Subjective evaluation of intraoperative performance of DisCoVisc in complex ocular environments

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CLINICAL STUDY

Abstract

Purpose To subjectively evaluate the intraoperative characteristics of DisCoVisc during phacoemulsification in complex ocular environments.

Patients and methods In this prospective observational study, two experienced surgeons (ARV and CZ) performed phacoemulsification on 100 consecutive patients with cataract associated with complex ocular environments. Inclusion criteria were eyes with shallow

anterior chambers (anterior chamber depth (ACD) of <2.1 mm), inadequate pupillary dilation (3 mm), dense cataract, and white mature cataract. The surgeons subjectively assessed the endpoints at each phase of phacoemulsification and various behavioural aspects of the ophthalmic viscosurgical devices (OVDs) were subsequently evaluated. **Results** The distribution was as follows: eyes with white mature cataract ($n=18$), eyes with grades 4 and 5 cataract ($n=56$), eyes with co-existing shallow ACD <2 mm ($n=24$), and co-existing small pupil size <2 mm ($n=18$). DisCoVisc behaved like a moderately cohesive viscoelastic in 94% of the cases. Injection of viscoelastic was easy in 38 (38%) eyes and very easy in 62 (62%) eyes. Visualization after the viscoelastic injection was excellent in 74% of the eyes. During phacoemulsification, DisCoVisc was moderately dispersive at all the stages of emulsification. The bag maintenance during IOL implantation was excellent in 56% eyes; IOL implantation was easy in 26% of the eyes and difficult in 20% of the eyes. Surgeons found viscoelastic removal easy in 68% of the eyes. At the time of OVD removal, DisCoVisc behaved like both a dispersive and a cohesive viscoelastic in 96% of the eyes.

Conclusion DisCoVisc provides both cohesive and dispersive properties. DisCoVisc alone, even in complex ocular environments, enabled the surgeon to achieve good intraoperative performance.

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Introduction

Ophthalmic viscosurgical devices (OVDs) are used to maintain space, facilitate IOL implantation and surgical manoeuvres, and protect the corneal endothelium and ocular tissues from surgical trauma.^{1–4} These multiple features enable them to facilitate the steps of intraocular surgery in a controlled manner. Different types of OVDs have been developed and their behaviour inside the eye has been evaluated.^{1–5} With the introduction of the soft shell technique,⁶ the differences between cohesive and dispersive OVDs were characterized and the OVDs were used at the appropriate phase of emulsification for protecting the corneal endothelium and maintaining space. The cohesive high molecular weight OVDs help sustain the anterior chamber during phacoemulsification.^{3,7,8} Dispersive OVDs react very differently because of their shorter, weaker connected chains, which decrease the tear and shear properties and so result in better coating of the corneal endothelium.^{3,7,8} This is mandatory if endothelial injury is to be avoided because of mechanical contact.

The ability of an OVD to coat the surface of endothelial cells and adequately maintain the

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anterior chamber is considered critical for endothelial protection.^{9–11} Recently, new viscous dispersive OVDs have been developed. DisCoVisc^{5,12} is a viscoelastic solution of sodium chondroitin sulfate and sodium hyaluronate with a viscosity of 75 000 (SD 35 000) millib Pascal seconds (mPas) at a shear rate of 1 s^{-1} and 25°C . It has been claimed that DisCoVisc has an intermediate cohesive/dispersive index, which facilitates both space maintenance and tissue protection.^{5,12} In a previous randomized clinical trial,¹³ we evaluated the postoperative outcomes in patients with uncomplicated age-related cataract undergoing phacoemulsification using DisCoVisc as against the soft shell technique. In this study, we showed that DisCoVisc is an effective OVD comparable with Viscoat and Provisc in its postoperative outcomes.¹³ After completing that trial, a clinical protocol was initiated to subjectively evaluate the intraoperative characteristics of DisCoVisc during phacoemulsification in more complex ocular environments. We consciously chose complex ocular environments with the reasoning that if we could prove the efficacy of DisCoVisc in these environments, we could logically conclude that it was as effective in simple ocular environments as well. Hence, in this prospective observational study of 100 consecutive patients, complex ocular environments were chosen to evaluate the intraoperative characteristics of DisCoVisc. Furthermore, no clinical trials have been reported on the intraoperative characteristics of DisCoVisc during phacoemulsification.

Materials and methods

This prospective observational study comprised 100 consecutive patients with complicated cataracts who underwent phacoemulsification at the Iladevi Cataract and IOL Research Center and SK Red Cross Eye Hospital, Dholka Ahmedabad from March to July, 2007. The Institutional Review Board granted its approval for the study. Informed consent was obtained from all the patients before enrolling them in the study. The following inclusion criteria were used: eyes of patients with cataract with co-existing compromised ocular environments such as shallow anterior chamber depth (ACD $<2.1\text{ mm}$), inadequate pupillary dilation (3 mm), dense cataract (grades 4 and 5 according to the Emery and Little classification),¹⁴ and white mature cataract.

Two experienced surgeons (ARV and CZ) performed all the surgeries under topical anaesthesia. The parameters used during different stages of the surgery varied based on the density of nuclear sclerosis and also the size of the pupil.

Various behavioural aspects (cohesive and dispersive properties) of the OVD were evaluated during different stages of the surgery. During capsulorhexis, the cohesive

property of the OVD was assessed by judging its pseudo-plasticity. We observed the ease of manoeuvrability of the anterior capsule flap while using both the cystotome and the Utrata forceps. The property of cohesiveness was also evaluated by observing the anterior chamber dome maintenance, which is classified as the working space maintenance and full chamber maintenance. OVDs were also assessed in terms of their ability to control the size of the capsulorhexis while it was being performed. Apart from the behavioural aspect, we also observed the ease with which the viscoelastic was injected during the placement of the incision and capsulorhexis. Further visualization of the anterior capsule after injection of the OVD was also observed.

In the present series, the anterior chamber dome maintenance was assessed as the working space maintenance and full chamber maintenance and was demonstrated during all the phases of phacoemulsification. This was gauged by a slit lamp attachment to the operating microscope. The following endpoints were subjectively and independently evaluated by the surgeons at each phase of phacoemulsification. During phacoemulsification, at the time of fragment removal, the endpoint was assessed for the presence of retained OVD. This was done by observing the presence of static lens fragments during fragment removal, which suggest trapped OVD within the fragments at the level of either the corneal endothelium or at the level of the angle recess. Finally, the operating surgeon also looked for visible repulse of the viscoelastic at the end of surgery and was arbitrarily given the percentage of retained OVD.

Bimanual irrigation/aspiration by ARV and coaxial by CZ was performed for cortex removal. Further behavioural aspects of the OVD were evaluated during implantation of the AcrySof SN60AT IOL with a C cartridge through the Monarch shooter inside the capsular bag. The cohesive property of the OVD was observed by judging the expansion of the capsular bag. Capsular bag maintenance during IOL implantation was also evaluated. Collapse of the anterior chamber was also noticed. Along with these two, the ease of IOL insertion was evaluated and graded—whether it was easy to insert, average, or difficult. Furthermore, the ease of IOL implantation was observed by judging the property of pseudo-plasticity. Finally, the removal of the OVD was observed by keeping the aspiration port stationary at the centre for aspiration. The ease of removal of the OVD was judged by observing the rapid fragmentation. These findings were recorded in questionnaires that were read out and duly filled by an unscrubbed nurse while the surgeries were being performed. Furthermore, we subjectively evaluated the difficulties during cataract extraction, difficulty of IOL insertion, difficulty of overall

surgery, anterior chamber dome maintenance (full chamber maintenance and working space maintenance) and capsular bag maintenance in eyes with small and dilated pupils, grades 3, 4 and 5 cataracts, and shallow and deep anterior chambers.

Results

The distribution was as follows: eyes with white mature cataract ($n = 18$), eyes with grades 4 and 5 cataract ($n = 56$), eyes with co-existing shallow ACD < 2 mm ($n = 24$), and co-existing small pupil size < 2 mm ($n = 18$). Table 1 represents evaluation of various behavioural aspects of DisCoVisc during various stages of phacoemulsification (including capsulorhexis, visualization of anterior capsule after OVD injection, fragment removal, IOL implantation, and OVD removal) observed by the two surgeons. During IOL implantation collapse of the anterior chamber was not noticed in any of the eyes and the capsular bag did not need to be refilled in any of the cases.

In eyes with the small pupils, both the surgeons did not use any pupil stretching devices during the surgery. While performing phacoemulsification, both the surgeons found overall difficulty to be more in 32 (80%) eyes with small pupils and in 48 (80%) eyes with well-dilated pupils. They also had difficulty in implanting the IOL inside the capsular bag in 12 (30%) eyes with small pupils and in 8 (13.3%) eyes with dilated pupils. While implanting the IOL, capsular bags were maintained in 18 (45%) eyes with small pupils and in 38 (63.3%) eyes with dilated pupils. The surgeons could remove the OVD easily in 26 (65%) eyes with small pupils and in 36 (60%) eyes with dilated pupils. The OVD was found to be both cohesive and dispersive in 30 (75%) eyes with small pupils and in 50 (83.3%) eyes with dilated pupils.

In dense cataracts (grades 4 and 5), the surgeons observed difficulty in performing phacoemulsification in 34 (77.3%) eyes, whereas with grade 3 cataract, they observed difficulty in 46 (82.1%) eyes. The capsular bag was very well maintained in 38 (67.9%) eyes with dense cataract whereas in eyes with grade 3 cataract, it was well maintained in 18 (40.9%) eyes. Aspiration of the OVD was easy in 34 (60.7%) eyes with dense cataract and in 34 (77.3%) eyes with grade 3 cataract.

While evaluating anterior chamber dome maintenance during capsulorhexis, with shallow anterior chambers, working space was maintained in 16 (29.6%) eyes and full chamber maintenance in 38 (70.4%) eyes. In eyes with deep anterior chambers, while performing capsulorhexis, working space was maintained in 6 (13%) eyes and full chamber was maintained in 40 (87%) eyes. During phacoemulsification in eyes with shallow anterior chambers, the surgeons found OVD to be moderately

Table 1 Subjective evaluation of intraoperative viscoelastic characteristics of DisCoVisc at different phases of phacoemulsification

Stages of surgery	No of eyes
<i>Visualization of anterior capsule after injection of OVD during capsulorhexis</i>	
Good	40
Excellent	60
<i>Capsulorhexis</i>	
Anterior chamber maintenance	22
Working space maintenance	78
<i>Behaviour of OVD during capsulorhexis</i>	
Both dispersive and cohesive	6
Moderately cohesive	94
<i>Phacoemulsification</i>	
Anterior chamber maintenance	36
Working space maintenance	64
<i>Behaviour of OVD during phacoemulsification</i>	
Moderately dispersive	96
Moderately cohesive	4
<i>Retained OVD (%) after phacoemulsification</i>	
0–10%	98
20%	2
<i>Capsular bag maintenance during IOL implantation</i>	
Good	42
Excellent	58
<i>IOL implantation</i>	
Anterior chamber maintenance	24
Working space maintenance	76
<i>Difficulty in IOL implantation</i>	
Easy	26
Average	54
Difficulty	20
<i>OVD removal</i>	
Very easy	8
Easy	68
Neither easy nor difficult	24
<i>Behaviour during aspiration</i>	
Dispersive	2
Moderately dispersive & cohesive	96
Moderately cohesive	2

dispersive in 52 (96.3%) eyes whereas in eyes with deep anterior chambers, it was dispersive in 44 (95.7%) eyes. While evaluating anterior chamber dome maintenance during phacoemulsification, working space was well maintained in 24 (44.4%) eyes with shallow anterior chambers and in 12 (26.1%) eyes with deep anterior chambers. Full chambers were maintained in 30 (55.6%)

eyes with shallow anterior chambers and in 34 (73.9%) eyes with deep anterior chambers.

While evaluating white mature cataract for anterior chamber dome maintenance during anterior capsulorhexis, the surgeons could maintain working space in 8 (44%) eyes and full chamber in 10 (55.6%) eyes. During capsulorhexis in all the eyes with white mature cataract, the OVD was found to be moderately cohesive in 18 (100%) eyes. While performing anterior capsulorhexis, the visualization of the anterior capsule after injection of the OVD was excellent in 16 eyes (88.9%) with white mature cataract.

Discussion

In this study, DisCoVisc was found to be sufficiently cohesive while anterior capsulorhexis was being performed, helping to maintain both a stable anterior chamber and an effective working space when using a cystotome in small pupils, dense cataracts, and shallow anterior chambers and also when using Utrata forceps in white mature cataracts. Furthermore, while performing capsulorhexis, DisCoVisc facilitated controlled manoeuvrability of the anterior capsular flap with the cystotome as well as with the forceps, thus allowing the surgeon to safely and easily complete the capsulorhexis. Similarly, Gubelalde *et al*,¹⁵ in a prospective randomized trial comparing DisCoVisc with Healon during phacoemulsification, observed the cohesive behaviour of DisCoVisc during capsulorhexis. Tognetto and co-authors, while evaluating the safety and efficacy of DisCoVisc, demonstrated its ability to maintain adequate working space during capsulorhexis, suggesting its cohesive property. (D Tognetto MD, D Fanni MD, A Fantin MD, L Michelone MD, G Ravalico MD 'Safety and effectiveness of a new viscous dispersive OVD'. Poster presentation at the XXIV Congress of the ESCRS, London, September 2006). In the present series, during all the phases of phacoemulsification, DisCoVisc did not hamper visibility. Similar observations were also documented by Gubelalde *et al*,¹⁵ and Tognetto and co-authors while evaluating DisCoVisc intraoperatively.

In the present series, during all the phases of phacoemulsification, DisCoVisc demonstrated excellent space maintenance, suggesting its cohesive property. The surgeons also felt that during fragment removal, small nuclear fragments did not adhere to the cornea or beneath the iris plane in eyes with small pupils. Furthermore, while assessing the retention of OVD at the completion of phacoemulsification, both the surgeons found that viscous dispersive DisCoVisc was retained in a majority of the eyes. A novel observation in this study was that some amount of residual DisCoVisc was retained very well during phacoemulsification.

We believe that this superior retention of DisCoVisc during phacoemulsification is due to its dispersive property. During phacoemulsification in animal eyes, Oshika *et al*¹⁶ made a similar observation while evaluating different types of OVDs for retention and removal. In another study, DisCoVisc showed superior retention as compared with Viscoat, which had earlier been reported to have the best retention time.⁵ Tognetto and co-authors, in their clinical trial, documented OVD retention during phacoemulsification. In another experimental study, a quantitative assessment of OVD retention was carried out using *in vivo* confocal microscopy.¹⁷ It was observed that both Viscoat and DisCoVisc showed superior retention and coating of the endothelium after simulated phacoemulsification procedures in laboratory animals.

In the present series, even in eyes with shallow anterior chambers, DisCoVisc was sufficiently cohesive, maintaining excellent working space with a stable anterior chamber during intraoperative manipulation and IOL insertion, thereby facilitating easy IOL implantation in all kinds of complex ocular environments. It has been found that its property of cohesiveness and pseudo-plasticity makes IOL implantation safe, maintaining working space during IOL insertion, and further avoiding endothelial injury with IOL contact. Similarly, Tognetto and co-authors and Gubelalde *et al*¹⁵ documented excellent working space maintenance during IOL implantation.

In addition to the ability of OVDs to remain in the eye, the ease that they can be removed is another important issue during cataract surgery. High viscosity cohesive OVDs tend to easily flow out of the eye and can be completely removed from the anterior chamber by aspiration. In contrast, dispersive OVDs are more difficult to remove from the anterior chamber, and complete removal is hard to achieve. It has been shown that Viscoat requires a much longer time to be aspirated.^{5,16,17} As shown in the results of the present series, the surgeons found that DisCoVisc removal could be done by rapid fragmentation with an irrigation/aspiration tip. In addition, DisCoVisc did not require behind the lens technique for the washout. Similarly, Tognetto and co-authors and Gubelalde *et al*¹⁵ observed easy removal of residual DisCoVisc after IOL implantation.

The limitation of this study, we believe, is that the surgeons could have been biased in judging space maintenance and also in the quantity of OVD retained as these aspects were subjectively evaluated. Furthermore, the intraoperative performance of DisCoVisc was not compared with viscoadaptive Healon 5 for evaluating the safety and efficacy of the former during phacoemulsification. Further studies need to be done comparing

DisCoVisc with the soft shell technique so as to prove its dual properties and also to prove that its performance is comparable with the latter.

To negate possible bias by a single surgeon, this clinical trial was undertaken by choosing two different experts in phacoemulsification using two different machine settings for evaluating the intraoperative performance of DisCoVisc. In this prospective observational study of 100 consecutive patients with complicated cataract, including dense and very dense cataracts with sclerosis greater than grade 4, white mature cataract, shallow anterior chamber, and small pupils, it was observed that DisCoVisc demonstrated both cohesive and dispersive properties, excellent working space, and easy removal at the end of surgery. This study has shown that only DisCoVisc provided both cohesive and dispersive properties, which worked appropriately at different phases of phacoemulsification.

Finally, based on this study, the surgeons have shown that the use of DisCoVisc can be considered as an alternative to the soft shell technique. As DisCoVisc facilitated good intraoperative performance in complex cases, it can be safely concluded that it will be as effective if not more in simple cataract surgeries.

Summary

What was known before

- DisCoVisc was claimed to be both cohesive and dispersive viscoelastic.

What this study adds

- DisCoVisc can be considered as an alternative to the soft shell technique. As DisCoVisc facilitated good intraoperative performance in complex cases, it can be safely used in simple cataract surgeries.

Conflict of interest

The authors declare no conflict of interest.

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