COMPARISON OF THE EFFECT OF HEALON[®] VS. VISCOAT[®] ON ENDOTHELIAL CELL COUNT AFTER PHACOEMULSIFICATION AND POSTERIOR CHAMBER LENS IMPLANTATION

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SUMMARY

To evaluate the protective effect of 1% sodium hyaluronate (Healon[®]) vs. a mixture of 4% chondroitin sulfate and 3% sodium hyaluronate (Viscoat[®]) on the central corneal endothelium during surgery, we prospectively examined 20 eyes of 20 patients who underwent clear corneal phacoemulsification and implantation of an intracapsular posterior chamber intraocular lens (PC-IOL) with either Healon[®] (10 eyes) or a combined use of Viscoat[®] and Healon[®] (10 eyes) as viscoelastic material. We compared the central endothelial cell counts, recorded by specular microscopy, preoperatively and 6 weeks postoperatively.

Our results suggest that Viscoat[®] offers no significant better endothelial cell protection during phacoemulsification than Healon[®].

RESUME

Afin d'évaluer l'effet protecteur de l'hyaluronate de sodium 1% (Healon®) vs. le sulfate de chondroïtine 4% et l'hyaluronate de sodium 3% (Viscoat®) sur

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received: 20.08.99 accepted: 27.09.99 l'endothélium de la cornée centrale, nous avons examiné de façon prospective 20 yeux de 20 patients qui ont subi une phacoémulsification par voie cornéenne avec implantation d'une lentille intracapsulaire utilisant comme matériel viscoélastique le Healon® (10 yeux) ou une combinaison de Healon® et de Viscoat® (10 yeux).

Nous avons comparé le nombre de cellules endothéliales centrales mesuré avec le microscope spéculaire avant et 6 semaines après l'opération.

Nos résultats suggèrent que le Viscoat[®] n'offre pas une meilleure protection des cellules endothéliales durant la phacoémulsification que le Healon[®].

SAMENVATTING

Teneinde het beschermend effect na te gaan van 1% natrium hyaluronaat (Healon®) vs. een mengsel van 4% chondroitine sulfaat en 3% natrium hyaluronaat (Viscoat®) op het endothelium van de centrale cornea, hebben we prospectief 20 ogen van 20 patiënten onderzocht die een phacoemulsificatie via corneale incisie hebben ondergaan met implantatie van een achterkamer intraoculaire lens, waarbij als viscoelastisch materiaal Healon® of een combinatie van Healon® en Viscoat® werd gebruikt. We vergeleken het aantal centrale endotheelcellen, gemeten met de speculaire microscoop, preoperatief en 6 weken postoperatief.

Onze bevindingen suggereren dat bij phacoemulsificatie Viscoat[®] geen betere bescherming van het centrale endothelium biedt dan Healon[®].

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KEY WORDS

Viscoelastic substances, endothelial cell protection, phacoemulsification.

MOTS CLES

Substance viscoélastique, protection endothéliale cornéenne, phacoémulsification.

INTRODUCTION

In recent years, numerous articles have described the characteristics of viscoelastic substances (VES) and their ability to facilitate cataract surgery and to protect the corneal endothelium from damage (4-7, 9-12, 14, 15, 17).

Prevention of injury to the corneal endothelium during phacoemulsification and IOL implantation indeed is a major concern for the cataract surgeon.

Nowadays, a range of products are available with varying physical profiles that make current VES more or less suitable in different surgical situations. All the currently available VES can be grouped into two categories: cohesive and dispersive.

Cohesiveness is the ability of the VES to adhere to itself and thus the resistance to dissolve. On the other hand, dispersive agents easily dissolve and have lower molecular weight, lower surface tension and lower pseudoplasticity (the decrease in viscosity under exposure to increasing shear rate) than the cohesive group (9). Each of these groups, the dispersive and the cohesive, has certain advantages in cataract surgery, but also certain disadvantages. For example, the low viscosity of Healon® (1% sodium hyaluronate) at high shear rates and the greater cohesiveness, greatly facilitate its iniection and aspiration (9). Healon® appears to be aspirated nearly completely at the initiation of phacoemulsification (9,15). Conversely, the high viscosity of Healon® at low shear rates enhances its ability to maintain opened intraocular spaces into which it has been injected (9). The potential advantages of Viscoat® (4% chondroïtin sulfate and 3% sodium hyaluronate) during phacoemulsification is its lower cohesiveness and higher viscosity at high shear rates (7,9). This enables it to be retained in the eye during phacoemulsification; disadvantages are the entrapment of air bubbles and the lower transparancy than Healon[®], thereby reducing visibility (4,7,9,15). Another disadvantage of Viscoat[®] is its resistance to removal (7,15). Theoretically, the greater coating capabilities of Viscoat[®] might enhance its ability to protect intraocular structures, such as the endothelium (5,7,12,15).

Tab. I: Mean peroperatively assessed parameters

	Healon®	Viscoat®	P-value
ultrasound time (in min.) ± SD	2.2±0.5	2.1±0.7	0.6
average ultrasound power (in %) \pm SD	36.6±2.2	35.7±3.4	0.5
total amount of irrigating solution (in ml.) \pm SD	199± 92	180± 85	0.7

Our aim was to try to find out which technique provided the best endothelial protection during phacoemulsification and IOL implantation using either Healon[®] or a combined use of Viscoat[®] and Healon[®] as the VES.

MATERIALS AND METHODS

A series of 20 consecutive patients, scheduled for phacoemulsification and IOL implantation, were randomly assigned to either Healon® (10 patients) or combined Viscoat®-Healon® (10 patients) groups. Exclusion criteria included a history of previous trauma, surgery or ocular disease other than cataract, abnormal specular microsopy (< 1650 cells/mm²) and major intraoperative complications such as posterior capsule rupture or vitreous loss. The procedures were identical and performed by one surgeon using the same phacoemulsification machine (Legacy® Alcon).

After retrobulbar anesthesia, a two-step corneal incision of 3.2 millimeters was made, using a microsurgical knife followed by a 3.2 mm keratome. The anterior chamber was filled with one of the two selected VES (Healon® or Viscoat[®]). After a circular capsulorhexis was made, the lens was hydrodissected with balanced salt solution (BSS). Following a 1-millimeter sideport, posterior chamber phacoemulsification was performed, dissecting the nucleus into four quadrants and removing the nucleus with the phaco-tip. Residual pheripheral cortex was removed with the irrigation/aspiration (I/A) handpiece. Balanced salt solution (BSS) was the irrigating solution in all procedures. The incision was then enlarged to 3,5 mm, Healon® was injected into the capsular bag and a foldable posterior-chamber IOL (Hydroview®; Storz) was implanted. After removal of the VES by I/A, the pupil was constricted with acetylcholine 10% and the incision closed with a single radial stitch (nylon 10-0). All patients finally received an antibiotic ointment before the eye was patched and shielded. Topical corticosteriods and antibiotics were administered as postoperative treatment.

The following parameters were assessed peroperatively: ultrasound time (in minutes), average ultrasound power (expressed as percentage) and the total amount of irrigating solution used during surgery (in ml).

The central corneal endothelium was examined and photographed with a Konan specular microscope by a single observer, preoperatively and approximately 6 to 8 weeks postoperatively. The observer was masked from the randomization. Three photographs were made and the mean endothelial cell count (cells/mm²) was calculated. Endothelial cell loss was expressed as a percentage of the preoperative cell density. The level of statistical significance used was P < 0,05, Differences between group means were tested with the paired Student's test.

RESULTS

The mean age of the patients was 69 years (range 54 to 82 years) in the Healon-group and 72 years (range 39 to 84 years) in the Viscoatgroup. The sex-ratio was 2/8 (M/F) in the Healon-group and 5/5 (M/F) in the Viscoat-group. The mean peroperatively assessed parameters (ultrasound time, average ultrasound power and total amount of irrigating solution) were similar in both groups and are shown in table I.

The mean time-interval between the pre- and postoperative endothelial cell count was 7 weeks in both groups. The mean absolute endothelial cell count (number of cells/mm²) was 2298 cells/mm² preoperatively and 2056 cells/mm² postoperatively in the Viscoat®-group. The mean

	Healon®	Viscoat®	P-value
absolute endoth. cell loss (in cells/mm ²) \pm SEM	-254 ± 15.6	-227±12.7	0.7
relative endoth. cell loss (in %) \pm SEM	10.2± 3.1	9.7± 2.6	0.8

Tab. II: Mean absolute and relative endothelial cell loss

absolute and relative endothelial cell loss was similar in both groups and is shown in table II. Relative endothelial cell loss was $10,2\% \pm 3,1\%$ in the Healon[®]-group and $9,7\% \pm 2,6\%$ in the Viscoat[®]-group.

DISCUSSION

Although recent developments in cataract surgery were helpful in minimizing endothelial cell trauma, the corneal endothelium sustains damage during cataract surgery no matter what technique is used.

Our aim was to analyze which VES (Healon[®] or Viscoat[®]) provided the best possible endothelial cell protection during routine phacoemulsification and IOL-implantation.

We found no significant difference in endothelial cell loss in the eyes in which Viscoat[®] was used as a viscoelastic, compared to those in which Healon® was used. This result supports the reported observations of Koch et al. (9) who also noted no significant difference in central endothelial cell loss between the Healon® and Viscoat[®] subgroup during uncomplicated PCphacoemulsification. They mentioned however that when iris-plane phacoemulsification was performed, Viscoat[®] provided significant better endothelial cell protection than Healon[®]. In a study of 56 consecutive patients (60 eyes) who underwent routine phacoemulsification and PC-IOL implantation, Rafuse et al. (15) found a mean endothelial cell loss that was greater in the Viscoat® group than in the Healon® group, but not significantly so. Several laboratory studies have also compared the endothelial protective effects of Healon® and Viscoat[®]. Glasser et al. (7) found no difference in endothelial cell loss in the rabbit cornea between the Viscoat[®] group and the Healon[®] group when phacoemulsification alone was done, but when phacoemulsification was combined with traumatic lens implantation Viscoat[®] offered better protection. Craig et al. (4) compared the protective effects of Healon® vs. Viscoat® in eye-bank eyes in which phacoemulsification was done with and without injection of an air bubble into the anterior chamber. They found that Viscoat[®] offered a remarkable protective effect on the endothelium compared to Healon[®] when air was present in the anterior chamber. Matsuda et al. (12) compared the corneal endothelial protective effects of sodium hyaluronate (Healon®) and chondroitin sulfate alone or in combination (Viscoat®), in vitro and in vivo. Their results show that Viscoat® provides better protection for the endothelial cell layer both in vitro and in vivo compared to either of its components alone.

We are well aware that our study design was limited by the fact that (1) only cell density in the central cornea was examined, (2) only early postoperative cell loss (6-8 weeks) was measured, (3) no specific endothelial cell characteristics like changes in pleomorphism (cell shape variability), polymegathism (cell area variability), average cell perimeter etc. were noted and (4) only a relatively small number of patients was included so that no statistically significant results could be obtained.

It is well established that cell loss during cataract surgery is greatest in the superior endothelium (8,13,17). This study did not assess potentially important changes in the superior cornea since only central corneal endothelial cell loss was measured. Some authors reported a transient decrease in endothelial cell density following cataract surgery, but a recovery by the third postoperative month (2,3,16). In our study, the maximum time of postoperative endothelial cell count was only 8 weeks, with a minimum of 6 weeks. However, it is not clear how long it takes exactly for the endothelial cell count to stabilize after cataract surgery. Liesegang and Bourne (11) even reported continued endothelial cell loss several years after ECCE and IOL implantation.

Although we compared the use of Healon[®] vs. Viscoat[®] as the VES, Healon[®] was always used to fill the capsular bag, even when Viscoat[®] was used to fill the anterior chamber, since a cohesive, high molecular VES with high viscosity at low shear rate like Healon®, greatly facilitates the bag distention, the insertion of the IOL and its unfolding. At the same time, because of the cohesive characteristics, the substance will be aspirated more easily (9,15). In contrast, Viscoat[®] is more difficult to remove from the eye, because of its dispersiveness. Rafuse et al. (15) even suggested that the greater effort needed to remove the Viscoat® in itself could be the cause of the increased endothelial cell loss. The manufacturer of Viscoat® has indicated that the product can safely be left in the anterior chamber after surgery without risk of rises in postoperative ocular pressure. There are, however, reports that demonstrate rises in pressure within the first 24 hours after surgery in patients in whom Viscoat[®] was left in the eye (6,10,14). However, Embriano (5) reported that leaving Viscoat[®] in the eye caused a smaller rise in pressure than Healon® even when it was removed at the end of the operation. Probst et al. (14) also demonstrated that retaining Viscoat® after phacoemulsification results in no significant change in the corneal endothelial parameters. The "soft-shell" technique, in which a cohesive and a dispersive VES are used simultaneously in the anterior chamber, aims to take advantage of the best properties of both. In this technique a thin shell of dispersive VES is placed up against the cornea. Subsequently, the cohesive VES is injected in the anterior chamber. The aim of this technique is mainly to eliminate the blurring irregular fracture boundaries sometimes seen when Viscoat[®] is used alone, together with an optimal endothelial protection.

CONCLUSION

In conclusion, our results seem to indicate that Viscoat[®] offers no significantly greater protective effect on the corneal endothelium than Healon[®] during a routine phacoemulsification procedure. However, it would be useful to investigate the protective capabilities of Healon and Viscoat in patients with complications in whom there is increased manipulation of the nuclear material near the corneal endothelium or in whom the endothelial status is marginal.

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