PROSPECTIVE RANDOMIZED TRIAL COMPARING DISCOVISC® VERSUS HEALON® IN PHACOEMULSIFICATION

ESTUDIO PROSPECTIVO RANDOMIZADO COMPARANDO DISCOVISC® VERSUS HEALON® EN FACOEMULSIFICACIÓN

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ABSTRACT

Objective: To compare the intraoperative behaviour of both, DisCoVisc® and Healon® used as viscoelastics in cataract surgery.

Method: We prospectively evaluated 35 patients with cataracts who underwent phacoemulsification and intraocular lens implantation. Patients were randomized into two groups. Group A included 17 patients in where Healon® was used as a viscoelastic, whereas group B included 18 patients where the viscoelastic used was DisCoVisc®. After each procedure, the surgeon filled in a questionnaire describing the behaviour of the viscoelastic during the different stages of phacoemulsification.

Results: DisCoVisc® behaved as both cohesive and dispersive viscoelastic during capsulorrhexis, phacoemulsification and viscoelastic aspiration, whereas Healon® acted as a cohesive substance during all surgical stages. DisCoVisc® enabled better visualization and transparency during all the surgical stages and maintains the capsular bag better during the intraocular lens implantation. Viscoelastic aspiration was easier with Healon®.

Conclusions: DisCoVisc® is a new viscosurgical device with both cohesive and dispersive properties, which avoids using two different viscoelastics to improve the performance at different surgical stages.
INTRODUCTION

In the past twenty years, viscoelastics have contributed to the development of extracapsular cataract surgery and phacoemulsification. After the introduction of the first viscoelastics made of hyaluronate sodium, new compounds have been added, such as chondroitin sulphate and hydroxypropylmethylcellulose. These compounds are frequently found in different mixtures and concentrations to attempt and improve their rheological properties and different surgical times. Nevertheless, it is clear that during cataract surgery there are enough different surgical times that turn the benefits associated with a certain rheological feature into an obstacle at other stages; Arshinoff (1) already pointed out this fact.

While intraocular viscoelastics must be used in aqueous, isotonic and PH-balanced solutions, most of their physical properties are determined by their molecular nature, chain length and concentration of rheologically active polymers (1,2). Usually, the most desirable properties for any viscoelastic include its viscosity at rest (cut-off 0) and degree of cohesion, which determines their classification as either cohesive or dispersive. Viscosity at 0 cut-off is correlated to the molecular weight of the rheologically active viscoelastic component and may be used to classify viscoelastic agents. Long-chain viscoelastics tend to aggregate and are known as cohesive viscoelastics; short-chain viscoelastics, which are not prone to aggregation, are easily broken down and known as dispersive (1,2).

Cohesive substances do not adhere to the tissues and leave the eye as a block due to their tendency to aggregate. They are ideal to maintain spaces whenever the cut-off rate is null or low, that is, at rest (for instance, capsulorhexis). Such substances are derived from hyaluronic acid, for example Healon®.

Dispersive substances tend to disperse or fragment when aspirated and show high adherence to the tissues, thus acting as excellent endothelial protectors. They maintain spaces at high or medium cut-off rates (during the introduction of phaco or during phacoemulsification). Examples of dispersive substances are the by-products of hydroxypropylmethylcellulose and mixtures of hyaluronate and chondroitin sulphate, such as DisCoVisc®.

DisCoVisc® is a new viscoelastic whose innovative rheological features attempt to harness the benefits associated with its properties, both cohesive and dispersive. It is made of hyaluronic acid (1.6%) and chondroitin sulphate (4%) (table I).

The present study attempts to compare behavior during phacoemulsification using DisCoVisc®, the last viscoelastic introduced in clinical practice, and Healon®, which was the first viscoelastic to be introduced and is still in use.

Table I. Marketed Solutions Containing a Mixture of Hyaluronic Acid and Chondroitin sulphate

<table>
<thead>
<tr>
<th>Viscoelastics</th>
<th>Hyaluronic acid MW (D)</th>
<th>C (%)</th>
<th>Chondroitin sulphate MW (D)</th>
<th>C (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DisCoVisc®</td>
<td>1.7 M 1.6</td>
<td>25 K  4.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viscoat®</td>
<td>500 K 3.0</td>
<td>25 K  4.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

C: concentration; D: daltons; K: thousands; M: millions; MW: molecular weight.
SUBJECTS, MATERIAL AND METHODOLOGY

This prospective and randomized study included 35 patients about to undergo cataract surgery via ultrasound phacoemulsification and intraocular lens implant, both procedures to be performed by the same surgeon.

Two groups were selected. Viscoelastic Healon® was used in Group A, consisting of 17 eyes belonging to 17 patients. DisCoVisC® was used in Group B, consisting of 18 eyes belonging to 18 patients.

Surveys were designed to analyze the behavior of viscoelastics at each surgical step, assessing the following stages: 1) Viscoelastic injection; 2) visualization during procedures; 3) preservation of the anterior chamber during capsulorhexis; 4) phacoemulsification; 5) intraocular implant; and 6) viscoelastic aspiration. The properties of both viscoelastics were also compared during capsulorhexis, phacoemulsification and viscoelastic aspiration. After surgery, the surgeon filled out the questionnaires, which were processed later on.

The results obtained for both groups were statistically compared using the t-student method, whose alpha value was set at 5 percent.

RESULTS

Both viscoelastics were compared at different times during surgery.

When introducing the viscoelastic in the anterior chamber, we observed that this step was easily completed in both groups. In group A, injection was easy in 70.5 percent of cases and in group B this percentage went up to 83.33 percent of cases; no significant differences were observed (p: 0.33) (fig. 1).

As for visualization during surgery, it was excellent in 5.8 percent of group A’s cases, versus 72.22 percent of group B’s cases (p: 0.0003).

Preservation of the anterior chamber during capsulorhexis (fig. 2), phacoemulsification (fig. 3) and IOL implantation (fig. 4) was also analyzed. During capsulorhexis (fig. 2), preservation of the anterior chamber was satisfactory (taking into consideration good and excellent results) in 47.05 percent (group A) versus 100 percent of cases (group B) (p: 0.14). During phacoemulsification, preservation of the anterior chamber was satisfactory in 82.35 percent (group A) versus 100 percent of cases (group B) (p: 0.0491).
During IOL implantation, both viscoelastics kept a good anterior chamber, while no statistically significant differences were observed between both groups (p: 0.97). Regarding the preservation of the capsular sac during lens implantation (fig. 5), no excellent cases were found in group A and excellent cases were found in 44.44 percent of cases in group B (P: 0.0056), although preservation was considered good in 55.55 percent in the cases belonging to group A.

Concerning the viscoelastic aspiration upon surgery completion, this procedure was easy in 94.11 percent (group A) versus 0 percent of cases (group B) (P: 0.0001) (fig. 6).

Other variables analyzed included viscoelastic properties during surgery. During capsulorhexis, Healon® behaved like a cohesive in 100 percent of cases, and DisCoVisc® demonstrated both properties in 72.22 percent of cases. We found the same results when analyzing viscoelastic properties during phacoemulsification. During viscoelastic aspiration, Healon® behaved like a cohesive in 100 percent of cases and DisCoVisc® behaved like a dispersive in 44.44 percent of cases, presenting both properties in 55 percent of cases. The greater difficulties encountered when aspirating DisCoVisc® were due to its dispersive behavior at this stage.

Viscoelastics ability to expand the pupil was also assessed, observing this ability in 77.78 percent (group B) versus 41.17 percent of cases in group A (p: 0.053).

**DISCUSSION**

Twenty-five years ago, viscoelastics implied a revolution in cataract surgery. However, since their introduction, there is no consensus as to which viscoelastic is best. Due to the different properties of viscoelastics, some might prove to be more useful in certain surgical scenarios; it is difficult to define "one good for all viscoelastic". Significant attempts have been made to: 1) describe the ideal rheological properties for viscoelastics to fulfil the needs in the different surgical stages during phacoemulsification; and 2) adapt the use of several viscoelastics to the different scenarios involved. To date, we believe that the best approach has been to use two viscoelastics, one dispersive and the other cohesive (1); this requires handling two independent syringes and a greater number of surgical steps. In recent
times, a new marketed solution has been introduced in clinical practice (DisCoVisc®) that combines in a single syringe one cohesive and another dispersive viscoelastic, aiming at harnessing the properties of both without the inconvenience of handling two syringes. However, its properties are merely the sum of properties of both cohesive and dispersive viscoelastics and it has even been suggested to classify them under a new category.

In the past years, we have come to know different viscoelastic agents, whether in isolation or in mixtures, with different molecular weights and at different concentrations. The most widely used in clinical practice are hyaluronic acid and chondroitin sulphate.

Hyaluronate sodium is a mucopolysaccharide present in the connective tissue. It is an N-acetylglucosamine and glucuronic acid biopolymer (2). 1% hyaluronate sodium, marketed as Healon®, was the first viscoelastic available for ophthalmic clinical use.

Chondroitin sulphate is a mucopolysaccharide that differs from hyaluronic acid in that it contains N-acetylgalactosamine instead of N-acetylglucosamine (2). Sulphate ester may be found in three formats: Chondroitin sulphate A, made of glucuronic acid and galactosamine sulphate; in its B form, glucuronic acid is replaced by L-iduronic acid; the C form differs from B in the position held by sulphate in the galactosamine residue (2). Chondroitin sulphate has a larger negative load than hyaluronate sodium and its electrostatic interaction with the corneal epithelium is stronger, since the endothelial cells have positive loads (3).

When dealing with viscoelastics, surgeons keep in mind two of their potential properties: cohesive-ness and dispersivity. Cohesive agents, also known by their high viscosity, maintain spaces and move and stabilize tissues; however, they easily leave the anterior chamber during phacoemulsification. On the other hand, dispersive or low-viscosity agents, firmly adhere to the endothelium, are capable of isolating tissues, have a lower ability to maintain spaces and are more difficult to extract.

DisCoVisc® is a new viscoelastic recently introduced in clinical practice, which combines hyaluronic acid (1.6%) and chondroitin sulphate (4%) in an attempt to harness the benefits of both compounds. Viscoat® also presents a combination of hyaluronic acid and chondroitin sulphate and the differences between both solutions are summarized in table I.

As already suggested, the rheological properties of DisCoVisc® should be taken into account when classifying the so-called ophthalmic viscosurgical devices (OVD), since the said properties do not fit the preexisting categories (4). This is the first solution where apparently there is a dissociation between viscosity and dispersion, being classified as dispersive viscoelastics. The greater viscosity at 0 cut-off rate was closely linked to a greater cohesiveness in all marketed viscoelastics until developing DisCoVisc®, which is the first viscoelastic with a relative high viscosity while being dispersive in nature (4).

Based on our experience, it does avoid the use of two viscoelastic syringes (one for a dispersive viscoelastic, the other for a cohesive viscoelastic), whose behavior provides exceptional transparency, better than the one observed in dispersive and cohesive viscoelastics, and excellent preservation of the anterior chamber at all stages during cataract surgery.

The intracameral injection of viscoelastics has been deemed easy by the surgeon and similar in terms of behavior to that shown by Healon® during this procedure (fig. 1), a procedure that at least theoretically could be simplified by low-viscosity viscoelastics.

An adequate preservation of the anterior chamber resulting from the use of DisCoVisc® was particularly useful at rest such as capsulorhexis and during the implantation of intraocular lenses, simplified due to its viscosity at low cut-off rates, although some authors suggest the possibility that viscoelastics’ elasticity is a more appropriate property than viscosity designed to that effect (5).

As in this case, at intermediate cut-off rates, when moving or handling instruments or intraocular lenses inside the viscoelastic, an appropriate viscosity is needed to simplify instrument handling inside the eye.

As for the preservation of the anterior chamber during phacoemulsification (fig. 3) and during the implantation of an intraocular lens (fig. 4), no differences were observed between both viscoelastics, although differences were statistically significant with respect to the preservation of the sac (fig. 5) during this last procedure.

During viscoelastics aspiration, due to its cohesive properties, Healon® was aspirated more easily than DisCoVisc®, although the latter’s aspiration, although dispersive, was not particularly difficult.
either. In spite of the above dispersive properties, the formation of bubbles was not significant and may be compared to the one observed during the use of Healon®, a relatively frequent problem encountered with other dispersive viscoelastics (6) such as Viscoat®, whose composition is similar.

We are aware of the study’s limitations, since surgery was performed by a surgeon who knew which viscoelastic he was using, and thus our paper may be biased, since it is not a double-blind study. However, surgical data were assessed by another individual who ignored which viscoelastic had been used.

Based on the above, in our view DisCoVisc® may be considered a dispersive viscoelastic of mild viscosity; its greatest benefits entail providing an extraordinary transparency of the anterior chamber’s structures, adequately preserving the anterior chamber during capsulorhexis, phacoemulsification and implantation of the intraocular lens. Among its prominent features and due to its dispersive properties, retention in the anterior chamber during phacoemulsification and endothelial protection, it is particularly useful in patients whose corneal endothelium is compromised.

REFERENCES