

## Ophthalmic Regional Anesthesia: Medial Canthus Episcleral (Sub-Tenon) Anesthesia Is More Efficient than Peribulbar Anesthesia

### A Double-blind Randomized Study

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**Background:** Regional anesthesia and especially peribulbar anesthesia commonly is used for cataract surgery. Failure rates and need for reinjection remains high, however, with peribulbar anesthesia. Single-injection high-volume medial canthus episcleral (sub-Tenon's) anesthesia has proven to be an efficient and safe alternative to peribulbar anesthesia.

**Methods:** The authors, in a blind study, compared the effectiveness of both techniques in 66 patients randomly assigned to episcleral anesthesia or single-injection peribulbar anesthesia. Motor blockade (akinesia) was used as the main index of anesthesia effectiveness. It was assessed using an 18-point scale (0-3 for each of the four directions of the gaze, lid opening, and lid closing, the total being from 0 = normal mobility to 18 = no movement at all). This score was compared between the groups 1, 5, 10, and 15 min after injection and at the end of the surgical procedures. Time to onset of the blockade also was compared between the two groups, as was the incidence of incomplete blockade with a need for supplemental injection and the satisfaction of the surgeon, patient, and anesthesiologist.

**Results:** Episcleral anesthesia provided a quicker onset of anesthesia, a better akinesia score, and a lower rate of incomplete blockade necessitating reinjection (0 vs. 39%;  $P < 0.0001$ ) than peribulbar anesthesia. Even after supplemental injection, peribulbar anesthesia had a lower akinesia score than did episcleral anesthesia. Peribulbar anesthesia began to wear off during surgery, whereas episcleral anesthesia did not.

**Conclusion:** Medial canthus single-injection episcleral anesthesia is a suitable alternative to peribulbar anesthesia. It provides better akinesia, with a quicker onset and more constancy in effectiveness. (Key words: Conduction; outpatient; eye; local anesthetics; ophthalmic surgery.)

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REGIONAL anesthesia commonly is used for ophthalmic surgery. Cataract surgery requires a potent motor blockade (akinesia) of the eyeball and eyelids. Retrobulbar anesthesia was the only technique used for many years. Rare but serious complications (globe perforation, brainstem anesthesia, postoperative strabismus, retrobulbar hematoma, optic nerve injury), however, have led many physicians to replace this technique with peribulbar anesthesia (PBA).<sup>1-3</sup> However, PBA has some limitations. First, it does not eliminate serious complications totally, although these probably occur less frequently than with retrobulbar anesthesia. Second, even with a two-injection technique, PBA has a sometimes excessive rate of imperfect blockade. This necessitates supplemental injection, with a rate of up to 50% in certain series. Performing multiple supplemental injections theoretically increases the risk of complications.

Episcleral anesthesia (ESA) was proposed as early as 1884 by Knapp.<sup>5</sup> It did not gain wide acceptance, however, until 1989, when Mein and Flynn<sup>6</sup> recommended its use as a preoperative complement to retrobulbar anesthesia. It subsequently was proposed as the sole anesthesia technique for various intraocular procedures.<sup>7-15</sup> Single-injection medial canthus high-volume

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ESA is an extension of those techniques.<sup>16-18</sup> The feasibility of such ESA has been shown in a preliminary study.<sup>16</sup> Its safety is being investigated on a large scale, and first results have been promising.<sup>19,20</sup> The aim of the current study therefore was to compare this ESA technique with PBA in terms of ability to provide total motor blockade (akinesia) of the eye and eyelids, time to onset of akinesia, and need for supplemental injection.

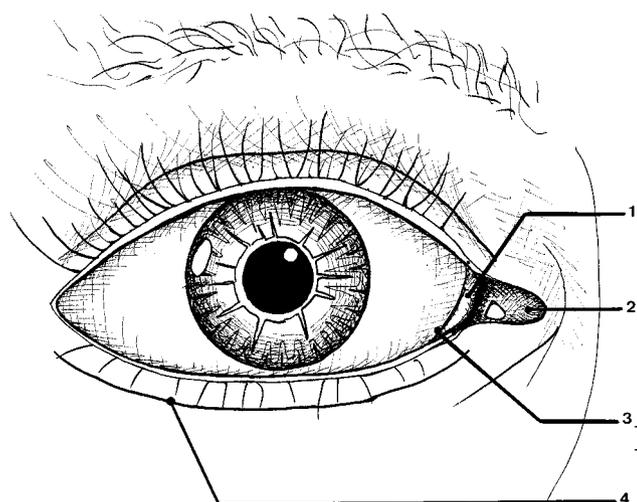
## Methods

### *Inclusion Criteria*

After approval of the local ethics committee (Comité Consultatif de Protection des Personnes pour la Recherche Biomédicale de Nîmes) and obtaining written informed consent, 66 patients scheduled for elective phacoemulsification cataract surgery with regional anesthesia were included in this randomized double-blind study. Exclusion criteria included the usual contraindications for regional anesthesia, clotting abnormalities, impaired mental status, uncontrolled glaucoma, recent surgical procedure on the same eye, and refusal to participate.

### *Anesthetic Management*

Patients were premedicated orally with 150  $\mu$ g clonidine 1 h before surgery. A peripheral intravenous catheter was inserted, and monitoring included continuous electrocardiography, pulse oximetry, and automated noninvasive blood pressure measurement. Before induction of blockade, oxybuprocaine drops were instilled and 0.2-0.5 mg/kg propofol was injected intravenously to obtain a brief period of sedation during eye puncture. Patients were assigned randomly to receive single-injection PBA or ESA (fig. 1). A randomization list was provided by the hospital biostatistics department. Assignment to a technique was obtained by opening a closed envelope. All punctures were performed by the senior anesthesiologist in charge of the patient, who was experienced in both techniques, using a 25-gauge short-bevel needle. In the PBA group, the needle was inserted transconjunctivally at the union between the medial two thirds and lateral third of the inferior orbital rim in a strictly posterior direction (fig. 2).<sup>1,21</sup> Depth of insertion of the needle was limited to 25 mm.<sup>22</sup> In the ESA group, the needle was inserted to contact the conjunctiva between the eyeball and the semilunaris fold, at a depth of less than 1 mm, with the bevel directed toward the globe.<sup>16-19</sup> The needle then was shifted slightly medi-

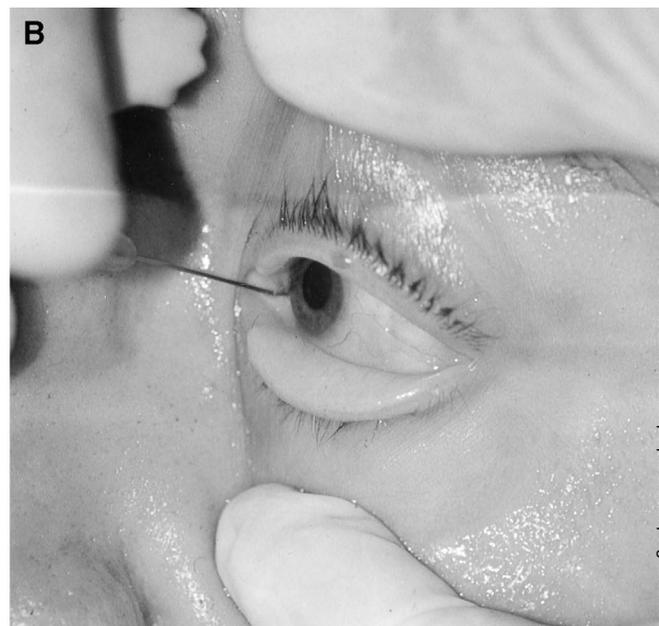
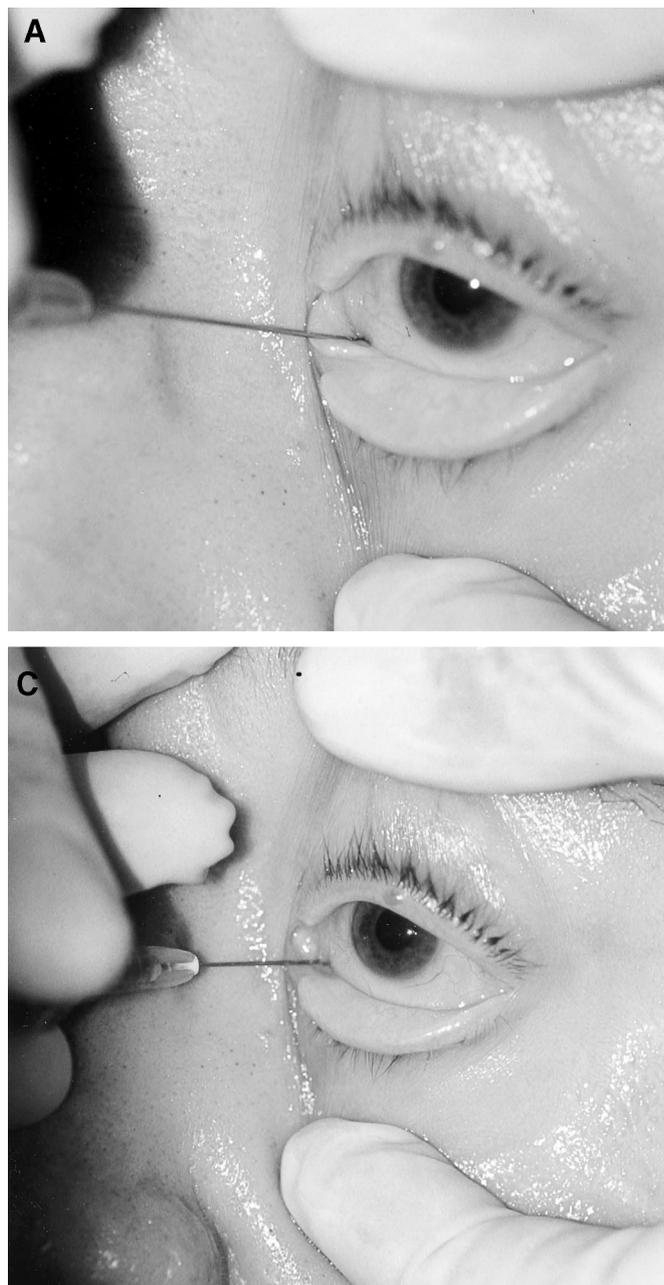


**Fig. 1.** Entry site of the needle for both techniques. Anterior view of a right eye. 1 = Semilunaris fold; 2 = caruncle; 3 = entry site of the needle for episcleral anesthesia; 4 = entry site for peribulbar anesthesia. Reprinted with permission.<sup>46</sup>

ally, displacing the semilunaris fold and caruncle away from the eyeball. The needle was advanced in an antero-posterior direction, with the globe directed slightly medially by the needle, until a "click" was perceived, at a depth of approximately 15-20 mm. At this moment, the globe returned to the primary gaze position (fig. 3). This point represents a reliable depth marker that confirms the episcleral location of the tip of the needle. In each



**Fig. 2.** Performing inferolateral peribulbar anesthesia. The needle is inserted strictly posteriorly, never more than 25 mm. Reprinted with permission.<sup>46</sup>



**Fig. 3.** Performing medial canthus episcleral anesthesia. (A) The bevel of the needle is inserted in the conjunctiva between the semilunaris fold and the globe. Before advancing, the needle is shifted medially to go away from the globe and pull the fascial sheath of the orbit (Tenon's capsule) and the conjunctiva, which are joined at this level. (B) The needle is advanced strictly posteriorly. The traction on the fascial sheath of the eyeball causes the globe to rotate nasally. (C) After a "click" is perceived, the globe returns to the primary gaze position. This indicates the passage through the fascial sheath of the eyeball to enter into the episcleral space. An aspiration test is performed, followed by small lateral movements, to ensure that the needle is moving independently from the eyeball (no globe perforation). Injection then is performed. Reprinted with permission.<sup>46</sup>

group, the local anesthetic solution was injected after an aspiration test, and a mixture in equal parts of 0.5% bupivacaine and 2.0% lidocaine with 25 IU/ml hyaluronidase was injected. The injected volume was not predetermined but adjusted to each patient: In the PBA group, the injection was continued until proptosis and lid fullness appeared with a sensation of "full orbit"; in the ESA group, the injection was continued until subconjunctival edema (chemosis), proptosis, and lid fullness appeared,

which are considered factors predictive for success of the blockade.<sup>16-19</sup> In both groups, intermittent compression was applied for 15 min using a Honan balloon set at 30 mmHg to lower intraocular pressure.

#### Evaluation

Akinesia (immobility) of the globe and eyelids was scored in a blinded manner by an investigator unaware of the technique of injection 1, 5, 10, and 15 min after

the end of the injection and at the end of the surgical procedure. An 18-point scale was used in which each of the four rectus muscles, levator palpebra, and orbicularis of the lids were scored between 0 and 3 (0 = no block, 1 = partial akinesia unsuitable for surgery, 2 = partial but sufficient akinesia, 3 = total akinesia); the final score was the total of these six subscores. If akinesia was judged to be insufficient after 15 min, supplemental injection was performed by the anesthesiologist in charge using the same mixture. The need for supplemental injection was judged by the anesthesiologist who evaluated the blockade in a blinded manner, with the aim of providing a total akinesia. In the ESA group, the reinjection was performed at the same site. In the PBA group, depending on the muscle with remaining activity, the reinjection was performed inferotemporally or superonasally.

#### Studied Parameters

**Comparability between Groups.** For each patient, age; gender; weight; side on which operation was performed; and axial length of the globe, as measured preoperatively using echography, were reported. For each anesthetic management, dose of propofol, depth of needle insertion (at 5-mm intervals), and volume of injected solution were noted.

**Primary End Points.** Akinesia score was used as the main index of the quality of anesthesia. Best akinesia score was defined as the highest akinesia score obtained for each block without or before supplemental injection if necessary. Time of onset was defined as the time that elapsed from the end of injection to best akinesia score. Need for supplemental injection was noted. If supplemental injection was necessary, akinesia was scored 5 and 10 min after this reinjection.

Three global anesthesia-related satisfaction scores were established postoperatively by the surgeon (blinded), the patient (unaware), and the anesthesiologist in charge of the patient (aware), using a subjective verbal scale from 0 (total dissatisfaction) to 10 (total satisfaction).

**Secondary End Points.** For each surgical procedure, duration and technique were reported. Immediate incidents and complications were noted. If supplemental injection was needed, each of the groups was divided into two subgroups: one with and the other without the need for supplemental injection. Concerning best akinesia score and time of onset of the blocks, the statistical comparisons were repeated between the two following

subgroups: ESA without need for reinjection and PBA without need for reinjection.

Preincision akinesia score was defined as the highest akinesia score obtained for each patient, whether or not a supplemental injection was necessary. Overall onset of blockade was defined as the time that elapsed between the end of the first injection and the time at which the preincision score was reached, whether a supplemental injection was performed. Postoperative akinesia score was defined as akinesia score at the end of surgical procedure.

#### Statistical Analysis

Sample size was calculated as that needed to detect supplemental injection rate of 1% in the ESA group *versus* 30% in the PBA group.<sup>1,3,4</sup> For an  $\alpha$  risk of 5% and a  $\beta$  risk of 10%, the calculated size of each group was 32.

Results are expressed as the median (5th to 95th percentiles) or mean  $\pm$  SD as indicated. A nonparametric Kruskal-Wallis test or Student *t* test was used, as appropriate, to compare the quantitative variables between the two groups. Chi-square analysis or the Fisher exact test was used, as appropriate, to compare qualitative values between the two groups. Bonferroni correction for repeated comparisons was applied if necessary.  $P < 0.05$  was considered significant, and  $P < 0.1$  was defined as a tendency toward a significant difference.

## Results

#### Demographic Data and Anesthetic Management

Demographic features in the two groups were similar. Duration of surgical procedure was similar: 20 (15–40) *versus* 20 (15–40) min. The only difference between two groups was depth of needle insertion and injected volume (table 1).

#### Primary End Points

Akinesia score was higher in the ESA group at 1, 5, 10, and 15 min after first injection. The best akinesia score was higher in the ESA group. Onset of blockade was quicker in the ESA group: 5 (1–10) *versus* 5 (1–15) min;  $P = 0.02$ . Supplemental injection was necessary in 13 patients (39%) in the PBA group *versus* none (0%) in the ESA group ( $P < 0.0001$ ).

Satisfaction scores were not different for the surgeon between two groups: 10 (10–10) *versus* 10 (8–10);  $P = 0.15$ . There was a tendency toward a higher satisfaction score of the patients in the ESA group: 10 (10–10) *versus*

**Table 1. Demographics Values, Anesthesia Techniques Specifications, and Duration of Surgical Procedures**

Group	Age (yr)	Height (cm)	Weight (kg)	Sex F/M	Side Operated R/L	Axial Length (mm)	Propofol Dose (mg)	Depth of the Needle (mm)	Injected Volume (ml)	Duration of Surgery (min)
PBA n = 33	78 ± 8	163 ± 8	69 ± 13	18/15	18/15	22.8 (21.5–25.9)	20 (10–40)	25 (15–25)	10 (9–11)	15 (10–35)
ESA n = 33	76 ± 9	161 ± 9	65 ± 11	23/10	14/19	22.8 (21.6–26.3)	20 (20–40)	15 (10–20)	10 (6–11)	15 (10–50)
<i>P</i>	0.41	0.46	0.31	0.20	0.32	0.55	0.41	0.0001*	0.002*	0.81

Results are expressed as mean ±SD or median (5th to 95th percentiles), depending on whether they are of gaussian repartition. For further explanation, see text.

10 (8–10) [range 5–10];  $P = 0.07$ . Satisfaction score of the anesthetist was higher in the ESA group: 10 (10–10) versus 8 (8–10);  $P = 0.01$ . Data for primary endpoints are shown in table 2.

#### Secondary End Points

Supplemental injection, if necessary, improved akinesia score in the PBA group. In 1 of 13 patients who received reinjection, sufficient akinesia was not achieved, and a third injection obtained satisfactory akinesia. After reinjection, however, preincision akinesia score was still lower in the PBA than in the ESA group: 18 (15–18) versus 18 (16–18);  $P = 0.02$ . Overall onset of blockade was of longer duration in the PBA group than in the ESA group: 5 (1–10) versus 5 (1–30) min ( $P = 0.03$ ). This was mainly because of additional onset time for supplemental injection in the PBA group (5 [5–15] min) compared with no additional time in the ESA group. The postoperative akinesia score was higher in the ESA group: 18 (16–18) versus 18 (13–18);  $P = 0.014$ .

In patients of both subgroups who did not require supplemental injection, best akinesia score and onset of blockade were not significantly different between groups. This means that all the differences exposed above were only due the patients who required a supplemental injection.

#### Adverse Events and Complications

No serious anesthesia-related or surgical complications occurred as a result of insufficient anesthesia. In two

cases (one ESA, one PBA) surgical tear occurred in the posterior capsule of the lens. In two cases (one ESA, one PBA) the surgeon had to convert to a manual technique of extraction of the lens. In three cases of PBA, motor blockade of the orbicularis muscle of the lids began to wear off before completion of surgery, leading to slight blinking of the lids. Two patients in the PBA group reported very slight pain (pricking sensation), but surgery was uneventful. One of these patients assigned satisfaction score of 5 of 10, which was the only satisfaction score less than 8 of 10. In four patients (one PBA, three ESA) corneal edema occurred, leading to surgical difficulties without complication. One case of peribulbar hematoma occurred in the PBA group. In four cases in the PBA group, very intense chemosis occurred at the end of the injection, probably accounting for an inadvertent episcleral injection.

#### Discussion

In this randomized double-blind study, ESA provided more constantly effective block than did PBA, with shorter time to onset of blockade, better maximal akinesia, and no need for supplemental injection. No serious adverse event, major incident, or complication occurred.

The satisfaction score assigned by the anesthesiologist (who was aware of the technique used) was higher in the ESA group; there were no differences in score assigned by patients and surgeons (both unaware). The

**Table 2. Comparison of Total Akinesia Scores during Onset of the Block, Best Akinesia Score, and Akinesia Score after Supplemental Injection if Needed (Preincision) and at the End of Surgical Procedure (Postoperative)**

Score	1 min	5 min	10 min	15 min	Best Akinesia Score	Preincision	Postoperative
PBA	10 (1–18)	17 (5–18)	18 (7–18)	18 (7–18)	18 (7–18)	18 (15–18)	18 (13–18)
ESA	16 (8–18)	18 (15–18)	18 (16–18)	18 (16–18)	18 (16–18)	18 (16–18)	18 (16–18)
<i>P</i>	0.0008*	0.002*	0.0004*	0.0004*	0.0001*	0.0275*	0.014*

Results are expressed as median (5th to 95th percentiles). Group PBA versus group ESA. For further explanation, see text.

\* $P < 0.05$ .

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anesthesiologist often assigned a bad score to blockade that necessitated supplemental injection, even if such an injection resulted in a satisfactory block. The difference between groups was greater for the postoperative score than for the preincision score (table 2). In the ESA group, akinesia score did not change from preincisional to postoperative values, in contrast to the PBA group in which the akinesia score decreased from the preincisional to the postoperative values. This means that akinesia began to wear off during surgery only in the PBA group. If patients requiring supplemental injection (all in the PBA group) are excluded from comparison, time to onset of blockade and best akinesia score were not significantly different between groups. Thus, all the differences we found resulted from patients in the PBA group who required supplemental injection because of imperfect akinesia (39%). Similarly, overall onset of the blockade clearly was longer in duration in the PBA group, mainly because of the additional time spent administering supplemental injection and waiting for blockade onset. Therefore, PBA is less constantly effective than ESA.

#### Anatomic Considerations

Differences between PBA and ESA can be explained anatomically. PBA has been used for years, but its success rate is still insufficient. Wong *et al.*<sup>23</sup> stated that PBA "utilizes the tissue compartment principle in which a needle is inserted into a compartment and the local anesthetic injected spreads by virtue of its pressure and volume throughout the compartment." The target structures to be blocked are a number of small sensory and motor nerves dispersed throughout the corpus adiposum of the orbit, especially in the intraconal space. After PBA, local anesthetic must spread from the extraconal space into the intraconal space.<sup>24,25</sup> Because the corpus adiposum of the orbit is separated into multiple compartments by a small network of septa, this spread of local anesthetic is sometimes heterogeneous and incomplete.<sup>24-27</sup> This irregular spreading accounts for imperfect blockade in up to 50% of patients in some series,<sup>4</sup> or for the need for multiple injections or very high volumes in PBA.

The episcleral (sub-Tenon's) space is a virtual space that allows the rotation movements of the eyeball in the connective tissues of the orbit. It is adherence-free and therefore injectable. Episcleral space is limited by the sclera and the fascial sheath of the orbit (Tenon's capsule). It has been hypothesized that ESA acts by spreading the local anesthetic through the fascial sheath of the

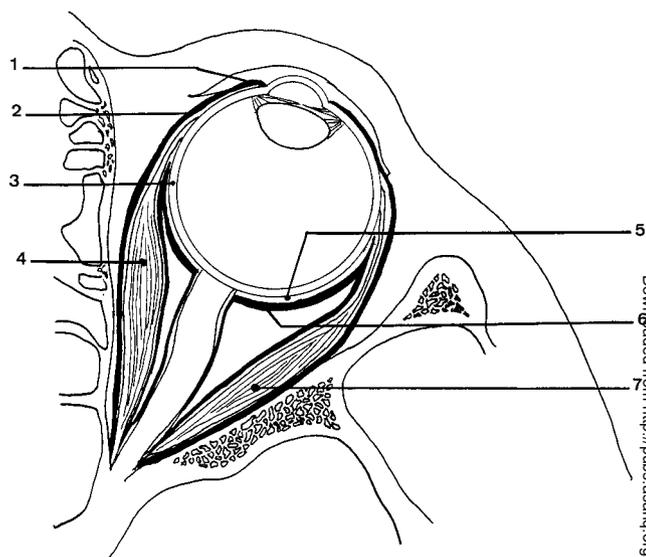


Fig. 4. Semischematic view of an horizontal anatomic section of a human orbit. 1 = Fascial sheath of the eyeball fuses with the bulbar conjunctiva before inserting near the corneal ring; 2 = anterior part of the fascial sheath of the orbit (Tenon's capsule); 3 = sclera; 4 = medial rectus muscle with its sheath; 5 = episcleral space (note that this space surrounds the whole scleral portion of the eyeball); 6 = posterior part of the fascial sheath of the orbit (Tenon's capsule); 7 = lateral rectus muscle with its sheath. Note the continuity between muscular sheaths and fascial sheath of the eyeball. Note the continuity with the subconjunctival space. Note that anteriorly, the fascial sheath of the orbit which is not sealed, allows the excess amount of local anesthetic to flow into the lids.

eyeball from the episcleral space to the intraconal (retrobulbar) space.<sup>6,13,28-31</sup> Another hypothesis that explains ESA effectiveness is that the cannula introduced into the episcleral space pierces the fascial sheath of the eyeball to enter the intraconal space.<sup>15</sup> The ciliary nerves, responsible for the sensory innervation of the globe, pass through the episcleral space and are bathed by any anesthetic solution injected into this space, resulting in a good sensory blockade of the eyeball. It has been confirmed that spread of the local anesthetic is guided by the fascial sheath of the orbit into the episcleral space around the eyeball.<sup>17,18</sup> ESA often is performed using a surgical approach to the fascial sheath of the eyeball.<sup>6-15,28-33</sup> Some ESA needle techniques also have been presented.<sup>34-37</sup> In most of these reports, the volume of local anesthetics injected into the episcleral space is less than 4 ml. This may account for incomplete motor blockade in many cases, especially with regard to lid akinesia, with the need for additional facial nerve block.<sup>9,11,31-34,37</sup> The technique used in the current study, however, is based on the injection of a relatively high volume.<sup>16</sup>

The fascial sheath of the eyeball extends to the sheaths of the rectus muscles (fig. 4). This anatomic disposition may explain that a high volume of local anesthetic is guided preferentially to those muscle sheaths to produce good akinesia.<sup>17</sup> Moreover, the fascial sheath of the eyeball guides the injected solution to the lids and, in particular, to the orbicularis muscle to provide akinesia of the eyelids.<sup>17,18,29</sup> One can compare the anatomic difference between PBA and ESA to the difference between epidural and spinal anesthesia.

#### *Effectiveness of Each Technique*

The effectiveness of ESA reported herein is in agreement with our findings in series of 802 patients, with a reinjection rate of less than 1%.<sup>19</sup> To our knowledge, few studies have compared PBA and ESA. In a retrospective study, Briggs *et al.*<sup>38</sup> found no difference in the need for reinjection or in perioperative pain. They found ESA to be superior to PBA in terms of onset of the blocks and pain at injection, but they did not compare akinesia. To compare both techniques in terms of sensory block but not akinesia, however, is inadequate. For cataract surgery, analgesia is obtained easily by the only means of topical local anesthetic eyewash instillation. Kollaritis *et al.*<sup>39</sup> retrospectively evaluated 2,453 patients. In this series, 6.7% of the patients required additional sedation after ESA *versus* 26% after PBA. In a retrospective sample of 200 patients, they observed that patients in the ESA group experienced less pain and were more cooperative, but that akinesia was better in the PBA group. This difference with our results concerning akinesia can be explained easily by the lower volumes injected for ESA, as compared to PBA (1.5 *vs.* 6 ml). We previously explained why a small volume of local anesthetic injected into the episcleral space provides a good sensory block and why an increase in this volume is needed to provide akinesia.<sup>17,18</sup> The only randomized prospective study designed to compare PBA and our technique of ESA was that of Truc *et al.*<sup>40</sup> They found ESA to be more effective than single-injection PBA in terms of akinesia. It is questionable that complete akinesia is necessary for cataract surgery. Some surgeons accept dealing with imperfect or no akinesia and sometimes use only topical anesthesia. Akinesia is the more discriminating parameter, however, because total akinesia is much more difficult to obtain than analgesia. Akinesia still remains of interest for many surgeons in cataract surgery and other ophthalmic surgery procedures.

#### *Clinical Implications*

Reliability is useful, particularly in institutions with high volume and quick turnover.<sup>41</sup> Avoiding supplemental injections avoids additional delay and the risk of a second puncture. The complication rate of regional anesthesia is low but still existent: 1 in 1,300 to 1 in 16,000 for globe perforation and<sup>1,42</sup> 1 in 300 to 1 in 500 for brain stem anesthesia.<sup>2,43,44</sup> More than 350,000 cataract extractions are performed each year in France, most of them during regional anesthesia.<sup>45</sup> Lowering the reinjection rate from 39% to 1% would mean avoiding 133,000 punctures. This theoretically would correspond to avoiding 8-141 perforations of the globe and 266-443 cases of brain stem anesthesia per year in France alone.

In terms of safety, ESA must be evaluated on a much greater scale. By limiting the depth of insertion of the needle, however, the risk of complications (such as optic nerve injury or brain stem anesthesia) that result from deep insertion of the needle in the orbit should be reduced.

The final result of this study confirms that if there is no need for reinjection, time to onset is short in both groups. This means that there is no need to wait more than 10 min after injection of PBA before deciding to perform a supplemental injection.

In conclusion, our study showed ESA to be superior to PBA in terms of akinesia and rate of requirement of supplemental injection. This is the result of greater reliability and constancy in effectiveness of ESA.

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