EFFICACY AND SAFETY OF HYPROMELLOSE IN OCULAR IMPLANT SURGERY

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Abstract

In order to assess the efficacy of hypromellose as a viscoelastic substance in cataract surgery with posterior chamber intraocular lens implantation, we studied a series of 88 cases who underwent surgery with either alternate use of a viscoelastic substance (hypromellose, 39 patients, or sodium hyaluronate, 5 patients) or air (44 patients) in the anterior chamber. Endothelial cell loss was least in the group in which air was used (18 ± 3% céll loss, mean ± SEM), compared with hypromellose (26 ± 3%) and sodium hyaluronate (28±6%), but the difference in percentage cell loss between the groups did not reach statistical significance. Some operative difficulties were encountered in both groups. In both the air and hypromellose groups there were two patients with an early postoperative rise in intraocular pressure, but this was easily controlled, and in both groups there were two patients with postoperative corneal oedema which soon cleared. Viscoelastic substances used in this study were not shown to be superior to air in protecting the corneal endothelium. For this reason use of hypromellose should be confined to situations where its use is likely content some special advantage, as in the presence of a bound-down pupil in patient's with chronic glaucoma or perhaps to facilitate 'in the bag' implantation. Key words: Hypromellose, hydroxypropylmethylcellulose, sodium hyaluronate, viscoelastic substance,

air, implant surgery, corneal endothelium.

Viscoelastic substances are frequently used during extracapsular lens extraction to maintain the anterior chamber and to expand the capsular bag to facilitate insertion of a posterior chamber intraocular lens. Alternatively air may be used to maintain the anterior chamber, but it may escape with sudden flattening of the anterior chamber with the risk of the lens touching the corneal endothelium thus affecting the integrity of the cornea. Balanced salt solution used to maintain the anterior chamber lacks the viscosity of the viscoelastic substances and may also escape with loss of the anterior chamber and corneal endothelial touch.

The most frequently used viscoelastic substance is sodium hyaluronate (Healon),¹⁻³ which is unfortunately expensive. Other substances have been proposed as substitutes for sodium hyaluronate including hydroxypropylmethylcellulose and hypromellose^{4,5} although their use has been criticised.⁶

It is claimed that viscoelastic substances protect the corneal endothelium, but reports conflict.⁷ There is a risk of postoperative rise in

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intraocular pressure with viscoelastic substances, particularly sodium hyaluronate.⁸⁻¹⁰

We have compared the relative efficacy of 3% hypromellose with air in facilitating the implantation of posterior chamber lenses. The technical difficulties with implantation, postoperative intraocular pressure, corneal clarity, anterior chamber reaction and corneal endothelial cell counts before and after operation were monitored. Sodium hyaluronate was also used in a few patients receiving a viscoelastic substance.

MATERIALS AND METHODS

After routine extracapsular cataract extraction a posterior chamber intraocular lens was implanted under air in 44 cases and under viscoelastic substance in 44 patients (3% hypromellose in 39 cases, and sodium hyaluronate in 5 cases). Surgery was performed by a member of the staff or by the registrar under his direction. Air or a viscoelastic substance was used on alternate cases. Intraoperative difficulties and facility of implantation were noted. Intraocular pressure was recorded on the first day and one week after operation, together with corneal clarity, degree of anterior chamber reaction and visual acuity.

Hypromellose was injected prior to expression of the nucleus and was also used to coat the intraocular lens. Air or further hypromellose was injected immediately after routine extracapsular extraction and removed by aspiration at the conclusion of the procedure.

The 3% hypromellose in balanced salt was supplied by Sigma Pharmaceuticals. It was filtered to remove particles above 10 microns and sterilised in presterilised vials by heating at 120 °C for 30 minutes. The contents of the vials were subjected to sterility testing to Standard for Therapeutic Goods, Therapeutic Goods Order Number 11 of the Commonwealth Department of Health. Three per cent hypromellose is a clear viscous gel of pH 7.18, total solids 3.71% w/v.

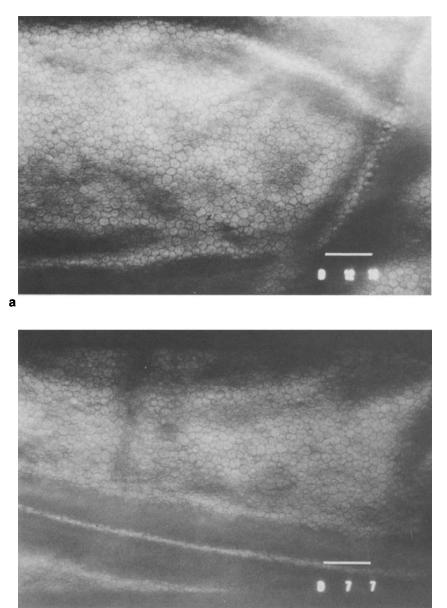
Specular microscopy of the corneal endothelium was performed using the wide field Pocklington contact specular microscope, following the instillation of topical oxybuprocaine hydrochloride 0.5% and without the use of a contact lens as described previously.¹¹ Statistical analysis of the data was performed using the Mann-Whitney test.¹²

RESULTS

In seven patients in whom air was used operative difficulties were experienced. These included loss of air, corneal touch, prolonged operative time, difficulty in expressing the nucleus, difficulty with insertion, and disinsertion of the iris, but the most serious was one case of vitreous loss. An anterior chamber lens was inserted in this latter case after wound toilet and anterior vitrectomy. In three patients postoperative inflammation was severe and in two others some corneal oedema was present which cleared. One patient with psuedoexfoliation of the lens capsule had an intraocular pressure of 60 mmHg on the second postoperative day; this was quickly controlled to 16 mmHg with medication and did not rise again. Another patient with pre-existing chronic open-angle glaucoma had a pressure of 30 mmHg on the second postoperative day; this was controlled to 10 mmHg and did not rise again. There were no other rises in pressure.

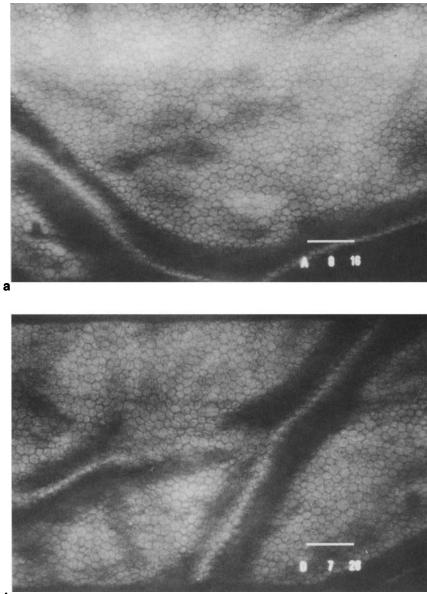
In ten patients in whom hypromellose was used operative difficulties were experienced. These included difficulty with aspiration in four patients, difficulty in delivering the nucleus in two patients, an operative hyphaema in one patient, a bulging eye in one patient, a McCannel suture was needed for one zonular disinsertion and in another air was needed to insert the lens. Two patients had postoperative oedema which later cleared, and one had fibrin deposition on the lens. A postoperative pressure rise to over 20 mmHg was detected in two patients, but was serious in only one with pre-existing chronic open-angle glaucoma where a pressure of 44 mmHg responded quickly to treatment, and there were no cases of late rise in pressure.

The five cases in which sodium hyaluronate was used included two with glaucoma in whom full iridectomies were needed, but the procedure was otherwise uneventful. One other patient had a flat anterior chamber for two days after operation, and another had heavy release of pigment on lens insertion. No case of postoperative rise in pressure occurred.



b

Figure 1: Specular microscopy of 75-year-old female. (a) Before surgery, endothelial cell count 2225 cells/mm² with regular mosaic. (b) After uncomplicated extracapsular cataract extraction and posterior chamber intraocular lens implant with use of air, endothelial cell count 2050 cells/mm² with mild pleomorphism and polymegathism. Bar = 100 μ m.



b

Figure 2: Specular microscopy of 79-year-old female. (a) Before surgery, endothelial cell count 2600 cells/mm² with regular mosaic. (b) After extracapsular cataract extraction and posterior chamber intraocular lens implant using hypromellose. Surgery complicated by bulging eye, loss of anterior chamber and iris prolapse. Lens was dialled into position. Endothelial cell count 2500 cells/mm² with mild pleomorphism and polymegathism. Bar = 100 μ m.

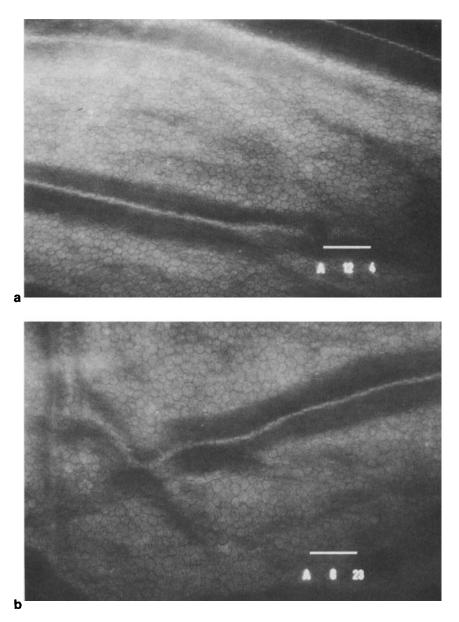


Figure 3: Specular microscopy of 60-year-old male with angle-closure glaucoma, prior to peripheral iridectomy and miotic pupil on pilocarpine. (a) Before surgery, endothelial cell count 2550 cells/mm² with mild pleomorphism and polymegathism. (b) After extracapsular cataract extraction and posterior chamber intraocular lens implant using sodium hyaluronate. Peripheral iridectomy was converted to broad iridectomy and a scissors capsulotomy performed. Endothelial cell count 1800 cells/mm² with moderate pleomorphism and polymegathism. Bar = 100 μ m.

 TABLE 1

 Specular Microscopy Before and After Surgery: Endothelial Cell Counts/mm² and Cell Morphology

Air		Hypromellose	
After	Before	After	
 1475 moderate P&p 2075 mild P&p 2000 mild P&p 1850 regular 2200 mild P&p 2000 regular 1800 moderate P&p 2075 mild P&p 1925 moderate P&p 2755 mild P&p 2375 mild P&p 2375 mild P&p 2400 mild P&p 2400 mild P&p 260 mild P&p 2925 regular 2000 mild P&p 	1350 moderate P&p 2775 mild P&p 2900 regular 2325 mild P&p 2950 regular 2800 mild P&p 3300 mild P&p 2500 regular 3050 mild P&p 2600 regular 3450 mild P, moderate p 2975 regular 3875 regular 1825 moderate P&p 3750 regular 950 regular 2975 regular 3050 regular	805 moderate P&p 1575 mild P&p 12225 mild P&p 1625 moderate P&p 2625 mild P&p 2630 mild P&p 2775 mild P&p 1625 regular 1975 mild P&p 2500 mild P&p 2575 mild P, moderate p 2475 regular 1250 moderate P&p 2325 mild P&p 700 mild P&p 2050 moderate P, marked p 1125 moderate P&p	
	1475 moderate P&p 2075 mild P&p 2000 mild P&p 1850 regular 2200 mild P&p 2000 regular 1800 moderate P&p 2075 mild P&p 1925 moderate P&p 1925 moderate P&p 2725 mild P&p 1575 mild P&p 2375 mild P&p 2400 mild P&p 2400 mild P&p 2650 mild P&p 2925 regular	1475 moderate P&p 1350 moderate P&p 2075 mild P&p 2775 mild P&p 2000 mild P&p 2900 regular 1850 regular 2325 mild P&p 2000 mild P&p 2950 regular 2000 regular 2325 mild P&p 2000 regular 2300 mild P&p 2000 regular 2800 mild P&p 2000 regular 2800 mild P&p 2000 regular 2800 mild P&p 1800 moderate P&p 300 mild P&p 2075 mild P&p 2500 regular 1925 moderate P&p 3050 mild P&p 1450 moderate P&p 2600 regular 2755 mild P&p 2975 regular 2375 mild P&p 3875 regular 2400 mild P&p 1825 moderate P&p 2400 mild P&p 3750 regular 2400 mild P&p 950 regular 2925 regular 2975 regular 2925 regular 2975 regular 2050 mild P&p 3050 regular	

P = Pleomorphism; p = polymegathism.

No significant difference in percentage cell loss between air and hypromellose before and after surgery (U = 247, p > 0.05, Mann-Whitney).

Not all patients attended for postoperative endothelial cell counts, but the 19 in whom air was used and for whom preoperative and postoperative endothelial cell counts were obtained showed an endothelial cell loss of $18 \pm 3\%$ (mean \pm standard error of the mean) (Figure 1); of 19 in whom hypromellose was used the cell loss was $26 \pm 3\%$ (mean \pm SEM) (Figure 2), and for sodium hyaluronate $28 \pm 6\%$ (Figure 3). The endothelial cell counts for air and hypromellose are shown in Table 1. There was no statistically significant difference in the percentage cell loss between the groups (U = 247, p > 0.05, Mann-Whitney).

DISCUSSION

The operative difficulties were similar in each group, but perhaps less severe when a viscoelastic substance was used. Some difficulties were experienced in drawing up hypromellose and injecting it into the anterior chamber through a very small bore cannula, but these difficulties were easily overcome with the use of appropriate instrumentation. In both the group with air and that with a viscoelastic substance there were two patients with some postoperative corneal oedema which cleared and two patients with a postoperative rise in intraocular pressure which was easily controlled. Postoperative inflammation also occurred occasionally in each group.

Our figures for preoperative and postoperative endothelial cell counts do not support any superiority for hypromellose over air in protecting the corneal endothelium during the implantation of intraocular lenses. Endothelial cell loss was least with air, intermediate with hypromellose, and greatest with sodium hyaluronate, but these differences were not statistically significant. The number of cases in which sodium hyaluronate was used was small and surgically more difficult than most patients in this series. Viscoelastic substances were not superior to air in preventing endothelial damage in this series; this agrees with the findings of Bourne et al.7 Viscoelastic substances do not appear to have made routine surgery any safer in this respect. The routine use of viscoelastic substances should be questioned unless there is likely to be a definite gain from their use, as in cases with previous glaucoma surgery where there is a small or bound-down pupil, or if the surgeon feels their use confers some special advantage such as easier insertion of the lens "in the bag".

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