‘Silicone rubber’ lenses in aphakia

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SUMMARY Tesicon, one of the commercially available ‘silicone rubber’ lenses, was used in the correction of aphakic patients. In 74% of cases the lenses were considered successful for a daily wear regimen by the patient. Furthermore, a small number of patients could wear this lens without interruption for 3 to 6 days at a time. Despite this good acceptance by patients, corneal problems (mainly staining) and lens problems (dry surfaces) were frequently encountered.

‘Silicone rubber’ has been used in tissue implants in the human for at least 20 years, mostly by plastic surgeons, and abundant references on their uses and adverse effects are available. As a contact lens the first patent was issued to Becker (1959), but it was only in the early 1970s that Mueller Welt (Black, 1972) in the USA and later Dow Corning made lenses available for investigation to use in human eyes. The original Dow Corning lenses, and the lenses manufactured by Titmus Eurocon (Giefer, 1977) and used in this study are surface coated in the form of a grafted hydrophilic surface. These differ from the material formulae (based on Siloxane) in the Volk and the Danker and Wohlk lenses. Furthermore, in all instances there are dissimilar lens designs. Therefore, while some conclusions will be concerned with silicone lenses in general, others will be for the specific lens used in this study.

Silicone rubber material interests the contact lens practitioner because of its possible higher gas permeability than any other material, but the in-vitro and in-vivo measurements by Simons *et al.* (1977), and Fitzgerald and Jones (1978) tended to show the latter are lower than expected. The coating process decreases the gas permeability, since it involves the use of non-silicone molecules. Although considered to be soft contact lenses, silicone rubber lenses are approximately 5 times more rigid than an equivalent 50% water content hydrophilic lens (Ruben, 1975).

The present study was carried out to assess the use of silicone rubber lenses in aphakia and to confirm the favourable impressions reported by Albarea *et al.* (1978), and Sundmacher (1978) as to their use as extended-wear lenses. The complications and adverse effects are also reported.

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Table 1 Patients with previous contact lens experience

Successful	Hard C/L	7	Soft C/L (DW)	2
Failure	Hard C/L	12	Soft C/L (DW)	6

Table 2 Technical data on Tesicon lenses (from Giefer, 1977)

O ₂ permeability coefficient (in vitro)	2.75 × 10 ⁻⁵ cm ² per second
H ₂ O absorption	0.5%
Transparency	98%
Refractive index	1.423
Density at 25°C	1.07 g/cm ³
Tensile strength	100%

Material and methods

Thirty-two aphakic patients (19 males and 13 females) aged 14 to 73 years (mean 50.2 years, SD 15.0 years) were fitted with silicone rubber lenses. These totalled 46 aphakic eyes with a mean keratometry of 7.82 mm (range 7.35 to 8.35 mm, SD 0.28 mm) and a mean difference in corneal radii 0.25 mm (range 0.00 to 1.00 mm, SD 0.19 mm). Of these 46 eyes 19 had never been fitted with contact lenses and were chosen at random, while the remaining 27 had previously worn contact lenses (Table 1).

The lenses used in this investigation were the silicone rubber lenses manufactured by Titmus Eurocon of Schaffenburg, West Germany. They were made of Tesicon, whose physical characteristics are given in Table 2. These lenses, as all silicone rubber lenses, are manufactured by a moulding process, and the range of fitting parameters available

is limited. In the present study back optic radii (BOR) were available in 0.1-mm increments from 7.4 to 8.4 mm, the overall size (OS) was 12.7 mm, and the power range from -20.00 to +20.00 D. Some minus lenses were used to correct phakic eyes when uniocular aphakia was being treated.

The fitting philosophy was based on a trial lens approach after a complete prefitting ophthalmological investigation, when particular attention was given to aspects relevant to contact lens practice. During the biomicroscopic examination the tear break-up time (BUT) was recorded, and the central corneal thickness and visible iris diameter were measured. During our fitting we aim at the flattest possible lens which permits a centred fit. The trial lens of first choice was usually 0.3 mm flatter than the flattest keratometric value and with an OS of 12.7 mm and a power of +15.00 D. An over-refraction was performed after the lens with the correct fitting parameters had been worn for 1 hour.

The lenses were issued to the patients as daily-wear lenses with a recommended wearing time of 2 hours initially and an increase of 1 hour daily up to a maximum of 8 hours, the patients being seen after 1 week. Further follow-up visits were arranged at 1 month, 3 months, and then every 3 months for 1 year. Some successful patients were switched to extended wear protocol for periods of 3 to 7 days, with usually a control visit after 24 hours.

Results

The average follow-up time was 8.48 months (range 3 to 12 months) at the time of the survey. Thirty-four eyes (74%) were considered as successfully fitted. Criteria for successful fitting were taken from the patient's viewpoint—a minimum of 10 hours' comfortable daily wearing time. In the 12 other eyes (26%) either contact lens wear was abandoned (11 eyes) or 10 hours' wearing time could not be reached (1 eye).

Six patients were permitted to sleep with their lenses for periods of 3 to 6 days, and in all but 1 instance this was possible without problems of tolerance. But in most instances prolonged wear resulted in poor surface quality and punctate corneal staining with fluorescein. In 2 patients serious neovascularisation occurred and in 1 uveitis with stromal necrosis.

The reasons for failures are recorded in Table 3. The commonest causes were discomfort and poor visual acuity (VA). The discomfort was conclusively linked to poor wetting surface in 1 case, while for the 3 others it seemed to be due to the small diameter of the lenses used; the edges impinge over the limbus with decentred lenses. The poor visual acuity was

Table 3 *Causes for failure on daily wear*

Discomfort	4
Poor VA	5 (with dry spots)
Ulcer	2
Oedema	1
Total	12

due to a poor wetting surface from the first day (3 eyes) and after 3 months (2 eyes) to surface deterioration.

Among the 34 eyes considered successful from the patients' viewpoint routine follow-up revealed various corneal problems, mainly corneal staining (10 eyes), new vessels (3 eyes), limbal indentation (5 eyes), oedema (1 eye). The corneal staining observed with Tesicon lenses is a punctate epithelial necrosis of the central cornea, more typical of hard contact lenses than soft contact lenses. New vessels were in most instances of the pannus type and in the superior quadrant, but 1 patient showed extensive new vessels after extended wear (Fig. 1). Limbal indentation was most obvious in 1 case of extended wear with a lens showing no movement at all, but 24 hours after contact lens removal no corneal staining was present.

The study of the lens surface showed dry spots in 11 cases (Fig. 2). These dry spots were linked to mucous deposits (8 cases) and/or cloudy lenses (4 cases). Therefore, despite the good acceptance of Tesicon lenses by aphakic patients, corneal problems, sometimes serious, are encountered.

The fitting characteristics of both successful and failed cases of daily wear were analysed and showed

Fig. 1 *Gross pannus due to continuous wear of silicone rubber lens*

Fig. 2 New silicone rubber lens showing mucous deposits and water droplets after half-hour wear

that no systematic bias was introduced by using different fitting increments: the mean flattening was $+0.35$ mm for the successful group and $+0.26$ mm for the failure group. The difference was not statistically significant. These findings support the manufacturer's recommended trial lens choice.

Discussion

So far no extensive comparative studies involving Tesicon lenses have been published. However, the present work enables certain conclusions to be drawn.

Because of the limited number of parameters available it was not easy to obtain an accurate fitting. However, when the vision was less than expected, it was difficult to pinpoint the reason for this subnormal VA, whether of soft lens aetiology or because of poor surface quality.

In general, the lenses were well tolerated, particularly by wearers who had failed with hard contact lenses. Few patients could manage extended wear with these lenses, but no more than 3 to 4 days is advisable. When the lens was immobilised there was no corneal staining, which suggests that staining was traumatic in origin, hence a need for better wetting properties of the lenses manufactured in the future. In our opinion, the optimal silicone rubber lens should be a thin, small lens. A thin lens, particularly at the edge, would avoid limbal grooving induced by the high rigidity of this material, and a small lens minimises interference with the corneal metabolism.

The commonest problem encountered is that of

dry spots. The pre-lens tear film is not continuous (Fig. 3). One remedy for this is to use contact lens solutions. On that point various approaches have been put forward: first soft-lens solutions were used, then specially formulated solutions were developed, neither with great success. Now the manufacturers recommend the use of hard-contact-lens solutions, which had been advocated for some time by Ruben (1978).

Because of the lens rigidity a posterior lens tear film is present between the lens and the cornea and collects mucus, as seen with hard scleral lenses.

Fig. 3 Typical drying of surface of silicone rubber when on the eye. Also showing corneo-lens tear space floating deposits

Fig. 4 Phase contrast photograph magnification of silicone rubber lens surface showing fine granulations with some deposits ($\times 50$)

Deposits were present on both lens surfaces. It was therefore surprising to find few complications involving the palpebral conjunctiva. On the contrary, silicone rubber lenses were shown to create the most corneal staining in a study conducted by Hamano (1979), comparing hard corneal, daily, and extended wear hydrophilic and silicone rubber lenses. Recently, scanning electron microscopical observations by Hamano (1979) and contrast phase studies by Ruben and Guillon (1978) (Fig. 4) have shown the poor surface quality of the present silicone rubber lenses.

Finally, the deposits encountered on Tesicon lenses are not of the mulberry types but mucous, lipids, and foreign body materials in isolated areas. This suggests that with hydrophilic lenses degenerate polymer is present and causes some forms of deposit formation.

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