DEEP SCLERECTOMY WITH HEALA FLOW

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Abstract: *The study presents the case of a patient in which deep sclerectomy with the use of Heala-Flow was performed. It aims to assess the intraocular pressure (IOP) lowering effect of this procedure and to evaluate intra-and postoperative complications. Main outcome measures were postoperative IOP at day 1, month 1 and 3, presence and type of complications. Postoperative IOP was significantly reduced compared with baseline, and no intra- and postoperative complications have been encountered.*

INTRODUCTION

Deep sclerectomy is a nonpenetrating glaucoma procedure for the surgical treatment of medically uncontrolled open-angle glaucoma. The classic trabeculectomy procedure with or without antimetabolites has a well-known complication rate. Deep sclerectomy technique was designed to lower the risk of complications in the immediate postoperative period such as hypotony, choroidal detachment, and flat anterior chamber, offering both the surgeon and the patient a more convenient safer option. The main advantage of this procedure is the presence of trabeculo-Descemet membrane that prevents the appearance of these complications and makes the procedure a nonpenetrating one. Deep sclerectomy prevents sudden hypotony by creating progressive filtration of aqueous humor from the anterior chamber to the subconjunctival space without perforating the eye. To avoid secondary collapse of the superficial flap a space-maintaining implant may be placed into the scleral bed. The concept of placing in the intrascleral space of a space-occuping device has been proved to improve success rate significantly in deep sclerectomy.(1)

By now, several types of implants, both absorbable and non-absorbable types, have been used.

This study aimed to assess the IOP lowering effect of Heala-Flow,a slowly resorbable, cross linked viscoelastic gel with long lasting effect, in deep sclerectomy. It is a non-toxic, highly purified, non-animal/biofermentation origin gel, having less risk of allergy cased by animal proteins. It can be used in any type of glaucoma surgery(penetrating, nonpenetrating, shunts, stents, tubes). It is an sterile, colorless, totally transparent injectable implant, not recommended for placement in the anterior chamber. It behaves like a drainage implant and limits the postoperative fibrosis, thus improving the surgical success rate.

PURPOSE

This study presents the IOP lowering effect of deep sclerectomy with the use of Heala-Flow. It shows the effect of the placement of this gel in the scleral bed, acting like a true space-maintainer. The effect of this product was investigated in a case of medically uncontrolled pseudoexfoliative glaucoma, in a type of prospective, observational and longitudinal analysis.

CASE REPORT

The study presents the case of an adult white man, D.V, 83 years old, from urban environment with pseudoexfoliative glaucoma in both eyes, age-related cataract in right eye, and posterior chamber intraocular lens in the left eye. IOP in both eyes is showed in table no. 1. The patient was under triple antiglaucomatous therapy for about 2 years (a prostaglandin analogue and a fixed combination of beta-blocker and carbonic anhydrase inhibitor). After the patient gave an informed consent he was scheduled for deep-sclerectomy with t Heala-Flow in his left eye, on March 2nd this year, in the County Hospital of Piatra Neamț, Romania. Surgical procedure was performed by a trained surgeon in non-penetrating procedures (G.D.C). Ocular findings at baseline are presented in table no. 1.

Table no. 1. Ocular findings at baseline

	OD	OS
BCVA (best corrected visual acuity)	0.5	1/50
Biomicroscopy	• natural lens with moderate nuclear sclerosis • internal pterigyum gr.1 • pseudoexfoliative material at pupillary margin	• posterior chamber intraocular lens placed in the bag • pseudoexfoliative material at pupillary margin
IOP (Goldmann applanation tonometry)	22	21
Gonioscopy	Open angle grade 3(Schaffer system) with trabecular pigmentation	Open angle grade 3 (Schaffer system) with trabecular pigmentation
Visual field (Goldman kinetic perimetry)	Not reliable	Not recorded because of low VA
C/D	0.6	0.9
Preoperative medication	Monopost, Cosopt	Monopost, Cosopt

After the patient gave an informed consent he was scheduled for deep sclerectomy with Heala Flow in his left eye. The surgical procedure was performed under laterobulbar anesthesia comprising bupivacaine 0,75% and lidocaine 4%. A superior cornean traction 7:0 silk suture was placed for adequate exposure of the deep sclerectomy site. The conjunctiva and Tenon's capsule were opened at the limbus. Bleeding was

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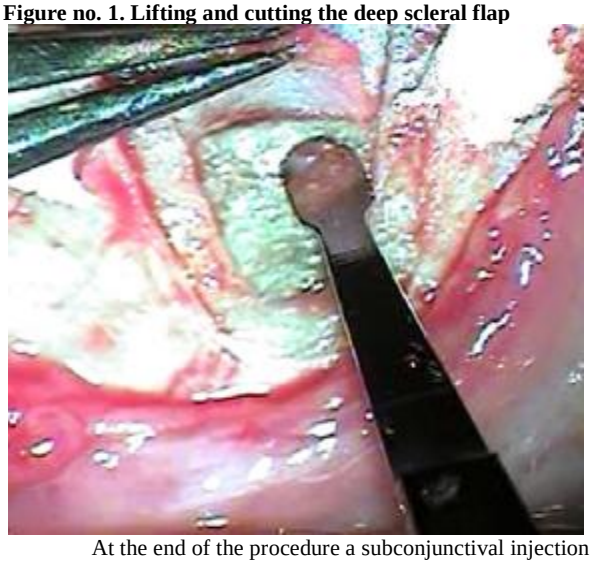
controlled with epinephrine solution applied on the sclera and with sponges, avoiding wet field cautery in order to preserve the integrity of collector channels.

A roughly one-third limbal based scleral flap measuring 5x5 mm was dissected. In order to reach Descemet membrane latter in the dissection the superficial scleral flap has to be dissected 1-1,5 mm anteriorly into the clear cornea. A second, deep scleral flap was dissected, 1mm inside the superficial flap. The deep scleral flap constitutes the deep sclerokeratectomy and is 4x4 mm, smaller than the superficial one. It leaves a step of sclera allowing for a tighter closure of the superficial flap in case of an intraoperative perforation of the trabeculo-Descemet's membrane. The deep scleral flap is dissected horizontally with a blade, starting from the posterior part of the superficial flap and leaving the remaining scleral layer as thin as possible (figure no. 1).

In the anterior part of the dissection Schlemm's canal is found anterior to the scleral spur where the scleral fibers are regularly oriented, parallel to the limbus. Here the canal is unroofed and the dissection is prolonged anteriorly for 1-1,5 mm in order to remove the sclero-corneal tissue behind Descemet's membrane and anterior trabeculum.

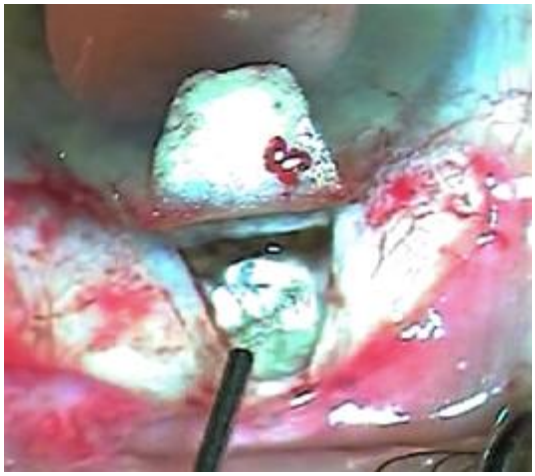
These two structures are gently detached using a spatula, a sponge or a blunt metallic blade. To perform the sclera-corneal dissection it is best to do two radial corneal cuts without touching the anterior trabeculum or Descemet's membrane. This surgical step is quite challenging because there is a high risk of perforation of the trabeculo-Descemet membrane. After the adequate width of the membrane is achieved (approximately 1mm) the deep scleral flap is cut using the scissors. At this stage of the procedure, aqueous humor was seen to percolate through the thin trabeculo-Descemet membrane. After drying the exposed inner wall of Schlemm's canal, the thin canal endothelium and the juxtacanalicular trabeculum are peeled using a small blunt forceps. This procedure represents an ab-externo-trabeculectomy. For keeping the created intrascleral space patent Heala Flow is injected in the scleral bed (figure no. 2) and then superficial scleral flap is repositioned and sutured with 8:0 interrupted Vicryl sutures. Heala Flow is then reinjected under the scleral flap and applied on the flap, subconjunctivally, after suturing the conjunctiva with separate 8:0 Vicryl sutures.

Figure no. 1. Lifting and cutting the deep scleral flap



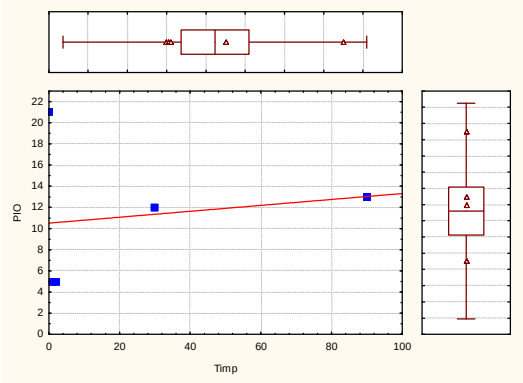
At the end of the procedure a subconjunctival injection of gentamicin and dexamethasone was applied.

Figure no. 2. Filling the decompression chamber with Heala Flow



There was no intra- or postoperative complications. Postoperative IOP was 5 mmHg at day 1, 12 mmHg at month 1, and 13 mmHg at month 3, significantly reduced compared with preoperative IOP (IOP dependency in time, fig.3). At day 1 antiglaucomatous medication was discontinued and recommenced at the follow-up visits according to the IOP levels. The patient was evaluated at day 1, and at 1 and 3 months postoperatively. At each follow-up visit we performed general ophthalmic examination including best-corrected visual acuity and IOP measurement. In addition, at the last follow-up visit, visual acuity was the same as baseline. There were no intra- or postoperative complications and no need for further antiglaucomatous medication.

Figure no. 3. IOP dependency in time



DISCUSSIONS

Classic glaucoma teaching consider surgery to be a last resort for the treatment of primary open-angle glaucoma after topical therapy and argon laser trabeculoplasty have failed to control IOP.(3) Most surgeons prefer to delay surgery because of the well-known complications of the still gold standard of glaucoma surgery. These include hyphema, hypotony, choroidal detachment or hemorrhage, flat anterior chamber, bleb failure or endophthalmitis. However, surgery remains an effective way to reduce IOP. Bylsma hypothesizes that if the safety margin of glaucoma surgery could be increased significantly without sacrificing efficacy, surgical intervention for glaucoma might be considered earlier.(4) Nonfiltering techniques avoid intraocular penetration reducing overdrainage or the risk of endophthalmitis. Peripheral iridectomy is not

required, reducing the breakdown of the blood-aqueous barrier, resulting in less anterior chamber inflammation with fewer cataracts, synechiae and bleb failure. These techniques became an increasingly popular alternative to the conventional glaucoma surgery because of the lower postoperative complication rates and quick visual rehabilitation Nonpenetrating glaucoma surgery encompasses all the variants (trabeculectomy ab externo, deep sclerectomy, viscocanalostomy) of the same glaucoma operation which allows filtration through a naturally occurring membrane, the trabeculo-Descemet membrane.(5) The reports of long term results shows clearly the benefits and advantages of nonpenetrating glaucoma surgery.(6,7,8,9)

In order to avoid secondary collapse of the superficial flap, a space-maintaining implant is placed in the scleral bed. Several types of implants have been used by now. The first was the collagen Aquaflow implant (STAAR, Surgical AG Nidau Switzerland), a highly purified porcine collagen dehydrated into a cylinder. The device is sutured radially on the remaining scleral layer, as far anterior as possible to be in contact with the trabeculo-Descemet membrane. It swells rapidly when comes in contact with aqueous humor and is reabsorbed within 6 to 9 months after surgery.(1) Another type of implant is the reticulated hyaluronic acid implant (SK-GEL), a biocompatible material composed of cross linked sodium hyaluronate derived from biosynthetic process and hydrated in phosphate buffer solution. The advantage of this type of implant is that it does not need to be sutured at the sclera. More recently a hydrophilic acrylic implant (T-flux implant), a nonabsorbable type, has been developed. It has a T-shape and each arm of the implant is inserted into one of the surgically created openings of Schlemm's canal. It needs to be sutured at the sclera and it is made by poly-megma, a highly hydrophilic acrylic material. Other nonabsorbable used implants are the acrylic type made of 2-hydroxyethyl-metacrylate (HEMA) and the cross-shaped rigid one made of PMMA. The results of deep sclerectomy with collagen implant have been presented by several studies. Demailly et al reported in a retrospective study of 219 cases a mean decrease in IOP of 9,1 mmHg.(10) Shaarawy et al reported their results of deep sclerectomy with collagen implant on 105 eyes of 105 patients with primary and secondary open angle glaucoma. The mean follow-up period was 43 months. The mean preoperative IOP was 26,8 mm Hg; the mean postoperative IOP was 5 mm Hg at day 1 and 12 mm Hg at month 78. The complete success rate (IOP<21 mm Hg without medication) was 61,9% at 60 months and 57 % at 96 months. The qualified success rate was 94,8% at 60 months and 91% at 96 months.

Heala Flow is a slowly resorbable crosslinked viscoelastic gel indicated for penetrating and non-penetrating glaucoma surgery. It is made up of 22,5mg/ml crosslinked sodium hyaluronate of non-animal origin, highly purified, thus with less risk of allergy caused by animal proteins. It is a good space filling product with a long lasting effect, stabilizing the patent scleral lake and a durable filtering bled beyond its slow resorbtion. It can be applied into the scleral lake, under the scleral flap, or under the conjunctiva, preventing the adhesions between flap and sclera and between conjunctiva and episcleral tissue. Sodium hyaluronate has an anti-inflammatory and antifibrotic effect, inhibiting cytokines, cell migration, phagocytose and lymphocyte transformation. Thus, the site of surgery remains quiet.

In a retrospective multicenter study conducted in Switzerland regarding Heala Flow use in trabeculectomy, deep sclerectomy and viscocanalostomy the results showed in important IOP reduction. J. Stuermer (Winterthur) performed trabeculectomy with Heala Flow in 50 eyes and had an IOP reduction from 22.6 mm (mean IOP) Hg, to 11.2 mm Hg(at the last follow up visit), with a mean follow-up time of 28 weeks. A.Mermoud (Lausanne) performed deep sclerectomy with Heala Flow in 19 difficult cases, with a mean follow-up time of 15.6 weeks, and had an IOP reduction from 19 mm Hg (mean) to 11.2 mm Hg, at the last follow up visit. G Sunaric Megevand (Lausanne) performed 40 viscocanalostomies with Heala Flow and after a mean follow-up of 21.2 weeks there was an IOP reduction from 22.4 to 11.3 (mean values).(11)

In this study, there was a significant reduction of IOP compared with baseline. There was a 3-month-follow up period. Heala-Flow seems to be a good option for use in deep sclerectomy for long term maintenance of a low IOP, because it acts as a drainage device and limits the postoperative fibrosis. It is easy to apply, and no adverse effects of its use have been reported.

CONCLUSIONS

The use of Heala-Flow in deep sclerectomy seems to lower significantly postoperative IOP, improving the surgical success rate. Further studies including more patients with longer follow-up time are mandatory for drawing more consistent results.

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