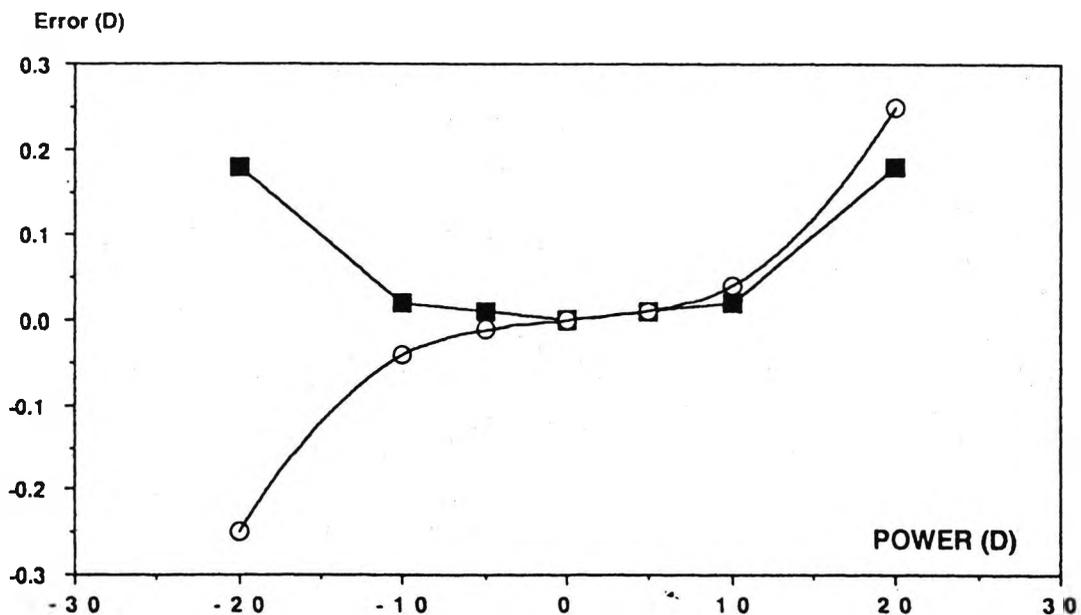
Figure 10.2 Calibration curves for two different focimeters. Both curves are non-linear and the use of linear regression to establish a best fit line is inappropriate. One can either join the points (solid squares) and intrapolate where necessary, or, fit a mathematical curve which has a polynomial equation (open circles).
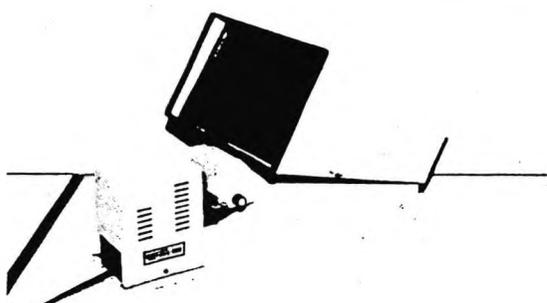
Figure 10.3 The Hydro-Vue™ soft lens analyser. This is an in-saline device where the image of the lens on a spherical dome is projected on to a translucent screen.

Figure 10.4 Hemispherical domes with different radii of curvature were the first development in the checking of back optic zone radius. The lens was transferred from dome to dome until the best match was found. This in-air method is not reliable with thin lenses and is not in current use.

matching technique (as used in the Söhnges projection system (Söhnges, 1973; Loran, 1974; Koetting, 1981a) and the American Hydro-Vue™ device (Fig. 10.3). In the latter case (Elmstrom, 1979; Lester & Lester, 1979; McDonald, 1981; Davis & Anderson, 1982), lenses are placed over hemispherical domes of different curvatures. The dome providing the best match gives the curvature of the lens surface. Although the dome and lens are in saline, there is no temperature control of the saline. The system uses a projection system and light from the projector lamp must warm up the saline unless a heat filter is incorporated. With lenses being generally thinner now than in the past, the lenses tend to wrap around the dome with the implication that some lenses fit a range of domes quite well. Template matching in air (Wodack, 1972) was the first simple method of verifying the posterior curvature (Fig. 10.4) but with the advent of thinner lenses and lenses of higher water content, its usefulness declined in favour of more applicable methods.

10.4.2 SAGITTA METHODS

The principle is to measure the sagitta above a known chord. In practice, this means supporting the soft lens on the circular face of a vertical cylinder (usually 8.0 to 10.0 mm) and gauging the distance from the centre of that face to the apex of the posterior lens surface. This distance (sagitta) can be converted to a radius value (r) using the expression:

$$r = s/2 + d^2/8s \qquad \text{(eqn 10.1)}$$

where s is the measured sagitta and d is the diameter of the chord (lens support).

In-air sagitta methods

All these systems use the electrical conductivity of hydrogel lenses to complete an electrical circuit. With the lens supported on a metallic cylinder, a central probe is moved upwards towards the apex of the posterior surface. When it just touches the lens, a circuit is completed and a meter or LED indicates the completed circuit. The apparatus designed by Wöhlk in Germany and Kelvin in the UK was similar and used this concept. The notion was taken further by the French company Medicornea, with their BC-Tronic (Duprat & Joinet, 1979; Koetting, 1981b). In this case the probe was adjusted manually but a transducer was used to mea-

sure the sag and a digital display indicated the result. Probably the most sophisticated design was the SM 100 by Neitz of Japan. The central probe movement was automated. When electrical contact with the lens was made, the probe reversed to its starting position. A digital display of sag or radius was given (Port, 1980b).

It has been found (Port, 1980b) that the main problem with in-air systems was the sagging of the lens on the support resulting in flat readings. Saline, being a denser medium supports the lens shape much better and also prevents dehydration.

In-saline sagitta methods

The mechanical determination of sagitta in saline was pioneered by two people. One was Peter Höfer (1977) in Germany and the other was John Coy in the UK. Coy, whilst working for Contact Lenses (Manufacturing) Ltd. designed a device (Fig. 10.5) which had a mechanically operated central probe and a telescope arrangement with which to view the lens apex and assess the point when the probe touches the lens. The lens support was too small and there was no simple way to centre the lens on it. When he left the company he evolved the design. The probe adjustment remained essentially the same, the lens support became larger (8.5 mm) and the the end-point was determined from a projection system where the image was viewed on a screen. Perhaps the major step forward was his excellent, patented, centration device. This enables the soft lens to be centred accurately on the lens support prior to measurement. The only exception to this is when soft lenses with prism are measured. The current model of his 'Optimec' (Fig. 10.6) uses a 10 mm lens support. Ancillary attachments have further improved the equipment. There is now the option for the saline wet cell to be temperature controlled and a filter system can be attached to keep the measurement saline clear. Besides BOZR, other con-

Figure 10.5 One of the original radius measurement devices designed by John Coy for Contact Lenses (Manufacturing) Ltd. The central lens support was too small and it was extremely difficult to centre the lenses. The operator used the integral telescope to assess when the central probe just touched the back vertex of the lens.

tact lens dimensions and properties can also be measured or assessed. The Optimec™ equipment is highly recommended as it is simple to use and performs its function well (Port, 1981a, 1982). The instrument must be calibrated carefully to reduce systematic error. The apparatus is now in widespread use by laboratories and practitioners.

With the Optimec system, the major operator variable which could affect random errors is the assessment of endpoint when the probe touches or lifts the lens. Some operators will try and see the probe just touch the apex of the back surface (Fig. 10.7) and some will look for one edge of the lens lifting slightly. With very thin lenses, the latter method is not reliable as the probe can distort the centre of the lens before an edge lifts. Conversely, with some lens powers and lenticular designs it is quite difficult to see
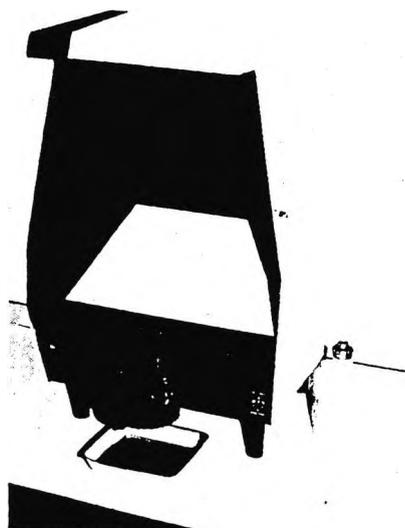
Figure 10.6 A current Optimec soft lens analayser. This model has two wet cells – one to measure the back optic zone radius and centre thickness, the other to measure total diameter and to carry out inspection of the surfaces.

Figure 10.7 The back optic zone radius of a soft lens being measured on an Optimec device. The soft lens is resting on the 10 mm cylinder and the central probe can be seen near the back vertex of the lens. It is also possible to assess the edge profile of the lens.

the probe and the lens apex clearly to make a good assessment of touch.

To overcome the mechanical limitations of the sagitta method Port (1976, 1979) described a method of determining sagitta using ultrasound. As the velocity of sound in saline varies with temperature it is essential to have a saline wet cell which is temperature controlled to ± 0.5 °C for this method. The quality and design of the transducer used are of paramount importance. The ultrasound beam must reflect from the lens apex and a beam which is too strongly focused gives reflections from paraxial regions of the lens. The Panametrics device (Patella *et al.*, 1982) is used quite widely but the Optison (Port, 1981b) has now been discontinued.

The Kelvin company designed an instrument which also did not rely on mechanical applanation of the lens surface. The principle utilized was that of proximity gauging but

the effect of different water content materials meant that calibration with anything other than the same hydrogel material was impossible (Port, 1983).

10.4.3   OPTICAL METHODS

Athough the Drysdale method has been mentioned, there are other optical methods which have been used viz interferometry (El-Nashar & Larke, 1980) and Moiré fringes (Rotlex Optics Ltd, 1991). These have been used primarily in research applications.

The ophthalmometer (keratometer) is conventionally used to measure the central curvature of the cornea (convex) but can be used to measure the corresponding area of the back surfaces of a soft lens. The soft lens has to be immersed in saline (at room temperature) so that the shape of the lens is normal. The use of the instrument to determine the BOZR was reported in 1973 (Chaston, 1973; Forst, 1973) and subsequent modifications to the keratometer method have been described (Vögel, 1977). With some keratometers, the light source has to be modified (Chaston & Fatt, 1979) as the original source gives rise to

very low intensity images. The Zeiss Jena ophthalmometer (Fig. 10.8) employs a high intensity light source which has a neutral density filter *in situ* for conventional corneal keratometry. For measuring the curvature of soft lenses in saline, the filter is removed.

The usual instrument scale cannot be used directly as it is relates to surfaces in air:

1. **Advantages of the keratometer method**:
   suitable instrument may be available;
   toroidal surfaces can be measured.
2. **Disadvantages**:
   light source may be inadequate;
   only central 3 mm of surface is sampled;
   reflections from anterior surface of lens may lead to confusion (Forst, 1974);
   saline wet cells are not temperature controlled;
   centration of lenses is time consuming.

Although it is theoretically possible to convert the normal keratometer scale to take account of curved surfaces in saline, it is worthwhile calibrating the instrument with a series of rigid surfaces in saline (Holden, 1975). These
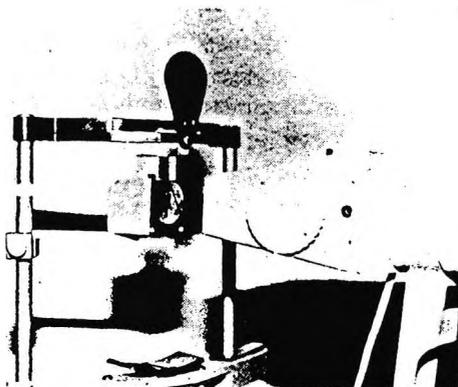
Figure 10.8 A wet cell (filled with saline and holding the soft lens) is clamped to the headrest of a Zeiss Jena ophthalmometer to enable the Back Optic Zone Radius to be measured. The instrument value for the soft lens in saline would not be accurate as the instrument conventionally determines radius values (of the cornea) in air.

reference surfaces are preferably precision surfaces made from glass. Probably the most convenient optical method is to use the Rodenstock CES ophthalmometer. This has an alternative objective lens so that recalibration for surfaces in saline is unnecessary.

10.4.4   DISPUTING BOZR VALUES

Before disputing radius values the following questions should be answered and recorded:

1. Has the machine been calibrated correctly and recently by its operator? Are the reference pieces of known accuracy?
2. Is the radius being assessed indirectly by sagitta determination or keratometry? If the former, which diameter lens support was used and which apparatus?
3. What temperature was used for measurement?
4. If standard ISO saline was not used, what formulation was used?
5. Was the lens 'conditioned' by storing it in measurement saline for 2–3 hours before measurement at the measurement temperature?
6. Is the lens inside out?
7. Were three independent measurements taken? ('Independent' implying that the lens was removed from the appararatus and replaced, between measurements).
8. Was the arithmetic mean or median value found?

Example

The three independent readings were 8.60, 8.75 and 9.20 mm. The arithmetic mean is 8.85 mm and the median value is 8.75 mm. If the radius specification was 8.60 mm and the tolerance ± 0.15 mm, then a result based on the mean value would fail the lens whilst one based on the median would pass the lens. In order to reduce the effect of 'outliers', the median value is recommended. To minimize the variations that can occur, it is recom-

mended that national or international guide-lines on the appropriate measuring methods are followed.

10.4.5 ASPHERIC SURFACES

The verification of aspheric concave surfaces is more difficult. The radius of curvature is flattening gradually from the centre to the edge of the lens. Two aspects are important – the apical radius and the degree of flattening (eccentricity, for conoid sections). Optical methods using the ophthalmometer or radiu-scope will give information about the central (apical) curvature but little information regarding the change in shape. If sagitta is determined, information regarding shape may be missed. However, Ciba Vision have two elliptical series – a 'flat' and a 'steep' and Bausch & Lomb have favoured a 'sag 0', 'sag 1' and 'sag 2' description. In the latter case, 'sag 0' has a smallest sagitta value and 'sag 2' the largest. It is interesting to note that most large volume manufacturers utilize the sag-itta measurement when checking samples from batches. If the total diameter of the lens and back surface geometry are known, the total back surface sagitta can be computed and this is verified during quality control procedures. As far as I know, there are no instruments commercially available to spe-cifically measure the total sag of the lens' back surface. Precision instrument manufac-turers, e.g. Mitutoyo, produce high quality projection systems which can be used for this purpose.

For the practitioner, it is quite simple to measure the sag above a 10 mm chord (a cylinder whose diameter is 10 mm) and this is recommended. The main reason for doing this is only to distinguish between different series and to check ordered lenses against trial lenses. In the case of aspheric surfaces, the absolute curvatures are not so important but the sags measured should be compa-rable.

With an aspheric back surface the term 'equivalent spherical radius' (ESR) is useful. If one measured the sag (s) of an aspheric lens above a given chord (d) the use of the normal expression for spherical surfaces is:

$$\text{ESR} = s/2 + d^2/8s \qquad \text{(eqn 10.2)}$$

Thus, for aspheric surfaces it is recom-mended to measure the sag above a known chord and /or convert this to an ESR. It would be extremely useful for manufacturers of such lenses to provide the kind of table shown in Table 10.1. It may be necessary to establish from manufacturers' information if the sag of the back surface varies with power (Port, 1992) for a given total diameter and lens series. All reputable manufacturers should have this data available.

10.5 DETERMINATION OF LENS DIAMETERS

In terms of lens dimensions, the total diam-eter has the largest numerical value. This implies that any changes affecting the lens dimensions will be more easily apparent by diameter changes as opposed to radius and thickness changes. Coupled to this, the mea-surement of diameter is considerably simpler than the measurement of thickness or radius. It is strongly advised that total diameter is the dimension to monitor if one is looking at dimensional changes in hydrogel lenses.

There are two approaches to total diameter measurement. First, to look at the lens from the side, and second, to take a plan view of

Table 10.1 Sample table for details of aspheric surfaces

Chord diameter (mm)	Flat series		Steep series	
	Sag	ESR	Sag	ESR
8.0				
8.5				
9.0				
9.5				
10.0				

Appendix 9

A comparison of two soft lens radiuscopes

M.J.A.Port

A Comparison of Two Soft Lens Radiuscopes

Michael Port, MSc, FBCO, DCLP

Michael Port is a full time Senior Optometrist in the Contact Lens department at Moorfields Eye Hospital, London.

Introduction

Port (1981) examined the JCB Optimec Contact Lens Analyser. The instrument enabled the user to measure Back Central Optic Radius (BCOR), Overall Size (OS) and Centre thickness (CT). Since then Optimec have introduced a complimentary series of instruments based on a front projection system (JCF) compared with the back projection system of the JCB models. The JCB model tested did not have a temperature controlled wet cell for lens measurement.

It was concluded from the study that radius measurement variance tended to increase with the water content of the lens. However, as there was no temperature control of the saline, the parameters of the higher water content lenses would be changed to a greater degree than the dimensions of lower water content lenses for a given temperature change. The results may well have reflected this point. Taking all groups of hydrogel lenses tested the standard deviation (SD) based on three independent measurements of each lens was 0.03mm.

Port (1982) examined the AMS Optison instrument. The instrument only measured radius and the saline wet cell was not temperature controlled. The lack of temperature control resulted in the need for very frequent recalibration of the instrument during use and almost certainly this resulted in a SD values (based on four independent measurements) of 0.06mm when all the groups of lenses were considered.

In the present study two temperature controlled insturements are compared for radius measurement:
1. The AMS Optison TC (OTC)
2. The Optimec JCF

Measurement Principles.

The OTC uses ultrasound to measure the sagitta of the lens surface above a known chord (8.5mm) and converts this to a radius value which is displayed digitally in 0.05mm steps. The JCF again measures the sag above the same size chord except that the sag measurement is made mechanically by a manual operation. From the radius dial 0.01mm steps were possible. To take account of ultrasound travelling at different speeds in different temperature and tonicity saline the OTC has to be calibrated. The JCF utilizing mechanical principles is virtually unaffected by environmental changes.

Temperature Control

Both instruments rely on the Peltier principle to maintain temperature control. The OTC has the ability to heat or cool the saline of the wet cell to a pre-set temperature (21.0°C in the instrument tested). The JCF has a cooling system as standard as in most circumstances the effects of the ambient temperature and the heat generated by the projection system will raise the temperature of the saline above the design temperature of 20.0°C. However, Optimec Ltd can incorporate a heating/cooling system if needed. The JCF and the OTC have a temperature tolerance of ± 0.5°C from the preset temperature.

Saline environment

Unfortunately both instruments were not available at the same time. Normal saline (0.09%) was used in the wet cells. In the Optimec test the pH was 6.5 (SD 0.25) and in the Optison test the pH was 5.4 (SD 0.30)

Selection of Lenses
Group 0 Very accurate concave spherical glass test surfaces
         (used on OTC only)
Group 1 PMMA lenses (F.L.O.M. type) N = 5 (JCF); N = 9 (OTC)
Group 2 29% water content hydrogel lenses: N = 10
Group 3 38% water content hydrogel lenses: N = 4
Group 4 55% water content hydrogel lenses: N = 6
Group 5 70% water content hydrogel lenses: N = 5
Group 6 85% water content hydrogel lenses: N = 5
The specification of the lenses is given in Port
(1982)

Experimental Procedures

Each lens was measured independently four times with the appropriate instrument. A mean ($\overline{Rm}$) and SD were recorded. The OTC was checked for possible recalibration after four of five sequential lens measurements. Temperature was checked periodically throughout the tests. After the test was finished the saline pH in each lens vial was measured with a Pye Unicam pH meter.

The centration device of the OTC was not used. Lenses were removed from vials with a nylon eye ointment applicator.

The 'FLOM' lenses were additionally measured with an Americal Optical Radiuscope. A mean ($\overline{Rr}$) and SD were obtained from four independent measurements.

The experimental radius means were compared to the specified radius values (Rs).

Results and Discussion.

Glass test spheres. When used on the OTC no usable signal was obtained. Even with a glass optical flat there was no correct display. It may have been that the signals reflected from glass were of a higher intensity than those from PMMA or hydrogels and some internal reflection within the support cylinder caused the error symbols to appear.
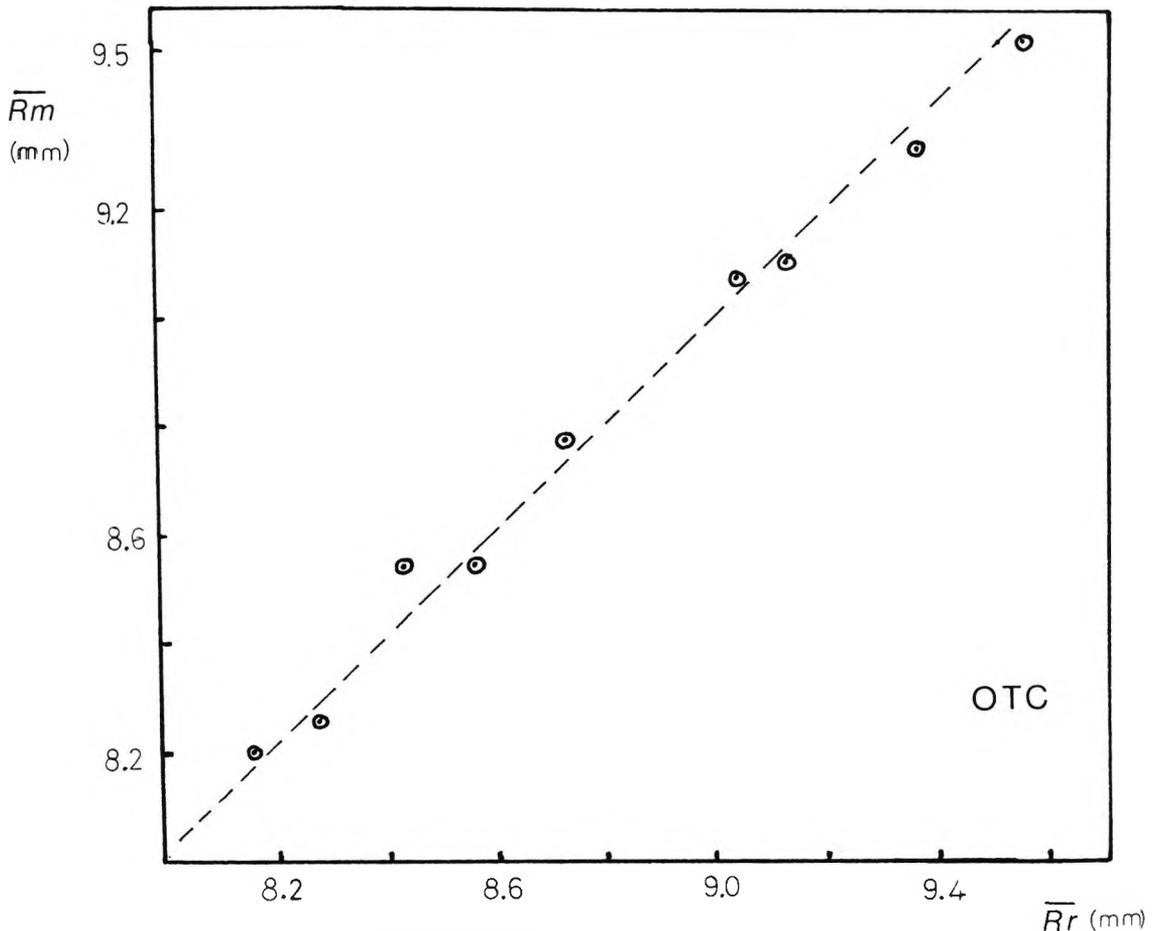
Fig. 1.   PMMA 'FLOM' lenses. The mean radius values (Rm) obtained from the Optison TC plotted against the mean vertex radii (Rr) obtained from an American Optical radiuscope.

PMMA lenses. The lenses used on both instruments are shown in Table A. The OTC results using these five lenses and the four additional lenses are shown in Fig. 1

29% Hydrogels. Results are shown in Table B

40% Hydrogels. These lenses had a CT of 0.1mm or less. The results are shown in table C.

55% Hydrogels. The results are shown in Table D. Results found with the non-temperature controlled Optison (NTCO) (Port, 1982) are included as the measurements were carried out in the same pH saline as the JCF used.

70% Hydrogels. Results are shown in Table E and again the NTCO results are given.

85% Hydrogels. Results are shown in Table F with the relevant NTCO measurements.

Table A (All measurements in mm)

Rs	Rr (AO)	Rm (OTC)	Rm (JCF)
8.25	8.27	8.25	8.34
8.50	8.56	8.55	8.56
8.75	8.73	8.75	8.78
9.00	9.12	9.10	9.32
9.25	9.37	9.31	9.50
Group mean	8.75	8.81	8.79	8.90
SD mean	—	0.01	0.04	0.03

Table B (All measurements in mm)

Rs	Rm (OTC)	Rm (JCF)
8.0	8.02	7.95
8.20	8.16	8.18
8.20	8.10	8.12
8.40	8.47	8.41
8.40	8.44	8.39
8.60	8.65	8.63
8.60	8.66	8.60
8.80	8.96	8.96
8.80	8.97	8.98
9.00	8.94	8.96
Group mean	8.90	8.54	8.52
mean SD	—	0.02	0.06

Table C (All measurements in mm)

Rs/OS/Power	Rm(OTC)	Rm(JCF)
8.4/14.0/plano	8.39	8.49
9.00/14.0/plano	8.94	9.13
aspheric/13.0/−1.00	8.75	8.68
aspheric/13.0/−3.00	8.59	8.98
Group mean	8.67	8.82
mean SD	0.03	0.03

Table D (All measurements in mm)

Rs	Rm(OTC)	Rm(NTCO)	Rm(JCF)
7.4	6.91	7.45	7.30
7.7	7.64	8.12	8.04
8.1	8.05	8.71	8.79
8.40	8.21	8.55	8.74
8.70	8.36	8.64	8.58
9.40	9.47	9.60	9.75
Group mean	8.28	8.11	8.51	8.53
mean SD	—	0.03	—	0.06

Table E (All measurements in mm)

Rs	Rm(OTC)	Rm(NTCO)	Rm(JCF)
7.9	7.76	8.12	8.29
8.1	8.27	8.81	8.96
8.4	8.27	8.57	8.72
8.7	8.83	9.07	9.31
8.6	8.56	breakage	8.86
Group mean	8.27	8.28	8.64	8.82
mean SD	—	0.04	—	0.05

(first 4 lenses in group)

Table F (All measurements in mm)

Rs	Rm(OTC)	Rm(NTCO)	Rm(JCF)
7.5	7.12	7.54	7.69
7.8	7.57	8.15	8.30
8.1	7.65	8.17	8.45
8.4	8.24	8.94	9.08
8.1	7.74	8.12	8.35
Group mean	7.98	7.67	8.18	8.37
mean SD	—	0.03	—	0.05

Temperature The OTC was used in an ambient temperature of 25°C. The saline temperature in the wet cell fell to 22.7°C in 17 minutes and took a further 25 minutes to fall to 21.6°C. During the OTC test 120 independent lens measurements were made. The saline temperature was measured 19 times at regular intervals. The mean temperature was 21.4°C (SD 0.18°C). The lowest recorded temperature was 21.1°C and the highest recorded temperature was 21.8°C. Thus a mean of 21.4 ± 0.4°C covered all readings.

The JCF showed just as good temperature control on some occasions eg for the 40 radius measurements on group 2 lenses saline temperature was in the range 20.5 ± 0.3°C but at other times eg for groups 4, 5, 6 the temperature was 23.1 ± 0.9°C. This may have been due to insufficient saline mixing within the wet cell.
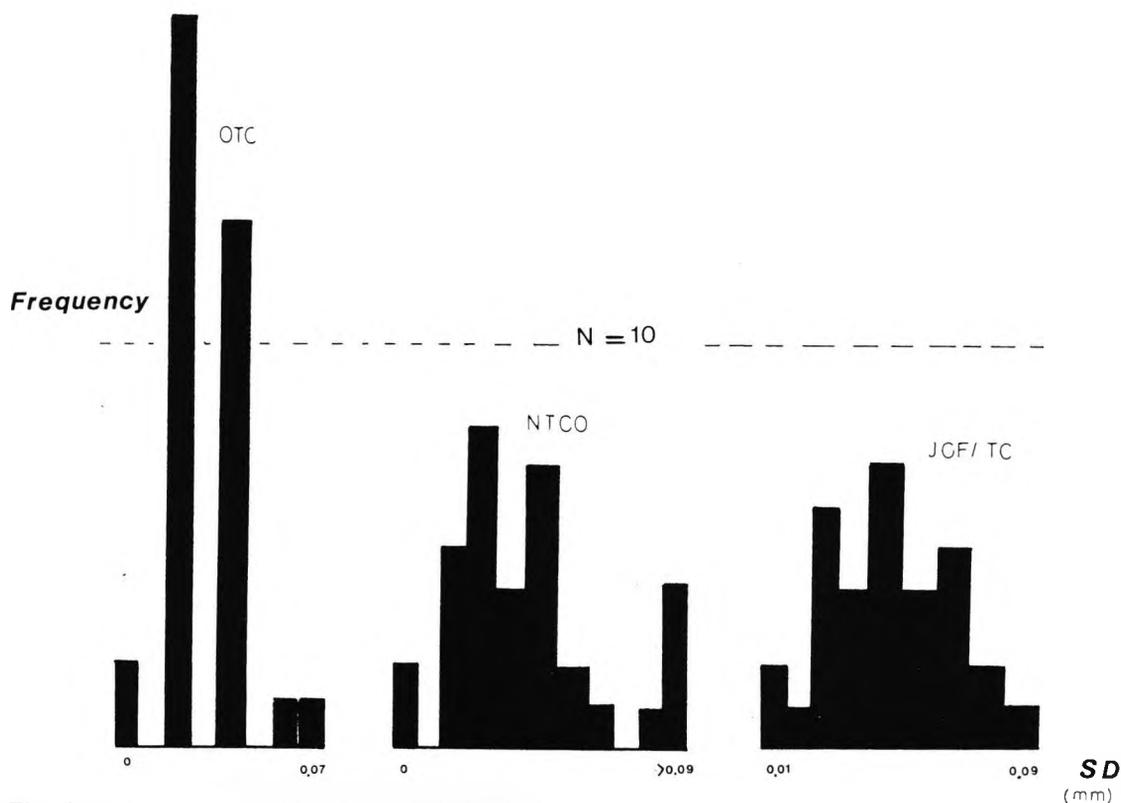
Fig. 2. Histograms of SD values for individual lenses measured on the temperature controlled Optison (OTC), the non-temperature controlled Optison (NTCO) and the Optimec JCF (JCF/TC)

Measurement consistency

The SD values for all lenses are shown in histogram form in Fig. 2.

The effect of temperature control on the Optison SD values was impressive. Without temperature control 21% of lenses tested in the NTCO had a SD of 0.02mm or less. When the same lenses were measured in the TCO 57% of the lenses had a SD of 0.02mm or less. With the JCF the SD values showed a more normal distribution with a modal value of 0.05mm.

Measurement time

For the JCF the average time to remove a lens from its vial, place it in the wet cell, centre it, measure it, and return it to the vial was in the order of 55 seconds. The same process in the OTC took about 10 seconds less as there was no mechanical adjustment needed to obtain a measurement. During the OTC test the equipment needed recalibrating only twice.

Radius differences between the instruments.

Table G summarizes the group means.

With the accurate glass test spheres being unusable on the Optison and not available for the JCF no conclusions on absolute accuracy are possible. The AO radiuscope obtains its radius estimate from the lens vertex whereas the soft lens instruments tested use a much larger part of the lens surface to obtain radius estimates. If the PMMA lenses were spherical over the whole measured surface then comparison of results is relevant.

In the higher water content groups the JCF gave flatter readings than the OTC. The difference between the two instruments increased as the water content of the lens group increased. It is reiterated that the pH of the saline was different for the two instrument tests. For this reason the results of the NTCO are included as these were carried out at the same time as the JCF test and the same pH saline was used. Figs 3, 4 and 5 show the results of the higher water content groups and it can be seen that when the pH is the same there is far better agreement between the JCF and NTCO radius estimates even though the JCF still tended to read slightly flatter than the NTCO instrument.
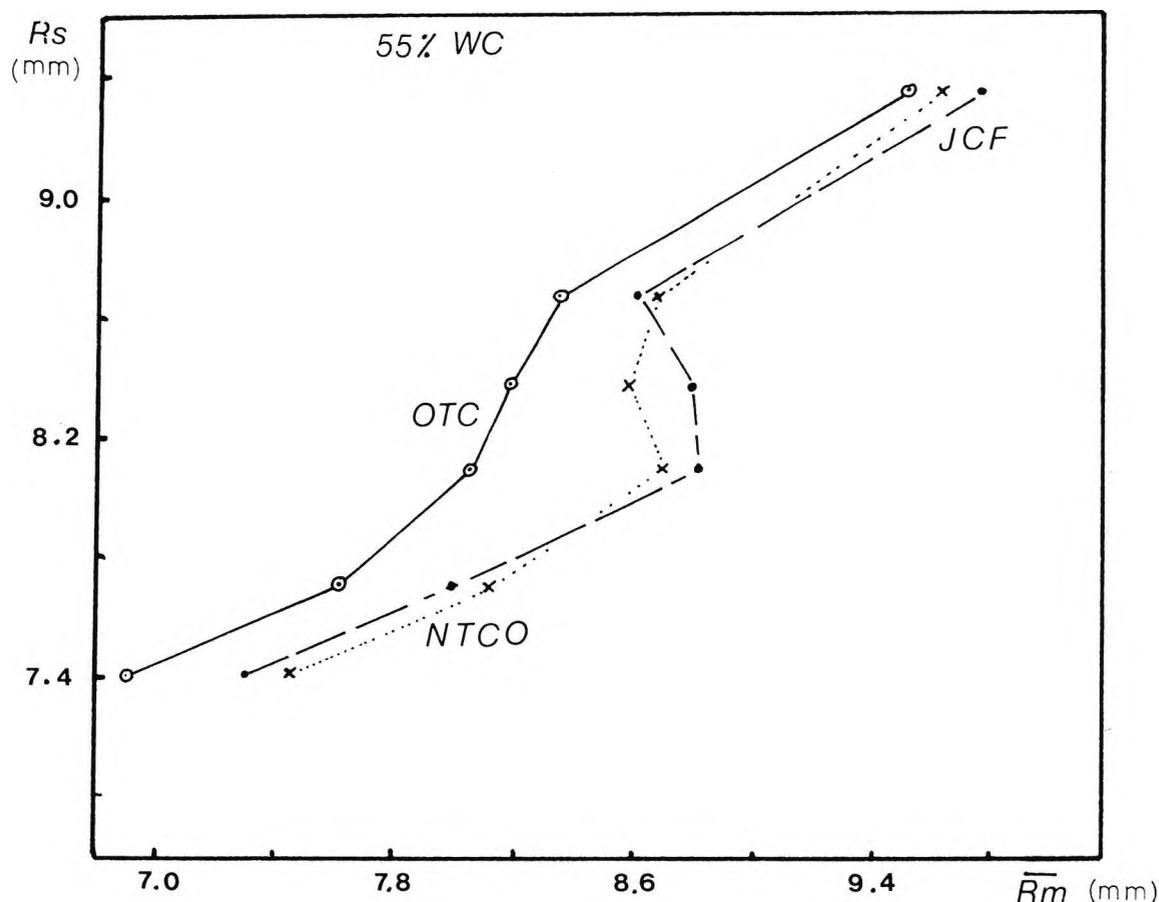
Fig. 3. The 55% water content group. The specified lens radii (Rs) are plotted against the experimental mean radius values (Rm). NTCO values and JCF values were obtained using the same pH saline.

Table G (All measurements in mm)   GROUP MEANS

Group	Material	N	Rs	Rr	OTC	NTCO	JCF	OTC − JCF
1.	PMMA	5	8.75	8.81	8.79		8.90	−0.11
2.	29%	10	8.90		8.54		8.52	+0.02
3.	38%	4	?		8.67		8.82	−0.15
4.	55%	6	8.28	8.11		8.51	8.53	−0.42
5.	70%	4	8.27	8.28		8.64	8.82	−0.54
6.	85%	5	7.98	7.67		8.18	8.37	−0.70

(Note: the Rm columns are headed OTC, NTCO, JCF)

Conclusions.

Understandably the lack of mechanical interference with the soft lens during its measurement on the OTC resulted in a lower SD (0.03mm) compared to the JCF (0.05mm). The centration of lenses in the wet cell of the JCF was very easy and efficient. The OTC still needs a better device for this part of the measurement procedure.

The lenses in groups 4, 5 and 6 were from the same family of copolymers. One component is PVP. It would appear that even given temperature controlled wet cells the pH variation can result in large radius changes. A pH change from 5.5 to 6.4 resulted in the 55% water content group flattening 0.3mm, the 70% water content group flattening 0.4mm and the 85% water content group flattening by a remarkable
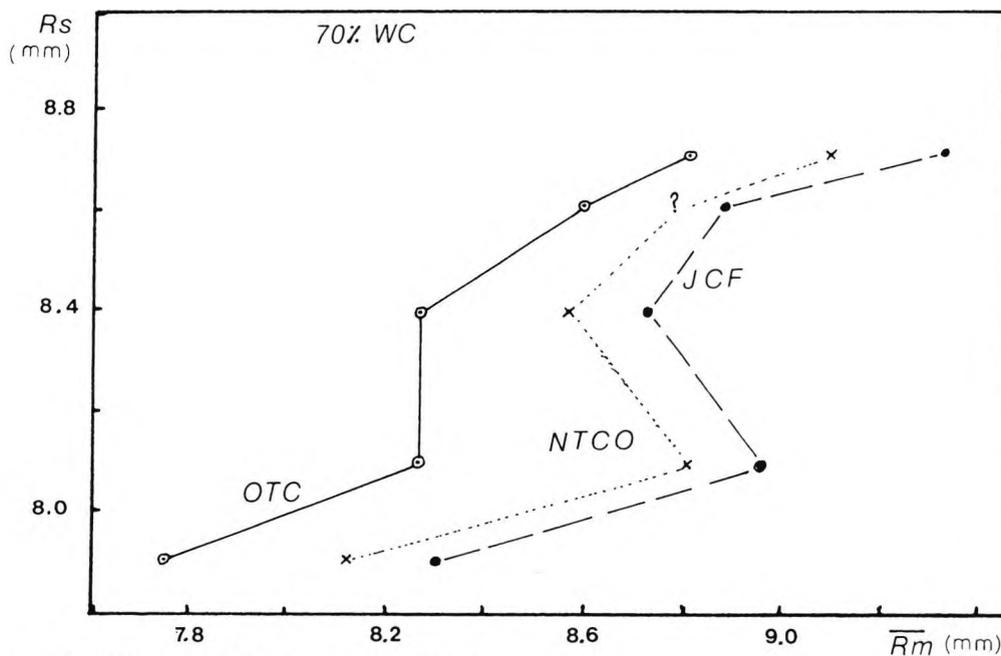
Fig. 4. The 70% water content group. The NTCO value "?" represents an estimate. The lens concerned broke and a true mean could not be obtained.
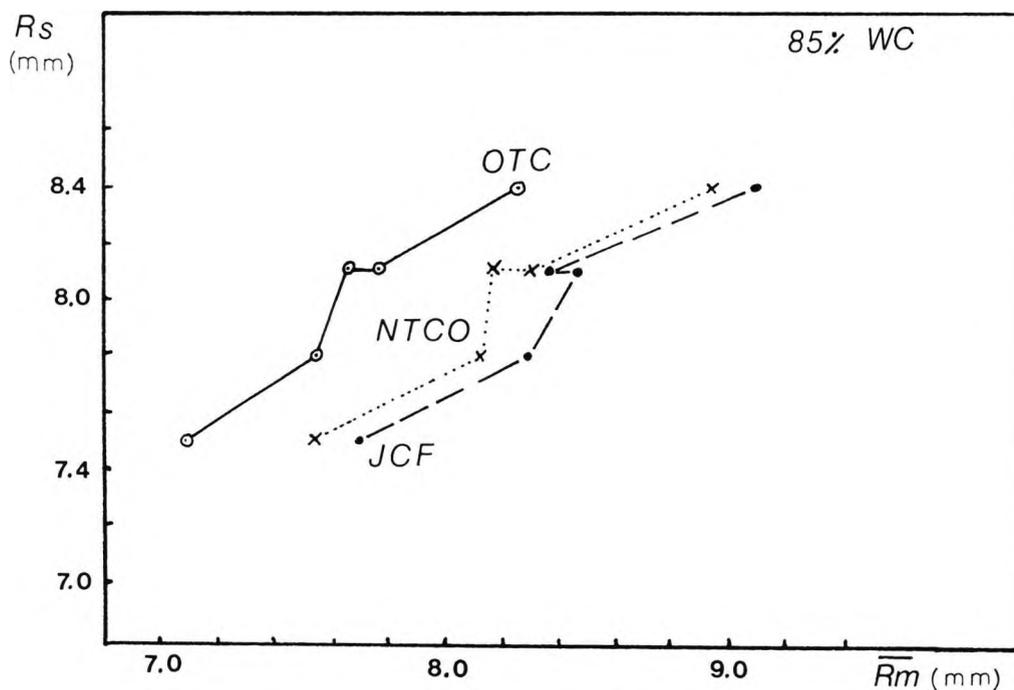
Fig. 5. The 85% water content group. The differences between the instruments show the same pattern as the 55% and 70% water content lenses.

0.6mm. Other workers (Masnick and Holden 1972, Poster and Skolink 1974, Gumpelmayer 1975, Carney and Hill 1976, Bennett and Holden 1977, Hofer 1976, Kemp 1979) have investigated and recorded changes in lens parameters when pH and tonicity have been changed. It is therefore important that if a user is measuring soft lenses that are prone to parameter changes due to the material concerned then the environmental variables (temperature, pH and tonicity) must be very carefully controlled or bizarre results can be obtained. Even if such lenses are measured on the same equipment by manufacturer and practitioner disagreement may well arise if environmental variables are different.

Both instruments can be obtained just to measure radii in saline under temperature controlled conditions. The JCF is obtainable in a range of models that measure BCOR, CT, OS as well as undertake surface inspection. If necessary all these functions can be incorporated into a single instrument with the temperature control incorporated. The Optison does not have these facilities as optional extras and can only be used as a radiuscope. The Optimec instruments may soon have wet cells available with a filter system in order to keep the saline clean and well mixed. Perhaps in the future the manufacturers will get together to combine the best features of both instruments.

BS 5562(1978) gives a tolerance for soft lens radii (hydrated) of ±0.20mm. Instruments should have an accuracy of at least half this value. If the SD values obtained in this study are doubled to approximate all errors then both instruments qualify to measure this dimension.

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Appendix 10

**Assessing a new soft lens radiuscope:
the AMS Optison**

M.J.A.Port

Assessing a new soft lens radiuscope: the AMS Optison

M J A Port

The four principal methods of determining the back central optic radius (BCOR or Base Curve) are:

- Keratometry
- Immersion Radiuscope
- Sagitta determination from a given chord diameter
- Matching techniques

The first two methods only use a small central area of the posterior lens surface to obtain a radius estimate. This radius can be referred to as the posterior apical radius (PAR) or vertex radius. The other two methods make use of a much larger area of the posterior surface to obtain the radius estimate. Spherical surfaces should give the same radius value whichever method is used. Aspheric surfaces will give disparate radius estimates depending on the particular method employed.

Radius measurement of soft lenses in air can be inaccurate for two main reasons. Firstly there may be evaporation from the lens surface during measurement causing a change in lens curvature (Sheridan and Shakespeare, 1981; Port, 1982). Secondly without the supportive nature of a saline environment the mass of the contact lens may cause some flexing and produce inaccurate radius estimates (Port, 1980). Measuring a soft contact lens in saline therefore provides a more satisfactory environment. The use of ultrasound to measure sagitta implies there is no mechanical interference with the lens once it has been centred. With good temperature control of the measurement saline the sound velocity remains constant and lens parameter change is minimised. The principles and development of sagitta measurement using ultrasound to find the radii of soft lenses had been described by Port (1976) and Port (1979).

With soft lens measurement the question of whether the surface is spherical or aspherical is not easy to answer. If it is aspheric and the measurement principles assume it to be spherical then the radius estimate is inaccurate. Holden (1977) hypothesised as to why soft lenses may present an aspheric surface when measured and Port (1981a) showed experimentally
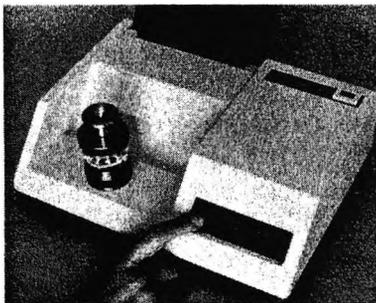
The AMS Optison

that a proportion of soft lenses intended to be spherical had aspheric surfaces. For this reason the author refers to radius estimates of soft lenses utilising the sagitta method as the Chord Related Radius (CRR). This concept takes into account the consideration that while two soft lenses may fit an eye identically they may give unequal radius estimates in the measurement situation when the radii are determined by different techniques.

The Panametrics soft lens radiuscope uses ultrasound to measure CRR and it has been described by Chaston and Fatt (1980) who compared the findings with radius estimates from other types of apparatus. The system is based on an industrial ultrasonic thickness gauge and is linked to a special wet cell that houses the transducer and contact lens.

The Optison also measures the CRR with ultrasound. A contact lens is supported on a hollow cylinder of known diameter(d). The lens is contained in a wet cell filled with normal saline. The radius is computed within the instrument from the expression

$$CRCR = \frac{d^2}{8s} + \frac{s}{2}$$

where 's' is the sagitta of the lens above the level of the lens support.

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In the Optison a concave transducer face is used to produce a 'strongly focused' ultrasound beam. The 'focus' or 'waist' of the beam is located where a contact lens surface with an average BCOR would be found. Contact lens surfaces other than of average BCOR are located either further from the transducer (steep lenses) or closer to the transducer (flat lenses) see Fig 1. Thus the incident ultrasound beam can be either slightly convergent, slightly divergent or parallel. These different effects can give rise to errors in sagittal measurement especially if the beam width is too great. The effects of highly curved surfaces in contact lenses can be minimised by using a narrow beam width. A 'weakly focusing' beam (longer focal length) can sometimes improve accuracy.
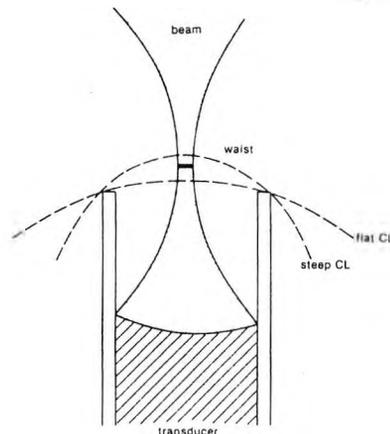
1 The principal part of an ultrasound beam formed by a strongly focusing transducer. Contact lenses of different curvatures are positioned in different parts of the beam.

The Optison system

All the necessary components are integrated into a single compact unit that measures $30 \times 23 \times 10$cms. The equipment is efficiently packed for transport. Its appearance is good with clean modern

lines. The neutral colouring of the casing is designed to blend harmoniously with office and professional equipment. The construction and workmanship appear to be first class. Certainly the user has the impression of a robust instrument that has been designed with a great deal of thought. The users handbook is well prepared and easy to follow.

Like the Panametrics apparatus the Optison wet cell (Fig 2) is not temperature controlled. For ultrasonic apparatus there are two sequelae. Firstly, the speed of sound varies with temperature and this affects the sag measurement obtained. Secondly, variations in saline temperature can affect lens dimensions. If the apparatus was used in a temperature controlled environment there would be few problems. The average contact lens practitioner is very unlikely to have this facility but the contact lens manufacturer might.

The instrument tested read the radius directly to 0.05mm intervals between 6.5 and 10.5mm. The radius is displayed digitally on red LEDs. Scaling to 0.02mm is available on request. Current cost of the equipment is £750 + VAT (1,500 US dollars).

Centration of the Contact Lens for measurement

Having fixed the wet cell in position and filled it with saline, the system is ready to be calibrated (see below). After calibration, lens measurement can be undertaken.

The Optison is provided with its own device for centring a soft lens on the support cylinder (see Fig 2).

2 The Optison wet cell and centration device for positioning lenses on the stainless steel lens support.

The contact lens is placed in the perforated basket and the wet cell lid screwed down. The lens should centre on the support with some vertical oscillation of the centration device. Several problems occurred with this device:
1 It was difficult to see the lens within the dome and check if it was well centred.

2 Bubbles of air were trapped under the lens on occasions which made measurement impossible.
3 Occasionally the lens slipped off the support and the edge was caught between the two baseplates of the centration device. If this happened it was impossible to recentre the lens.
4 The clip designed to hold the two baseplates together was not always functional.

The author abandoned the Optison centration device and merely used an 'Alexa' eye ointment applicator to remove the lens from the test vial, transfer the lens to the wet cell and centre the lens on the support cylinder. This proved to be a quick and simple method that did not damage any of the lenses tested. The steel lid of the wet cell was not used with this alternative method. Centration with the applicator was facilitated by placing a magnifying mirror behind the wet cell such that the operator had a side view of the lens and the lens support. An angle poise lamp was used to illuminate the wet cell. A built in light source—possibly using a fibre optic—to illuminate the lens in the wet cell would be very useful.

Calibrating the system

To take account of sound velocity changes within the saline the Optison has a calibration system. A Perspex (PMMA) flat is placed on the contact lens support. The instrument 'searches' for a velocity that gives a zero reading on the display. When this velocity has been found the calibration is complete. The time taken for this

calibration process depends on the ambient temperature of the saline in the wet cell. The higher the temperature the longer the calibration time. Typically the author found the calibration time to be in the order of 30 seconds. The frequency of calibration will depend on the change in saline temperature and tonicity.

There is no simple way to tell if recalibration is needed except by testing with the PMMA flat and noting if a zero reading is displayed. If an 'error' symbol is displayed then recalibration is required.

Lenses tested in the Optison
Series 1—rigid PMMA lenses

Lens no	Specified radius (Rs) (mm)	Optic diameter (mm)
1	8.25	13.50
2	8.50	13.50
3	8.75	13.50
4	9.00	14.50
5	9.25	14.50

Series 2—29 per cent water content hydrogel lenses
Back Vertex Power (BVP) —3.00DS
Overall Size (OS) 12.8mm

Lens no	Rs (mm)
5	8.80
6	8.80
7	8.60
8	8.60
9	8.40
10	8.40
11	8.20
12	8.20
13	8.00
14	9.00

Series 3—40 per cent water content hydrogel lenses; OS 14.0mm

Lens no	Rs (mm)	BVP (D)
15	8.40	−1.00
16	9.00	−1.00
17	aspheric	−3.00
18	aspheric	−1.00

Series 4—55 per cent water content hydrogel lenses

Lens no	Rs(mm)	OS(mm)	BVP(D)
19	7.4	13.0	−2.75
20	7.7	12.8	−3.50
21	8.1	13.2	−4.00
22	8.40	13.0	plano
23	8.70	13.5	−4.00
24	9:4	13.5	−1.50

Series 5—70 per cent water content hydrogel lenses

25	7.9	14.0	−4.00
26	8.1	13.5	−3.00
27	8.4	14.5	−2.75
28	8.7	14.0	−3.00

Series 6—85 per cent water content hydrogel lenses

29	7.5	13.0	−1.75
30	7.8	13.0	−4.25
31	8.1	13.0	−2.00
32	8.4	13.0	−2.50
33	8.1	13.0	+1.25

Methodology

Fresh saline was used to fill the measurement wet cell and a series of glass vials. Soft lenses in the series to be tested were removed from the manufacturers' vials and placed in the test vials. All saline was from the same batch and was renewed on a daily basis. Each lens to be measured was taken in turn from the test vial and transferred to the Optison measurement wet cell. There it was centred on the lens support and a single radius measurement (Rm) was taken. The lens was then returned to its test vial. The second and subsequent lenses were then measured in the same manner until a complete series had been measured once. The same series was then remeasured in the same way until each lens had been measured independently four times. For each lens a mean radius ($\bar{R}m$) and a standard deviation (SD) were obtained. Temperature of the saline was recorded with a narrow band laboratory mercury thermometer to 0.1°C. After all the lenses had been tested the pH of the saline in the test vials was recorded with a Pye Unicam pH meter.

Experiment 1 The lenses in series 1 were subjected to five independent trials using:

a The Optison

b The Optimec JCF Contact Lens analyser (Port, 1981b)

c An American Optical (AO) Radiuscope

Experiment 2 Radius estimates for lenses in series 2, 3, 4, 5, 6 were obtained with the Optison. $\bar{R}m$ values were compared to Rs values.

Experiment 3 Lenses 13 and 14 were measured at least 24 hours after experiment 2 in order to check for repeatability.

Results and Discussion

Experiment 1 The radius estimates ($\bar{R}m$) were closest to the specified radius values at the flat end of the range and furthest from Rs at the steep end of the range (see Fig 3).

3 The difference between the specified BCOR and the measured mean BCOR (y axis) compared to the specified BCOR (x axis). PMMA lenses measured with the Optison.
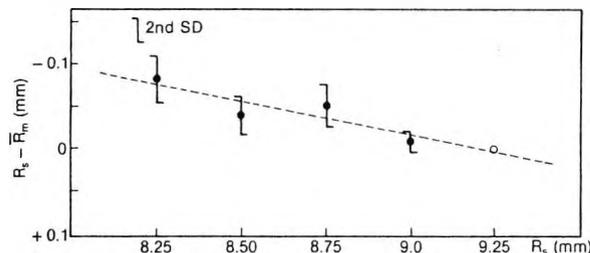
When the specified radius values were compared to the radiuscope measurements (Fig 4) the opposite effect was seen. However it should be restated that the radiuscope gives PAR and the Optison CRR. Without accurate glass testplates it is

4 The difference between the specified BCOR and the measured mean using a radiuscope compared to the specified radius.
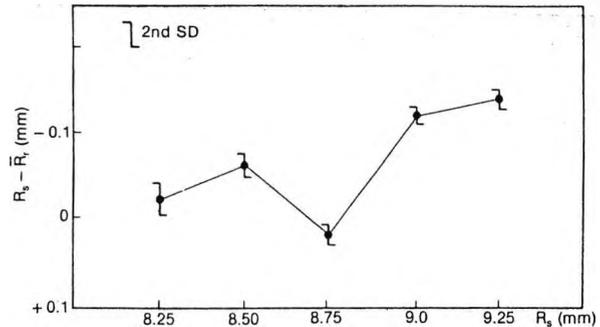
difficult to state categorically that the PMMA surfaces were spherical over the whole surface. The CRR values obtained with the Optimec instrument are shown in Table 1. For the rigid surfaces with Rs values of 8.25, 8.50 and 8.75mm the differences in mean values for the Optimec and the Optison were not greater than 0.02mm. The two flatter rigid surfaces gave means which were 0.33 and 0.25mm different for the two instruments. One might speculate that these two surfaces were not accurate enough to be used for the test. If they were ignored the remaining three surfaces showed quite a good agreement for radius values when the result of the three instruments were compared.

Experiment 2 The values of (Rs-$\bar{R}m$) are given in Figures 5 and 6. A summary of the SD values obtained is shown in Table 2 and a histogram of SD values for all the soft lenses is shown in Fig 7. The SD values do not show the trend found by Port (1981b) where the standard error increased with the water content of the lens. The reliability in this study of the Optison was certainly more variable because of no temperature control of the saline. It was found that whilst obtaining the necessary 40 measurements for Series 2 lenses the wet cell temperature varied between 17.8°C and 23.0°C. In this situation the operator had to recalibrate the instrument regularly to minimise the errors.

The author recalibrated after every five consecutive measurements. In those cases where the saline temperature remained fairly constant eg in Series 3 then the SD was low and gave some indication of the excellent consistency possible provided the

environment was kept to within ±0.5°C.

Experiment 3

Results:	Day 1	
Lens no	Rm (mm)	SD (mm)
13	7.97	0.03
14	9.00	zero

Result	Day 2	
Lens no	Rm (mm)	SD (mm)
13	7.95	0.04
14	8.94	0.02

From this small sample it can be estimated that the day to day repeatability was in the order of 0.04mm pH of saline:

The pH of the saline in the test vials showed a mean value of 6.5 (SD 0.25). The range measured was 6.2 to 7.0.

Saline temperature.

Lens series	Temperature range during measurements
1	18.6 to 21.0°C
2	17.8 to 23.0°C
3	22.5 to 23.1°C
4	18.8 to 19.4°C
5 and 6	21.3 to 24.6°C

Conclusions

BS 5562 (1978) states that the BCOR measurement of soft lenses should have a tolerance of ±0.1mm and soft lens radiuscopes should be capable of measuring to 0.05mm. It also advises measurement at a temperature of 20°C. The Optison has demonstrated its potential to measure all types of contemporary soft (hydrogel) lenses to a high level of consistency. The actual level of accuracy could not be easily found without the use of very accurate glass concave test surfaces that were known to be spherical over the whole area.

Provision of a temperature controlled wet cell would greatly enhance the ease of use and would provide more consistent measurement*. If this was not possible a

modification to provide automatic recalibration between measurements would be advantageous.

The centration device was not satisfactory in use and will certainly cause the user some frustration. The system can be used adequately without the device**.

The apparatus itself was reliable and no faults developed during the study. The average time to remove a lens from a vial, transfer it to the wet cell, take a measurement and return it to the vial was about 40 seconds. A skilled operator could reduce this time. The provision of three accurate rigid plano concave test blanks eg radii 8.0, 8.4, 8.8mm would be very useful to check the accuracy of the system over a range of commonly used radii. The process is analagous to checking a keratometer with steel balls.

The day to day repeatability was 0.04mm. It was felt that this figure could be reduced with temperature control of the wet cell. There was no problem at all in obtaining measurements with very thin lenses (Series 3) or high water content lenses (Series 6).

* A temperature control device that bolts on to the wet cell will be available in 1982.
** When the designers of the equipment were consulted it was found that they were aware of the shortcomings and that improvements were being incorporated into current production.

5 and 6 The difference between the specified radius and the measured mean radius using the Optison for individual lenses (hydrogels)
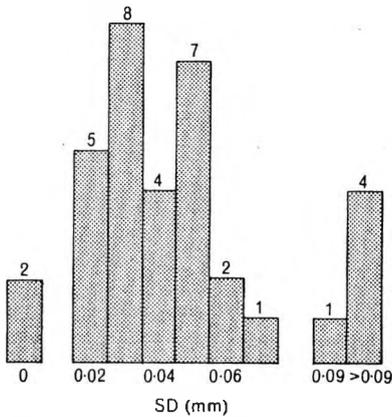
7 The distribution of Standard Deviations found for all the lenses tested with the Optison
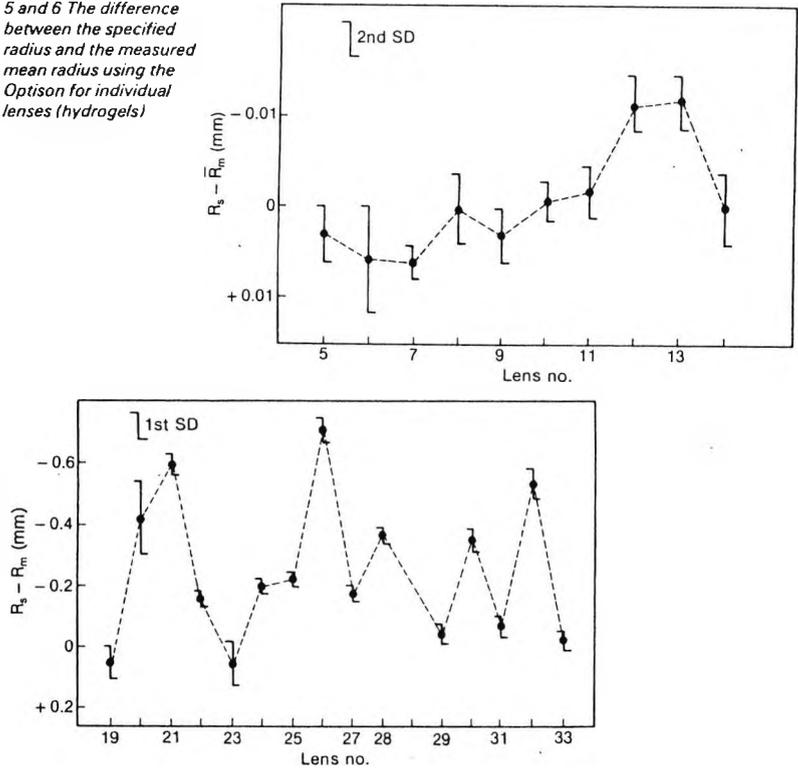
Table 1 (all values in mm)

Rs	CRR ($\bar{R}m$)		PAR (Rr)	Rr-$\bar{R}m$ (Optison)
	Optison	Optimec	AO Radiuscope	
8.25	8.33	8.34	8.27	− 0.06
8.50	8.54	8.56	8.56	− 0.02
8.75	8.80	8.78	8.73	− 0.07
9.00	8.99	9.32	9.12	+ 0.13
9.25	9.25	9.50	9.37	+ 0.12
Mean SD	0.04	0.03	0.01	

Table 2

Water content	Number of lenses	Mean SD	SD range
29%	10	0.06mm	0.03 to 0.09mm
40%	4	0.02	zero to 0.05
55%	6	0.11	0.03 to 0.25
70%	4	0.03	0.03 to 0.05
85%	5	0.07	0.05 to 0.09

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