



Research Article

Evaluation of deep topical fornix block versus topical anesthesia in patients undergoing implantable collamer lens procedure



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Abstract *Background and aim:* Local anesthesia nowadays became more popular in the ophthalmic surgery, especially in implantable collamer lens (ICL) procedure, with fewer complications and more patient satisfaction. Here we design a study to evaluate deep topical fornix nerve block (DTFNBA) versus topical anesthesia.

Methods: A double blinded randomized prospective controlled study of 107 eyes that were scheduled for implantable collamer lens procedure was included and divided randomly into two groups, group I topical anesthesia ($n = 53$), group II DTFNBA ($n = 54$). The two groups were monitored for pain and patient compliance.

Results: In group I, receiving topical anesthesia 27 patients (50.09%) reported pain, especially with implantation of the lens, tucking of the lens footplates and peripheral iridectomy that necessitated intracameral lidocaine injection. The others ($n = 26$) showed different grades of discomfort that was tolerated without the need for intracameral lidocaine. 40 patients (74.07%) in group II (DTFNBA), tolerated the surgery well, and slight discomfort was reported as a sensation of heaviness during the tucking of footplates. None of the patients had pain strong enough to require intracameral injection of lidocaine ($p < 0.05$).

Conclusions: Placing the anesthetic in the fornix makes the DTFNBA more effective and reliable block.

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1. Introduction

General anesthesia (GA) recently is not the first choice in phakic intra ocular lens (p IOL) surgery, which is attributed to the short duration of the surgery, potential general anesthesia complications, increased length of hospital stay, and increasing the costs of GA. By the time traditional retro and peribulbar injections recede to newer techniques that are safer and cheaper, sub tenon's block using a blunt needle took over due to the more safety profile [1–5]. Even though, still serious problems can occur especially in patients with long axial length. Deep topical fornix nerve block anesthesia (DTFNBA) and topical anesthesia gradually took over with promising and successful results, decreasing length of hospital stay and increasing patient satisfaction and fewer margins of complications [6–8].

Hypothetically, adding DTFNBA to topical anesthesia will augment the analgesic effect, improve surgical conditions and increase patient comfort.

In this study, we compared topical anesthesia alone with DTFNBA in patients undergoing posterior chamber phakic IOL surgery (Visian® ICL, V4B, STAAR, California, USA).

2. Patients and methods

110 patients candidates for elective Visian® ICL implantation surgery, were enrolled in this study after obtaining approval from the institutional ethical committee (Magrabi Hospital) and registered as NCT: 02196441 in the (www.clinicaltrials.gov), and all the patients signed consent after complete explanation. We were planning a study of matched sets of patients receiving the case and control treatments with 1 matched control per experimental subject. Prior data indicate that the probability of a treatment failure among controls is 0.05, and the correlation coefficient for exposure between matched experimental and control subject is 0.1. The true odds ratio for failure in experimental subjects relative to control subjects is 0.1, so we needed to study 51 experimental subjects with 1 matched control per experimental subject to be able to reject the null hypothesis that this odds ratio equals 1 with probability (power) 0.7. The probability of type I error linked with the test of this null hypothesis was 0.3. The sample size was increased to 110 patients (55 in each group) to exclude the dropout. Only those who are cooperative in understanding patients who were deemed suitable for topical and DTFNBA were included in the study. We excluded very anxious patients from the study. Group I received topical anesthetic drops and Group II received DTFNBA.

The study was planned to be randomized using a computer random number table, and double blinded for the patient and the surgeon, as the surgeon was not informed about the type of the anesthesia. A cannula was inserted into a peripheral vein and the routine monitor (Pulse, arterial blood pressure and oxygen saturation) was applied. The same surgeon (S.E.) did all the operations.

In group I, only topical anesthesia was applied with 2% tetracaine drops. In group II, after tetracaine drops instillation, DTFNBA was performed using two sponges (2 × 3 mm) soaked with 0.5% bupivacaine, applied deep in the conjunctival fornices – just before surgery-after anesthetising the conjunctiva with bupivacaine local anesthetic drops.

The sponges were removed by end of procedure (Fig. 1). The anesthetic effect was tested by grasping the limbus with 0.12 tissue forceps.

Pain was monitored using a simple pain score (no pain = 0; that does not interfere with the surgical technique, discomfort = 1; the surgical technique is performed with difficulty, pain = 2; the surgeon is unable to continue the surgical technique) [9].

A 3.20 mm temporal tunneled clear cornea incision was created, and the anterior chamber was filled with viscoelastic material (Microvisc 1%; Bohus BioTech AB). The PC pIOL (Visian ICL V4B; STAAR Surgical Inc., Monrovia, CA) was loaded into the cartridge and injected intracamerally very slowly to allow controlled slow lens unfolding. An iris manipulator (Asico, LLC) was used to tuck the footplate haptics of the lens within the posterior chamber. Pupil constriction was achieved by MioStat 0.01% (Alcon, Texas, USA) intracameral injection, before peripheral iridectomy done with outcome. The viscoelastic material was then removed using the Simcoe irrigation aspirating cannula [10].

We performed the pain scoring during every step of surgery: inserting a speculum, tolerance to the microscope light, 3.2 mm temporal incision of the cornea, intraocular Collamer



Figure 1 Surgical micro sponge before fashioning by scissors to 2 × 3 mm pieces and soaking in bupivacaine (bvi visitec, Dominican Republic).

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