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Safety and efficacy of two ocular anesthetic methods for phacoemulsification: Topical anesthesia and viscoanesthesia (VisThesia™)

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PURPOSE. *VisThesia™ is a new ophthalmic viscosurgical device (OVD) which has 1% lidocaine combined with 1.5% sodium hyaluronate. This is a prospective evaluation of the safety and efficacy of VisThesia™ used in association with phacoemulsification.*

METHODS. *A total of 114 eyes were divided into two groups. Fifty-nine eyes were treated with tetracaine + oxybuprocaine topical anesthesia and DuoVisc® OVD and 55 eyes were treated with VisThesia™, for use as both topical anesthetic and OVD. Endothelial cell counts were measured at 30 days postoperatively and compared to preoperative baseline values. Pain and discomfort was subjectively evaluated by patients using a visual analog pain scale (0–10).*

RESULTS. *All surgeries were uneventful with no intraoperative or immediate postoperative complications. Patients receiving topical anesthesia had a mean pain score of 1.1±6.8 compared to a mean score of 1.3±4.6 for patients receiving VisThesia™ (p=0.59). Postoperatively, endothelial cell loss at 1 month was greater for patients receiving VisThesia™ (20.32%±43.75) than for those receiving the topical anesthetic (8.8%±59.6; p<0.0001).*

CONCLUSIONS. *The results from the visual analog pain scale were comparable between groups, showing that VisThesia™ provides similar pain relief to topical anesthesia. Specular microscopy performed at 30 days postoperatively showed a significantly greater loss of endothelial cells with the use of VisThesia™, suggesting that the 1% lidocaine concentration used in VisThesia™ may be toxic to corneal endothelial cells. (Eur J Ophthalmol 2007; 17: 171-7)*

KEY WORDS. *Topical administration, Cell count, Endothelium, Corneal/drug effects/pathology, Hyaluronic acid/adverse effects/therapeutic use, Phacoemulsification/methods*

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INTRODUCTION

The use of topical anesthesia during phacoemulsification surgery and intraocular lens (IOL) implantation has been reported numerous times in the literature (1-5). Several studies comparing topical anesthesia to peribulbar anesthesia have reported similar results on the anesthetic effects obtained with either technique during both standard and complicated cataract procedures (3-5). Additional studies have shown that the efficacy of topical anesthesia can be enhanced by adding intracameral lidocaine at the beginning of the cataract procedure (6-9). A new ophthalmic viscosurgical device (OVD), VisThesia™, has recently been introduced to the international market and is the only available OVD that is a mixture of lidocaine and sodium hyaluronate. The benefit of such a product is the

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combination of corneal and intracameral anesthesia with an ophthalmic viscosurgical device. This technique of ocular anesthesia is known as viscoanesthesia.

The purpose of this study is to compare the safety and efficacy of VisThesia™ to our standard analgesic procedure for cataract surgery, which is the administration of topical anesthetic containing aqueous tetracaine and oxybuprocaine. Safety was evaluated by assessing the rate of intraoperative and postoperative complications and measuring the endothelial cell counts over time for the operative eye. Efficacy was evaluated by assessing patients' pain and discomfort during the surgery with a visual analog pain scale.

METHODS

This prospective study included 114 consecutive eyes in 83 patients undergoing cataract extraction by phacoemulsification and subsequent intraocular lens implantation. Patients were all operated on by the same experienced surgeon (J.M.P.) between May and July 2005. Inclusion criteria were vision impairing cataract in the operative eye, no previous ocular surgery (refractive, glaucoma, or retinal), and no additional ocular pathology. Exclusion criteria were history of glaucoma, uveitis, ocular trauma, retinal detachment, corneal dystrophy, and macular degeneration.

Products evaluated

Patients were divided into two groups: the topical anesthesia group (59 eyes) and the VisThesia™ group (55 eyes). Patients in the topical anesthesia group received ocular drops of preservative-free 1% tetracaine (Novartis Pharma SAS, Rueil Malmaison, France) and preservative-free 0.4% oxybuprocaine (Novartis Pharma SAS, Rueil Malmaison, France). Patients in the other group received VisThesia™ topical and intracameral (Carl Zeiss Meditec, Jena, Germany). VisThesia™ topical contains a formulation composed of 2% lidocaine and 0.3% sodium hyaluronate (volume 0.4 mL) and is provided in individual plastic blister packs. While the internal product is sterile the outside surface is not. Therefore, the blisters should only be manipulated outside the sterile surgical field. VisThesia™ intracameral component has a composition of 1% lidocaine and 1.5% sodium hyaluronate (volume 0.8 mL) and is provided in sterile, ready-to-use syringes.

Surgical technique

All patients had pupil dilation with Mydriasert® (phenylephrine 2.5% and tropicamide 1%, Ioltech Labs, La Rochelle, France). After pupil dilation ocular asepsis was achieved in the operated eye with ocular Betadine-iodine 5% (Viatris, Merignac, France). Patients in the topical anesthesia group received one drop of 0.4% oxybuprocaine 5 minutes before surgery and three drops of 1% tetracaine 1 minute before surgery. Patients in the VisThesia™ group received the same above anesthetic regimen, to which was added one blister of VisThesia™ topical (volume 0.4 mL) applied over the corneal surface just prior to corneal incision. The OVD used in topical anesthesia group was DuoVisc® (Alcon Labs, Fort Worth, TX), which is the standard OVD used in our clinic for phacoemulsification and IOL implantation. DuoVisc® comes in a package containing two individual preparations in separate syringes for intracameral injection. One of the syringes contains 3% sodium hyaluronate and 4% sodium chondroitin (Viscoat®, volume 0.35 mL) and the second syringe contains 1% sodium hyaluronate (ProVisc®, volume 0.40 mL).

All patients underwent the same surgical technique. After topical anesthesia, a 2.8-mm corneal incision was placed at the superotemporal position, followed by intracameral OVD injection (topical anesthesia group received Viscoat® and the other group received VisThesia™ intracameral). A continuous curvilinear capsulorrhexis of 5.0 to 5.5 mm was performed with the capsulorrhexis forceps (Duckworth & Kent, London, UK), followed by hydrodissection. Phacoemulsification was performed with the Storz Premiere® (Bausch & Lomb, Rochester, NY), using a divide-and-conquer technique. OVD was injected inside the capsular bag (patients in the topical anesthesia group received ProVisc® and the others received VisThesia™ intracameral). All eyes had a foldable IOL implanted (using an injector) through the original 2.8 mm corneal incision following the orientation from each manufacturer. Of the 114 eyes, 37.71% received an Akreos Adapt IOL implanted (Bausch & Lomb), 30.70% received an AcrySof SN60AT IOL implanted (Alcon Labs), 22.80% a Tripode IOL implanted (Ioltech Labs) and 8.77% an ACR6D IOL implanted (Corneal, Pringy, France). After IOL centration, an attempt was made to remove residual OVD from the eyes by bimanual irrigation/aspiration (I/A). Attention was taken to aspirate the OVD from above and behind the IOL. After implantation the incision was tested for leakage and a single 10-0 nylon suture was placed, if needed. Be-

fore the patient was removed from surgery dexamethasone and oxytetracycline ointment (Novartis Pharma SAS, Rueil Malmaison, France) were applied over the cornea and an ocular shield was fixed around the operated eye. The time of intervention (in minutes) was established as the period between the corneal incision and the leakage test (and/or corneal suture) at the end of the procedure and the value recorded.

Pain and discomfort assessment

The subject sensation of pain and discomfort experienced during surgery was evaluated 2 to 3 hours after surgery using a visual analog pain scale (10.0 cm horizontal line divided into 10 different segments, Fig. 1). Patients were asked to mark a location along the pain scale which represented the pain and discomfort they experienced during the surgical procedure. 0 meant complete absence of pain and discomfort and 10 meant the worst pain sensation the patient could withstand. Patients and nurse were masked as to which anesthetic technique was used during the procedure. The same nurse administrated the assessments for all patients, and each patient was assessed individually. After the evaluation, the distance between the 0 mark and the patient's mark was measured in cm and the value recorded.

Endothelial cell count

The endothelial cell counts were measured with the non-contact Topcon 2000 SP specular microscope (Topcon Corporation, Tokyo, Japan). Preoperative assessments were performed 1 and 7 days prior to surgery and postoperative measurements were performed within the ±7 days of the 30-day postoperative visit. The same experienced technician, who was masked as to which anesthetic was used in each patient, performed all preoperative and postoperative measurements. At each time point three pictures of the central cornea were obtained and the endothelial cell density determined. The mean value of the three assessments was used. Following the recommendations of the manufacturer, at least 50 cells were selected for evaluation from each picture.

Statistical methods

Statistical analysis was performed using Student *t*-test for comparisons between group means for all parameters evaluated. Values of $p<0.005$ were considered to be statistically significant.

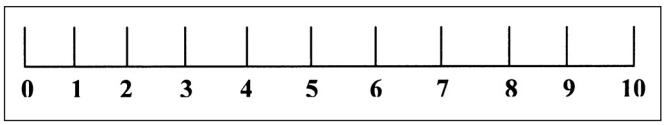

Fig. 1 - *Visual analog pain scale (original size is 10.0 cm in length).*

RESULTS

The average age of the patients in the topical anesthesia group was 73.5 years ± 35.5 and 71.6 years ± 33.6 in the VisThesia™ group (p=0.294). In the topical anesthesia group, 52% were females compared to 56% in the VisThesia™ group (p=0.685). The length of surgery was comparable for both groups: a mean of 10.5±7.5 min in topical anesthesia group and 11.3±8.6 min in VisThesia™ group (p=0.088). In the topical anesthesia group, 33% needed a 10-0 corneal suture compared to 43% in the VisThesia™ group showing no significant difference (p=0.29) between the groups. The mean power of the implanted lenses was +21.02±8.02 diopters in the topical anesthesia group and +21.93±8.07 diopters in the VisThesia™ group (p= 0.094). There were no intraoperative or postoperative complications during the 114 interventions, including no inflammation, no endophthalmitis, no posterior capsule rupture, no hyphema, no cystoid macular edema, no intraocular pressure spikes, no corneal edema, and no retinal detachments. In either group no additional anesthesia was needed other than that previously described. The mean pain and discomfort scores were similar between groups, with scores of 1.1±6.8 in the topical anesthesia group and 1.3±4.6 in the VisThesia™ group (p=0.59).

Endothelial cell counts

The mean preoperative baseline endothelial cell counts (ECC) were similar between groups, with 2463.1±763.8 cells/mm² in the topical anesthesia group and 2483.2±879.7 cells/mm² in the VisThesia™ group (p=0.76). The mean postoperative endothelial cell counts at 30 days were 2254.1±1549.1 cells/mm² in the topical anesthesia group and 1984.8±993.8 cells/mm² in the VisThesia™ group (Fig. 2, p=0.0027), resulting in a mean en-

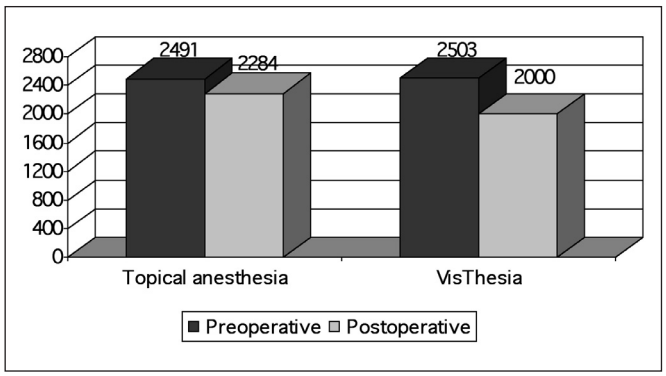

Fig. 2 - *Average endothelial cell measurement (cells/mm²) preoperatively and postoperatively at 30 days (n=114).*

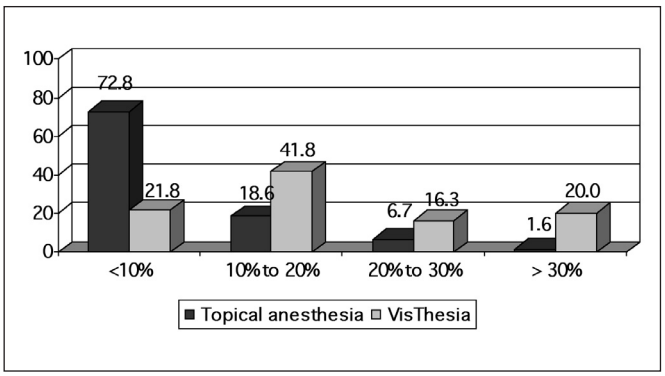

Fig. 3 - *Percentage decrease in endothelial cell counts (ECC) at 30 days postoperative compared to baseline (n=114).*

dothelial cell decrease of 8.8%±59.6 for the topical anesthesia group and 20.3%±43.7 for the VisThesia™ group ($p<0.0001$). Figure 3 illustrates the proportion of endothelial cell decreases in each group. In the topical anesthesia group, 72.8% of the patients had less than 10% ECC loss and 18.6% experienced 10–20% loss. Less than 2% of patients in this group had >30% ECC loss. In the VisThesia™ group, 21.8% had less than 10% ECC loss and 41.8% experienced 10–20% loss. Exactly 20% of patients had >30% ECC loss. Figure 4 separates patients into ECC loss at day 30. A total of 72.2% of the patients with less than 10% ECC loss are from the topical anesthesia group, whereas patients from the VisThesia™ group make up the majority of patients with 10% or greater ECC loss.

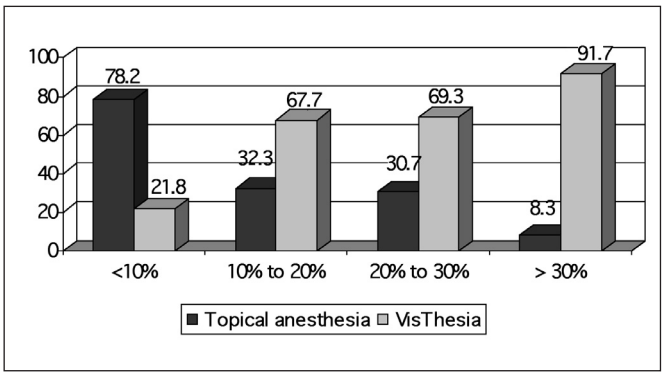

Fig. 4 - *Percentage decrease in the endothelial cells count (ECC) at day 30 compared to baseline. Patients are divided into four groups: ECC loss <10%, ECC loss between 10% and 20%, ECC loss between 20% and 30%, and ECC >30% (n=114).*

DISCUSSION

In this prospective evaluation we compare two groups of patients who have undergone phacoemulsification surgery: those receiving topical anesthesia with 1% tetracaine and 0.4% oxybuprocaine and those receiving viscoanesthesia, a combination of OVD and an intracameral mixture with 1% lidocaine. Our results show that both procedures were effective at controlling pain and discomfort during surgery. The mean pain and discomfort scores in the topical anesthesia group (1.16±6.84) and in the VisThesia™ group (1.34±4.66) are comparable to results obtained in previous studies (1-5). Patients in the VisThesia™ group did not observe any additional anesthesia benefit by adding intracameral 1% lidocaine to the topical anesthetic. Several authors reported comparable results to those obtained in our studies, demonstrating no added analgesic benefit with intracameral anesthesia (10-12). Intracameral lidocaine should, in theory, enhance anesthesia at the level of the iris and the ciliary body, ocular tissues which are not typically reached by standard topical anesthetic. In uncomplicated cataract surgery, however, the anesthesia of the iris and ciliary body is not necessary. Intracameral anesthesia could perhaps be beneficial in complicated cataract surgery, but this was not the focus of our study.

In this study, patients receiving VisThesia™ did exhibit a greater decrease in endothelial cells at 30 days postoperative compared to baseline, which may be associated with a toxicity of the product to the corneal endothelium. At this point we cannot determine if the potential toxic effect would result from the topical component (VisThesia™

topical) or the intracameral component (VisThesia™ intracameral). Published results have reported on the use of different concentrations of lidocaine in intracameral anesthesia (20-24). Concentrations above 1.8% were clearly associated with intraocular toxicity, while concentrations below 0.2% were considered to be harmless to the corneal endothelium. Anderson et al have demonstrated that the absorption of lidocaine after intracameral injection increases very quickly at the iris, ciliary body, and corneal endothelium. Nevertheless, concentrations decrease quickly upon intracameral irrigation of basic salt solutions during phacoemulsification (25). Published studies have demonstrated that the intracameral injection of 1% lidocaine, the concentration used in VisThesia™ intracameral, at the beginning of the cataract procedure is innocuous (13-19). The only difference between these previously published studies and this study is that in the previously published reports, intracameral aqueous lidocaine was injected only during the first phase of the surgery, just before capsulorrhexis. During phacoemulsification, the intracameral lidocaine was washed out from the anterior chamber, therefore limiting its contact with the corneal endothelium. VisThesia™, however, is recommended for use during all phases of the cataract procedure. Following manufacturer's recommendations, VisThesia™ is re-injected inside the capsular bag after phacoemulsification to increase space for IOL implantation. As a consequence, lidocaine is re-introduced inside the eye at the end of the procedure, when there is no need for additional intraocular anesthesia. After irrigation/aspiration, it is sometimes difficult to assure that all the OVD has been removed. Some amount of OVD often remains inside the eye. With traditional OVD use during surgery, complications associated with OVD retention are unlikely, aside from intraocular pressure spikes and transitory corneal edema. With the use of VisThesia™, sodium hyaluronate and lidocaine may remain inside the eye, prolonging the contact of lidocaine with intraocular structures. The higher endothelial cell loss observed in the VisThesia™ group in our study may be associated with the extended exposure of 1% lidocaine to the corneal endothelium.

There are few published reports on VisThesia™. Most of them are related to animal studies, which have not demonstrated any toxic effect of VisThesia™ on ocular structures in the rabbit (26-29). Poyales-Galan recently published on the use of VisThesia™ in human patients, reporting an average decrease of 5.87%±14.53 cells/mm^2 on the endothelial cell count at 3 months postoperatively compared to preoperative values in a group of 50 eyes operated by phacoemulsification with VisThesia™. There results differ from the ones observed in our study (20.32%±43.75 cells/mm^2 decrease at 30 days after surgery) (30). The author of the previously published study did not perform a comparative study with a standard OVD; therefore, no information is available on the endothelial cell decrease associated with OVD in the absence of lidocaine. Moreover, the results were based on the values obtained by two different surgeons and only descriptive statistic analysis was performed. No published reports were found on endothelial cell count decrease when VisThesia™ intracameral was used only during the first phase of cataract surgery (before capsulorrhexis), with standard 1.5% sodium hyaluronate used during IOL implantation. The reduced exposure time of lidocaine to intraocular structures in this scenario could perhaps result in lower overall endothelial cell decrease. Chang investigated the corneal endothelial cytotoxicity of different concentrations of aqueous lidocaine used for intracameral anesthesia. Results showed that although 1-minute exposure to lidocaine 1% or 2% appeared to be safe for cultured rabbit endothelial cells, longer exposures could cause time-dependent cytotoxicity (31).

Finally, DuoVisc® was the OVD used in the topical anesthesia group. DuoVisc® was selected for comparison to VisThesia™ because it was our standard OVD used in phacoemulsification. Viscoat®, which is a dispersive OVD, was used at the beginning of the cataract procedure to fill the anterior chamber and protect the corneal endothelium. Dispersive OVDs are known to remain longer inside the eye and are expected to provide better protection to the endothelial cells throughout the entire cataract procedure (32-35). ProVisc®, a cohesive OVD which can be easily aspirated at the end of the procedure, was used prior to IOL implantation. It would be interesting to compare VisThesia™ to a similar cohesive 1.5% sodium hyaluronate OVD without associated lidocaine.

In conclusion, our results show that both standard topical anesthesia and viscoanesthesia are efficient at relieving pain and discomfort during phacoemulsification and IOL implantation. We were not able to measure additional analgesic benefit by using VisThesia™ instead of a standard OVD. Moreover, the use of VisThesia™ resulted in a greater decrease of the endothelial cell counts at 30 days postoperative compared to standard topical anesthesia, which could be related to the increased exposure time of

the intracameral lidocaine to the corneal endothelium. This hypothesis would have to be prospectively tested in order to be confirmed.

The authors have no proprietary interest in any materials or methods mentioned in this article.

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