

New implant in deep sclerectomy: Dinop® - short time results

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Introduction

Non perforating deep sclerectomy has gained many adepts due to its lower profile of postoperative complications, compared to classic trabeculectomy. In order to increase the aqueous outflow and improve postoperative intraocular pressure outcome, various implants were designed to maintain the intrascleral space and some studies have shown better results when such devices are used. As presently there is no gold standard implant in deep sclerectomy, the available options are in a process of evolution in terms of materials and shapes.

We performed a prospective comparative study to compare the efficacy and safety of a new non-absorbable implant in deep sclerectomy, Dinop®, Henan Universe IOL, with the implant most commonly used in Spain, the Esnoper V2000®

Material & Methods

In a prospective comparative randomized study, from January 2013 to March 2013, 20 eyes of 20 consecutive subjects with medically uncontrolled moderate and severe glaucoma underwent mytomicin C-augmented deep sclerectomy, with Esnoper V2000® (AJL Ophthalmics, Spain) or Dinop® (Henan Universe IOL, China) implant.

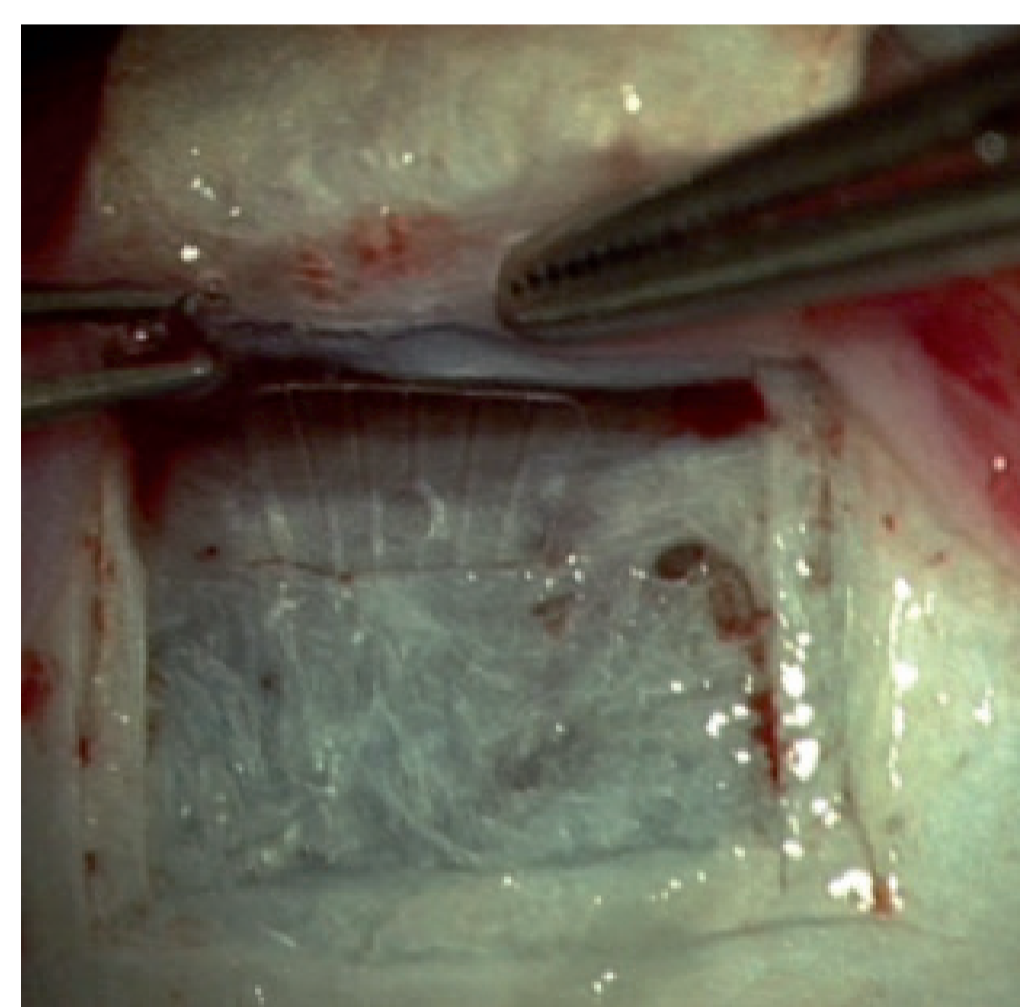


Fig.1. Esnoper® suprachoroidal implant

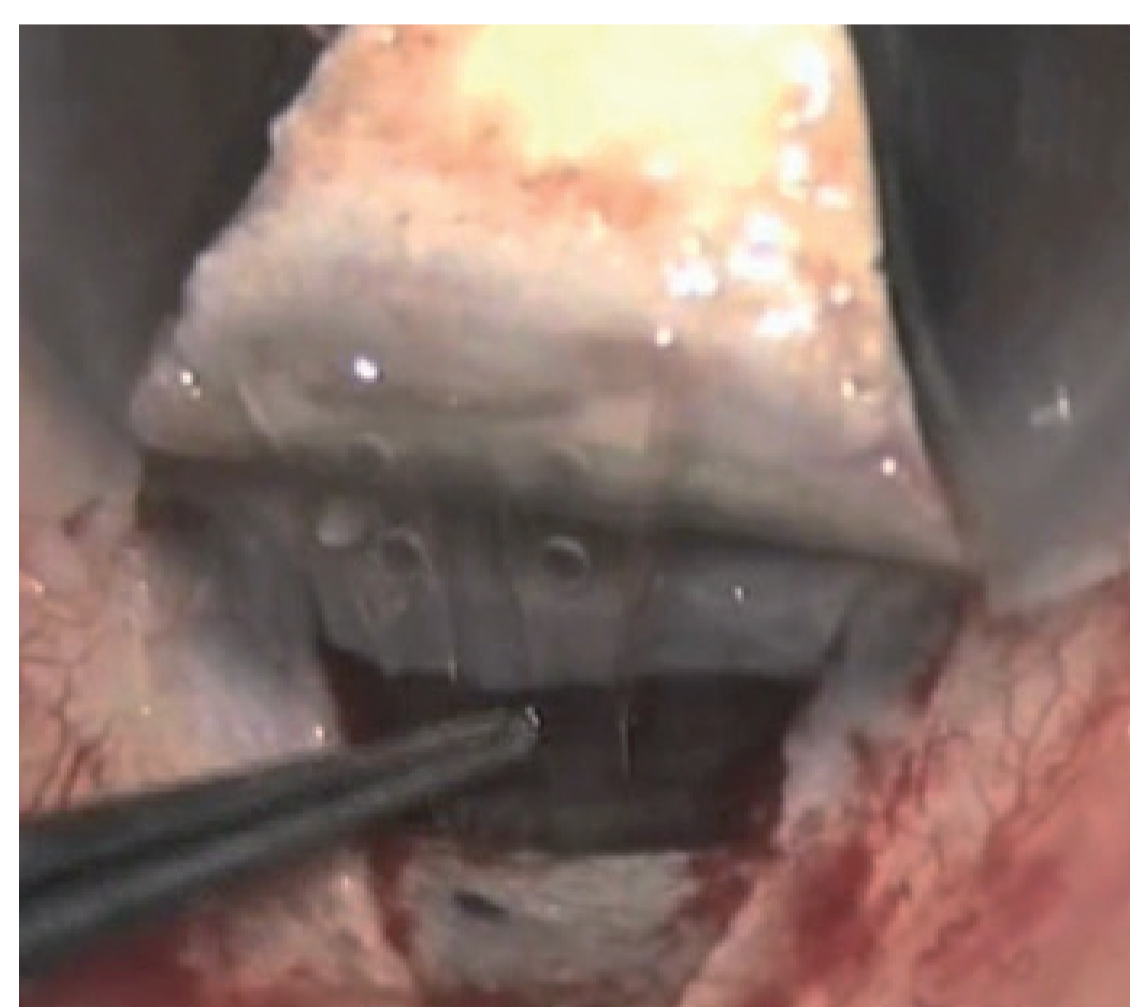


Fig.2. Dinop® suprachoroidal implant

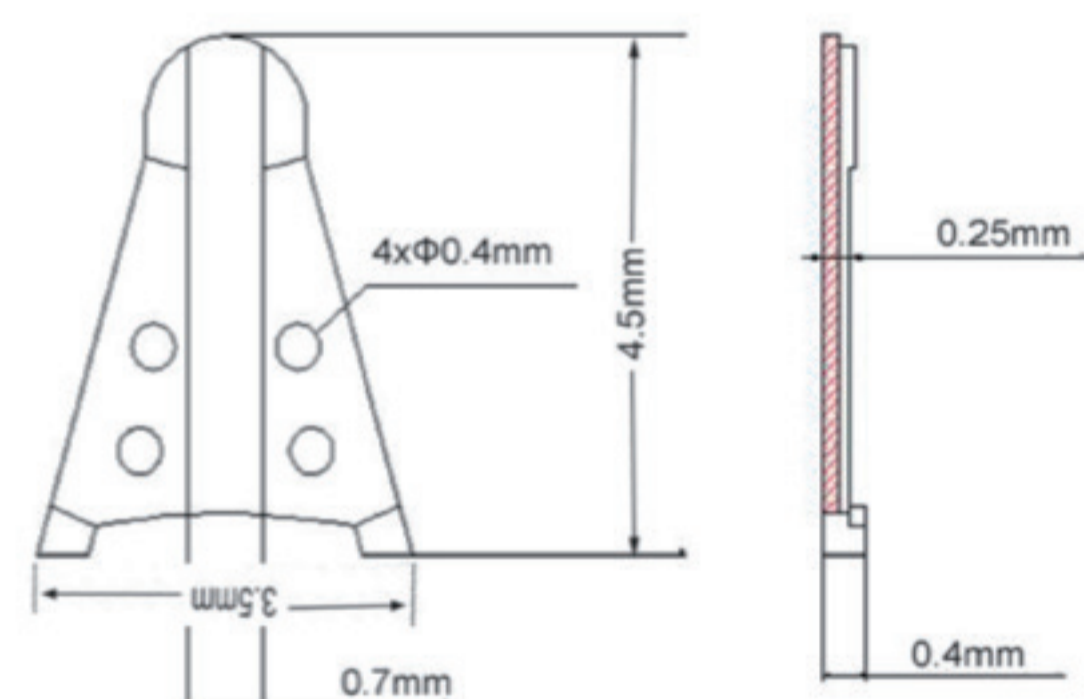


Fig.3. Esnoper

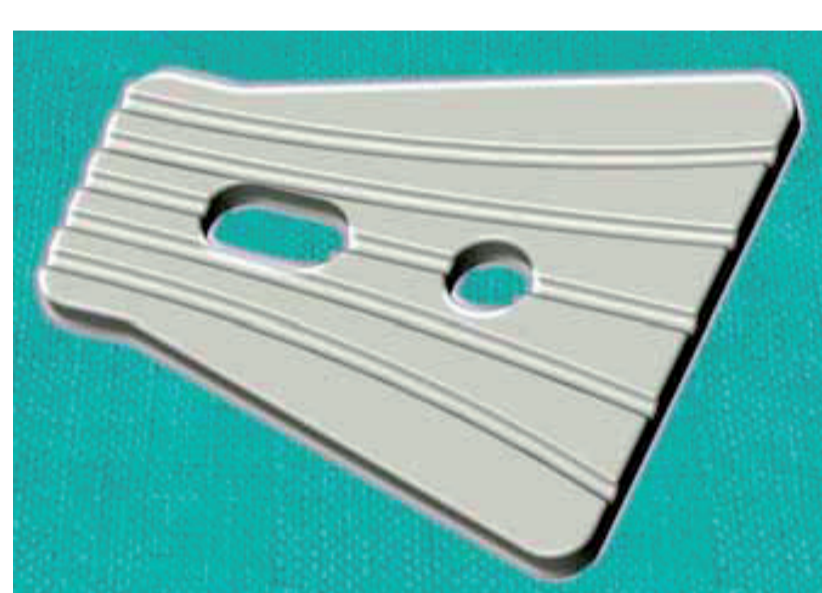


Fig.4. Dinop® design dimensions

Dinop® is a new 250 µm thick trapezoid hydrophilic acrylic implant measuring 4.5X3.5mm, presents 4 holes and one large longitudinal central sulcus designed to improve aqueous flow.

Esnoper® is a 200 µm thick and 3 mm long hydroxyethyl methacrylate HEMA implant, presents 2 holes and minute longitudinal channels.

Surgical procedure: Under retrobulbar anesthesia a fornix-based conjunctival peritomy and superficial 5X5mm limbus based scleral flap of 1/3 scleral thickness was performed. . Mitomycin C (0.02%) soaked sponges were applied for 3 minutes under the superficial scleral and the posterior tenon cover. Deep 4X4mm scleral flap, with a second deep scleral flap and deroofting of the Schlemm's canal was performed. The randomly chosen implant was placed within the suprachoroidal space, by means of a small incision on the scleral bed. Superficial scleral flap tied loosely with 2 single sutures and conjunctival closure.

Student's t-test was used to compare post-operative IOP between the two groups.

In these group of patients with moderate and severe glaucoma, complete success was defined as final intraocular pressure (IOP) below 15mmHg without anti-glaucoma medication.

Results

Mean follow-up time was 7.6 months in the Esnoper® group and 6.4 months in the Dinop® group. Preoperative IOP was 19.6 mmHg (SD 3.37 mmHg) and 17.20 mmHg (SD 3.89 mmHg) in the Esnoper® and Dinop® group, respectively. The mean number of glaucoma medication was 2.8 in both groups.

After deep sclerectomy, mean IOP in the Esnoper® group vs Dinop® group was 3.2 mmHg vs 8.8 mmHg on day 1 postoperatively, 5.8 mmHg vs 9.8 mmHg at Month 1, 9.2 mmHg vs 12.6 mmHg at Month 3 and 9.4 mmHg (SD 5.22 mmHg) vs 11.0 mmHg (SD 3.39 mmHg) at Month 6, respectively, without anti-glaucoma medications (p=0.004 on day 1, p=0.086 at month 1, p=0.205 at month 3 and p=0.283 at month 6).

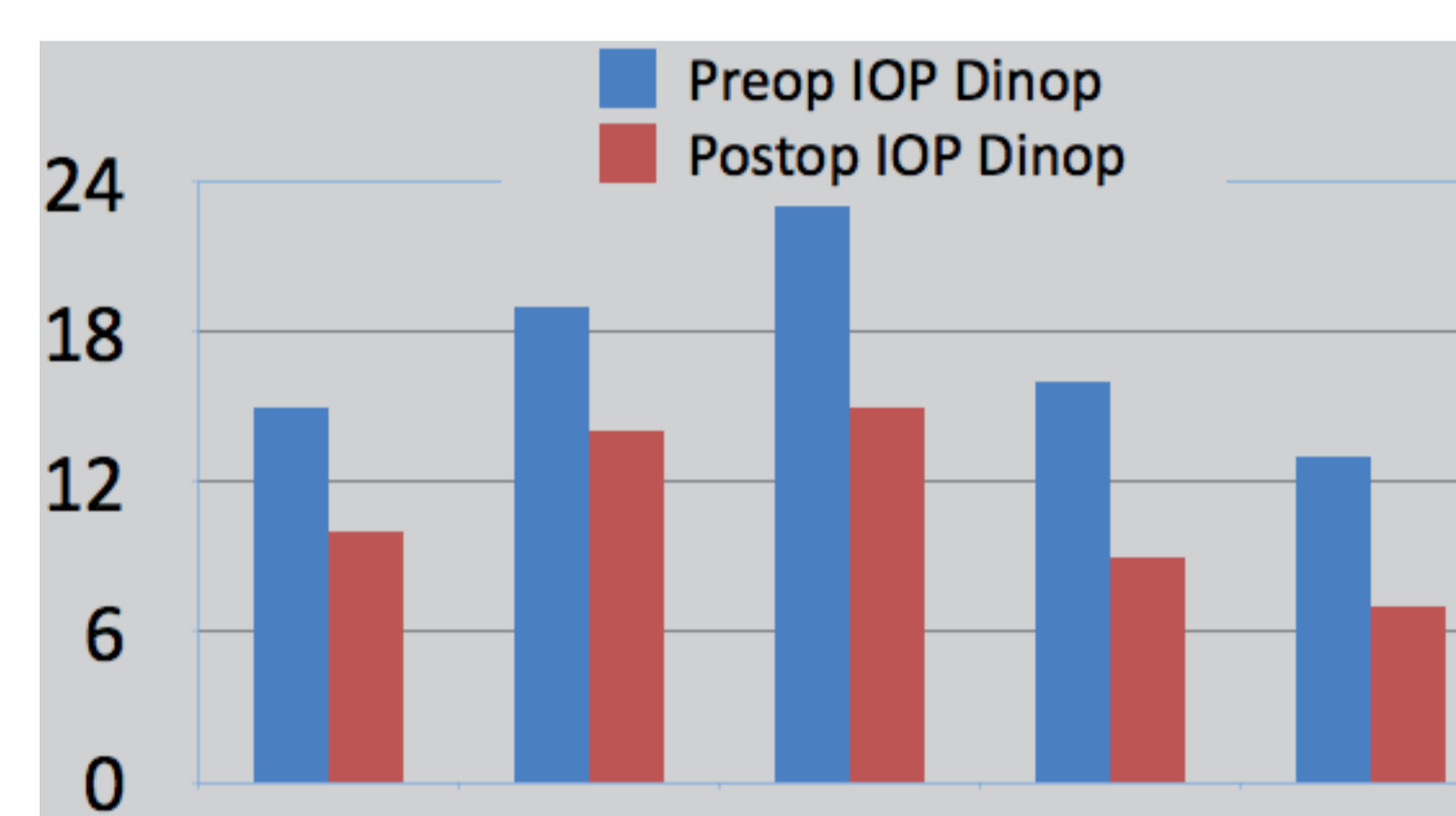


Fig.4. Preoperative and postoperative IOP in 5 consecutive patients with Dinop® implant

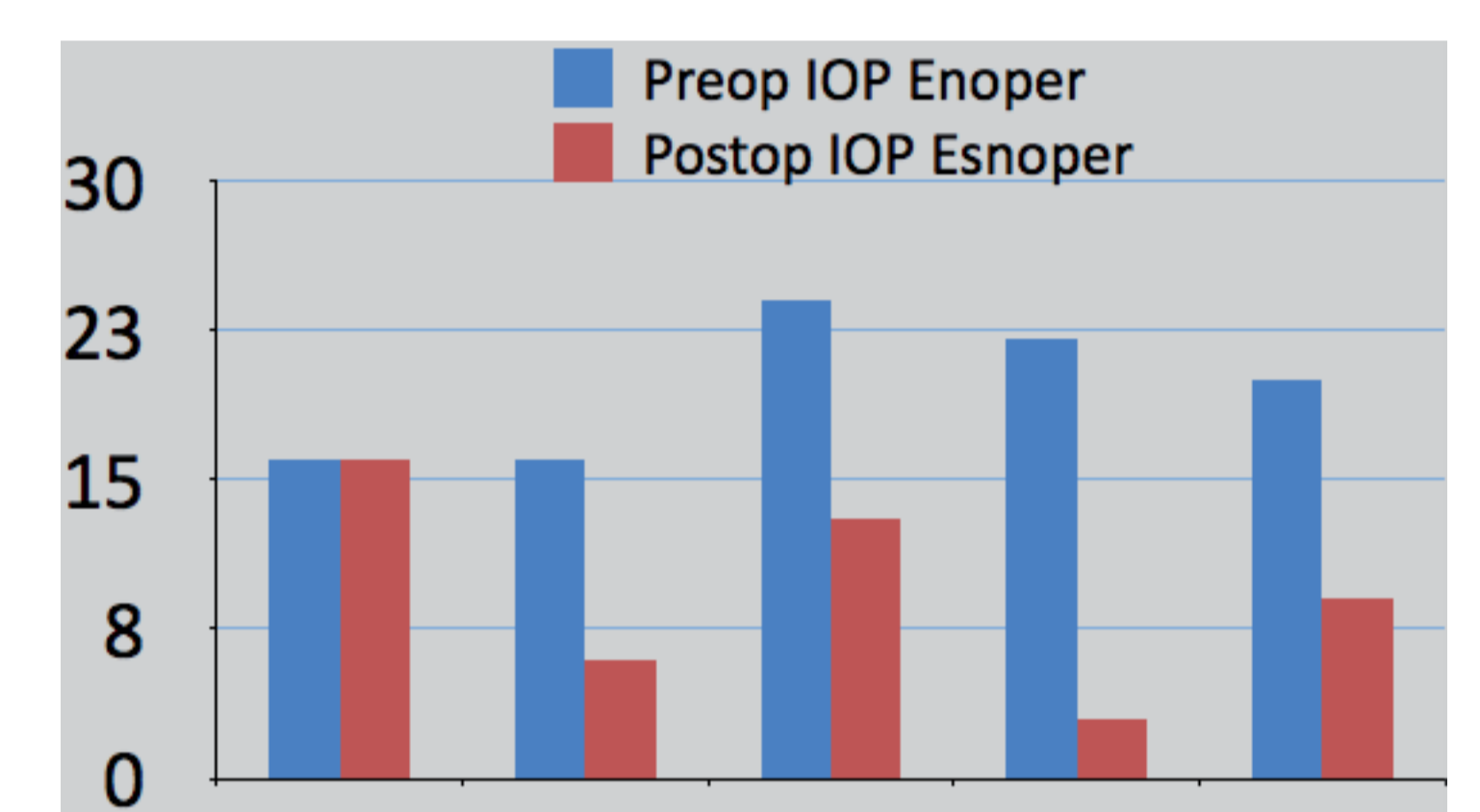


Fig.5. Preoperative and postoperative IOP in 5 consecutive patients with Esnoper® implant

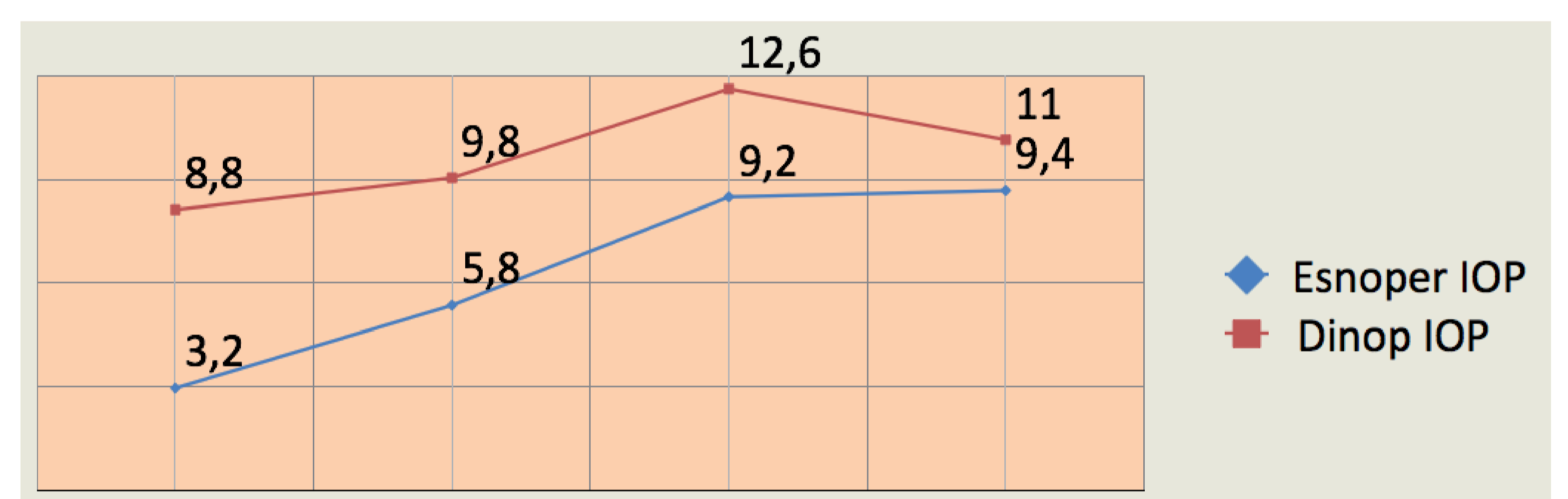


Fig.6. Comparative mean post-operative IOP at Day 1, Month 1, Month 3 and Month 6

The incidences of early post-operative complications were similar in the 2 groups. 1 patient required goniotomy in the Esnoper® group compared to 2 patients in the Dinop® group. In the Esnoper® group, 1 patient underwent compression bleb sutures for ocular hypotony and another patient presented choroidal detachment which resolved spontaneously.

Discussion

The mechanism of action of deep sclerectomy implants such as Esnoper® or Dinop® is to create a suprachoroidal or intrascleral space. Minor differences in the design of the implant do not seem to affect short-term results. When deep sclerectomy enhanced with suprachoroidal implant is performed in patients with advanced glaucoma in need of low teen postoperative IOP, the use of MMC seems mandatory. In our short series of patients with moderate and advanced glaucoma, both implants appear to offer similar efficacy and safety.

Conclusions

The success of deep sclerectomy and complications were similar in both Esnoper® and Dinop® groups at the end of 6 months. Mytomicin C-augmented deep sclerectomy with suprachoroidal implant is an appropriate technique for moderate and severe glaucoma patients in need of low postoperative IOP.

The authors declare no conflict of interest

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