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SURGICAL TECHNIQUE

# A New Implant for Deep Sclerectomy: Esnoper®

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**ABSTRACT**

Newer non-reabsorbing implants have been developed to maintain the hypotensor effect of nonpenetrating deep sclerectomy. In this article the authors discuss a new non-reabsorbing implant with 2-hydroxyethyl methacrylate (Esnoper®, AJL Ophthalmics, SA, Miñano, Alava, Spain), its design, technique of implantation and the available scientific evidence.

**Keywords:** Deep sclerectomy, Esnoper implant, Nonpenetrating glaucoma surgery.

## INTRODUCTION

Recent addition of nonpenetrating procedures in the surgical armamentarium of glaucoma is an attempt to reduce the complication profile of the 'classic' filtering surgery, namely major hypotony with its possible consequences: Flat anterior chamber, choroidal detachment and cataract formation. Even though it has a long learning curve, deep sclerectomy (DS) has gained many adepts among glaucoma surgeons, as it seems to show less complication rates than trabeculectomy.[1-3]

Nonpenetrating DS has passed through a series of changes that improved the final outcome, from designing fine instruments that peel off the Schlemm's canal to inventing devices that prevent the fibrosis between the superficial flap and the scleral bed. These implants maintain the intrascleral lake formed by removal of the deep sclerocorneal fragment and their use in DS enhances the success rates and lowers the need for postoperative medication.[4,5]

In the past 30 years, various materials have been used in the composition of the space maintainer DS implants. The absorbable implants include purified porcine-derived collagen (Aquaflow®, Staar Surgical AG) also called 'the collagen sponge' due to its property to expand its volume twice as soon as the aqueous humor contacts it and reticulated hyaluronic acid pieces (SK-GEL®, Corneal), which occupies a large volume in the filtering area, needs no scleral suturing and allows sufficient circulation of the aqueous humor. As the use of implants under the scleral flap necessarily makes the surgery more expensive, many concerned glaucoma surgeons have employed lower budget alternatives, such as 1.0 chromic suture material, amniotic membrane, autologous sclera or viscoelastics (Healon®, Healon HV®).[6-12]

The materials used in nonabsorbable implants vary from hydrophilic acrylic polymegma polymer (T-Flux®, Carl Zeiss) to polymethyl methacrylate PMMA (Homdec, Belmont, Switzerland) and 2-hydroxyethyl methacrylate HEMA (Esnoper®, AJL Ophthalmics, SA, Miñano, Alava, Spain and HemaAcrylic Mehta Stealth Implant, Dr Keiki Mehta, Dr Cyres Mehta, Mumbai, India). Aiming to lower the cost of the nonabsorbable implants, fragments of hydrogel contact lens have also been studied.[13-19]

Given the diversity in models and materials used in different SD implants which seem to show similar success rates, we can only state that the gold standard implant for DS is still in the process of being defined.

## ESNOPER® IMPLANT: DESIGN AND TECHNIQUE

Esnoper V-2000® is a new nonabsorbable acrylic implant designed by the ophthalmologist Julio de la Cámara, PhD and developed by AJL Oftalmics SA, Miñano, Alava, Spain. The material used is nonionic polymer of 2-hydroxyethyl methacrylate (HEMA) which prevents proteins from depositing on its surface. The Esnoper V-2000® implant has a trapezoidal design, size of 2.85×3×1.40 mm and a 0.3 mm thickness. It presents two holes: A smaller one for fixation to sclera and a larger one to improve the aqueous humor filtration. Aiming to maximize the fluid flow, the implant is provided with several minute longitudinal channels (Fig. 1).

The Esnoper® implant is used in the nonpenetrating deep sclerectomy as all other aforementioned implants, after the removal of the second scleral flap and peeling off the Schlemm's/juxtacanalicular membrane, and before closing the superficial flap and conjunctiva.

The Esnoper® implant is sutured to the lateral scleral steps (created due to the smaller size of the deep scleral flap compared with the superficial flap) with 10-0 nylon, using the central hole of the implant located and positioning the wider edge of the trapezoidal piece toward the cornea (Fig. 2). The authors advocate that the side facing scleral bed should be the one with the longitudinal channels, as intuitively it seems to improve the outflow.

Note that the implant can also be used under the sclera, facilitating the formation of a suprachoroidal drainage lake. A small incision (2-3 mm) is created just posterior to the scleral spur and the space between the sclera and the choroid is softly opened with a blunt spatula. The smaller end of the implant is then inserted under the sclera and the implant can be advanced into the new created suprachoroidal pouch. This nonstitch technique has been previously described for T-flux implant, showing promising results.[20]

The gonioscopic view after Esnoper® implantation shows intact trabeculodescemetic membrane and the wider end of the Esnoper® just posterior to it. The implant is placed with the longitudinal channels facing down (Fig. 3).

Anterior chamber optical coherence tomography (Visante, Carl Zeiss) can be used to assess the position of the implant in the postoperative period and to quantify the amount of intrascleral lake and the existence of the suprachoroidal new created space, in the case of suprachoroidal Esnoper® insertion (Fig. 4).

## ESNOPER®: SCIENTIFIC EVIDENCE SO FAR

While there are many publications on other types of DS implants, the scientific evidence on Esnoper® is scarce, mainly because it is a relatively new product and, to our knowledge, surgical experience with Esnoper® is confined to the Spanish territory.

The first results of nonpenetrating deep sclerectomy with Esnoper® implant were described in 2006 in a series of three patients who underwent phaco-DS.[13] The model used was the first marketed Esnoper®, with one hole and not provided of longitudinal channels. Using ultrasound biomicroscopy, the authors analyzed the characteristics of the intrascleral lake, the thickness of the trabeculodescemetic membrane and the presence or absence of a suprachoroidal hypoechoic area at 12 months after the surgery. All the patients presented intrascleral space and in one patient a subscleral hypoechoic space was present, despite suprascleral implantation of the Esnoper®. This finding can be explained by the fact that in nonperforating DS, the aqueous humor present in the intrascleral lake may filter through the very thin scleral layer into the suprachoroidal space. As noted above, inserting the implant in a pouch-fashion, new created suprachoroidal space, may enhance the nonconventional uveoscleral drainage.

**Fig. 1:** Esnoper® trapezoidal design with longitudinal irrigation channels, a round hole for scleral fixation and a larger hole to improve the aqueous humor flow

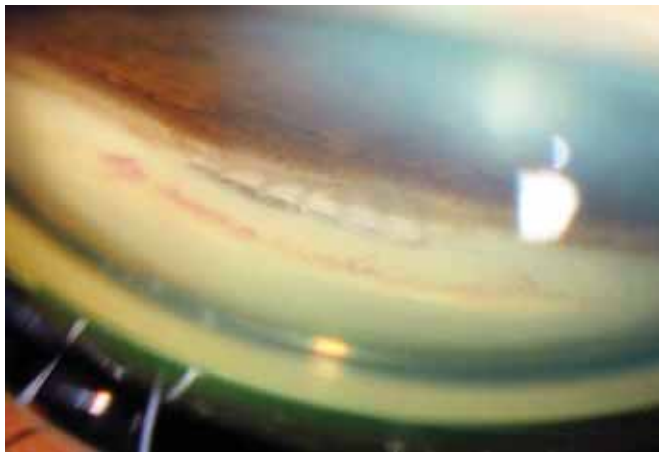

**Fig. 3:** Gonioscopic view of the Esnoper® behind the trabeculodescemet membrane

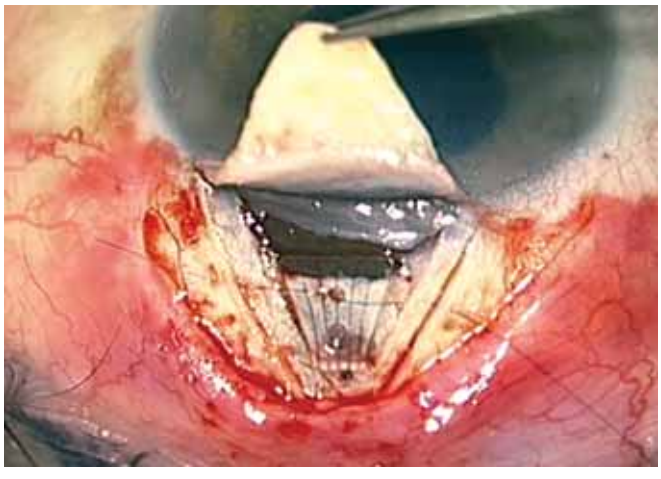

**Fig. 2:** Esnoper® implant sutured to the lateral scleral steps

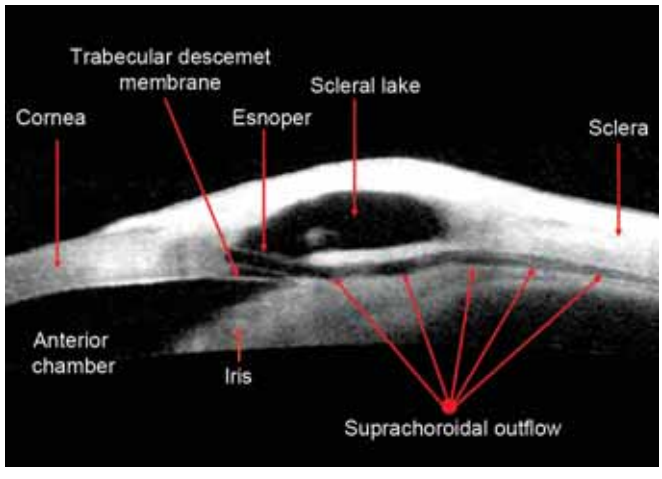


**Fig. 4:** Anterior segment OCT showing Esnoper® positioned under the sclera, enhancing the suprachoroidal outflow

There is still a debate on whether the implant, as it leans on the trabecular descemet membrane, might interfere with the aqueous humor flow through it, while it seems acceptable that the thickness of the membrane is inversely proportional to the postoperative intraocular pressure.

The rate of success and the ultrasound biomicroscopy exploration of the filtering blebs in DS with Esnoper V-2000® were recently described in a prospective study in 18 patients, evaluated at 1, 3 and 6 months postoperatively.[21] Intraocular pressure significantly decreased from a mean of 23.5 mm Hg (SD 3.5) preoperatively to a mean of 13.1 mm Hg (SD 7.6), 13.2 mm Hg (SD 4.3), and 13.3 mm Hg (SD 3) at 1, 3 and 6 months respectively. At 6 months, lower IOP levels significantly correlated with hyporeflective blebs with the presence of hyporeflective suprachoroidal space and with the presence of hyporeflective area around the scleral lake. The authors also noted that the presence of those three filtration signs together correlated with lower IOP levels compared with the presence of only 1 or 2.

Other scientific evidence on the Esnoper® V-2000 model was found as poster presentations in the European Glaucoma Society Congress, Madrid, 2010 and World Glaucoma Congress, Paris, 2011.

In the European Glaucoma Society Congress held in Madrid in 2010, a prospective study on 60 patients showed that the postoperative IOP at 1, 3 and 6 months and 1 year were not statistically different in the group implanted with Esnoper® V-2000 compared with T-Flux® group and the two groups presented similar rates of goniopuncture, needling and use of antimetabolites.[22] In a retrospective study, presented in 2011 at the World Glaucoma Congress, the authors compared the efficacy and safety of two different positions of the Esnoper® implant: Under the scleral flap *vs* a portion of the implant introduced in the suprachoroidal space in 32 patients. The results showed comparable outcomes, yet fewer medication was required in the partially suprachoroidal group.[23]

## DISCUSSION

Surgeons' armaments against the fibrosis between the superficial flap and the deep scleral layer include antimetabolites (mitomycin C and 5 fluorouracil), implants and gentle tissue manipulation. The efficacy of the implant in DS has been described in several studies.

A prospective study in 168 eyes with a 9-month follow-up comparing the results of DS with and without collagen implant showed that complete and qualified success rates were better when the collagen implant was used. There was significantly less bleb fibrosis when the collagen implant was used (2% *vs* 11%).[24] These results were corroborated in patients followed for a longer period of time (44 months) in another prospective study on 104 eyes.[4]

An interesting analysis was published on DS in one eye *vs* DS with collagen implant in the contralateral eye of the same patient. This long-term follow-up study (4 years) showed that in those eyes treated with DS with scleral implant, IOP was 3.21 mm Hg lower than for those treated with DS and the qualified success rate: Patients who achieved IOP below 21 mm Hg with or without medication, was 69% (9/13 patients) at 48 months for the DS group and 100% (13/13 patients) for the DS with collagen implant group.[25]

As for nonabsorbable implants, a prospective study on 48 eyes with 2 years of follow-up found the mean IOP lower and the IOP decrease in percentage greater in the nonabsorbable hydrophilic implant group compared with the control group.[4]

Interestingly, similar rates of sucess were reported in works comparing nonabsorbable and absorbable implants: T-Flux® versus SK-GEL®, T-Flux® versus Healon GV®, polymethylmethacrylate implant *vs* collagen device or implantation of nonresorbable implant in one eye and resorbable implant in the contralateral eye.[7,12,14,26]

The new acrylic nonresorbable implant Esnoper® seems a safe and economic option presently in Spain, where it emerged as a quest to find the equilibrium between the costs and the efficacy of the DS surgery in a moment when global economic and financial crisis weighs on Spanish public medical health. Esnoper® is a cheaper implant with promising results; nevertheless, further prospective studies are needed to establish its efficacy and equally important, its effectiveness.

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