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External trabeculectomy with T-Flux implant

S. JUNGKIM, S.K. GIBRAN, K. KHAN, A. MURRAY

Department of Ophthalmology, Cork University Hospital, Cork - Ireland

PURPOSE. *To evaluate the efficacy and safety of T-Flux implant in nonpenetrating glaucoma surgery.*

METHODS. *This clinical interventional case series study included 35 eyes of 35 patients with medically uncontrolled primary open angle glaucoma. External trabeculectomy with T-Flux (ETTF) is a technique of nonpenetrating glaucoma surgery, in which after removing deep scleral tissue and un-roofing the canal of Schlemn (CS) the external trabecular tissue is peeled off to enhance the aqueous drainage without opening the anterior chamber. A non-absorbable T-Flux implant (IOL TECH Laboratories, France) was sutured in deep intrascleral space to keep it patent. Snellen's best-corrected visual acuity, slit lamp biomicroscopy, intraocular pressure (IOP), gonioscopy, funduscopy, and optic disc assessment were performed preoperatively and postoperatively at 1 day, 1 week, and 1, 3 , 6, and 12 months. Visual field testing was performed preoperatively and at 6 and 12 months postoperatively.*

RESULTS. *For three eyes, surgery was converted to standard trabeculectomy owing to the perforation of trabeculo-Descemet's membrane and iris prolapse and excluded from the study. The results of the remaining 32 eyes were included in the study. Preoperative IOP (mean ± SD) of 32.88 ± 5.7 mmHg decreased to 15.44 ± 1.6 mmHg after 12 months. Ten eyes (28.6%) had microhyphema that resolved spontaneously; 3 eyes (8.6%) had microperforation without iris prolapse so ETTF was proceeded routinely. The preoperative number of antiglaucoma medications per patient reduced from (mean ± SD) 2.74 ± 0.61 to 0.11 ± 0.32 postoperatively at 12 months. Visual acuity and visual fields remained stable.*

CONCLUSIONS. *ETTF appears to provide significant control of IOP and have low incidence of complications. (Eur J Ophthalmol 2006; 16: 416-21)*

KEY WORDS. *External trabeculectomy, Nonpenetrating glaucoma surgery, T-Flux*

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INTRODUCTION

Nonpenetrating glaucoma surgery/deep sclerectomy is a modified form of trabeculectomy whereby reduction of intraocular pressures is achieved by removing the deep scleral tissue and outer wall of Schlemm's canal and by preserving the internal trabeculum in order to avoid the many postoperative complications associated with standard trabeculectomy (1).

External trabeculectomy or ab externo trabeculectomy is a technique of nonpenetrating glaucoma surgery, in which after removing deep scleral tissue and un-roofing the canal of Schlemm (CS) the external trabecular tissue (juxtacanalicular) is peeled off to enhance the aqueous drainage without opening the anterior chamber (2).

The T-Flux (IOL TECH Laboratories, France), made up of Poly-Megma hydrogel, is the first nonabsorbable implant used in deep sclerectomy. It is T-shaped with arm length of 4.00 mm and body height of 2.75 mm (Fig. 1). It is designed to create a permanent intrascleral space through which aqueous can drain from the anterior chamber. Because of its shape it creates an evacuating canal. A suture through its central hole helps to anchor it to sclera (Fig. 2) and is thought to stabilize the trabeculo-Descemet membrane after surgery. The properties of Poly-Megma are those of a hydrophilic polymer, which is

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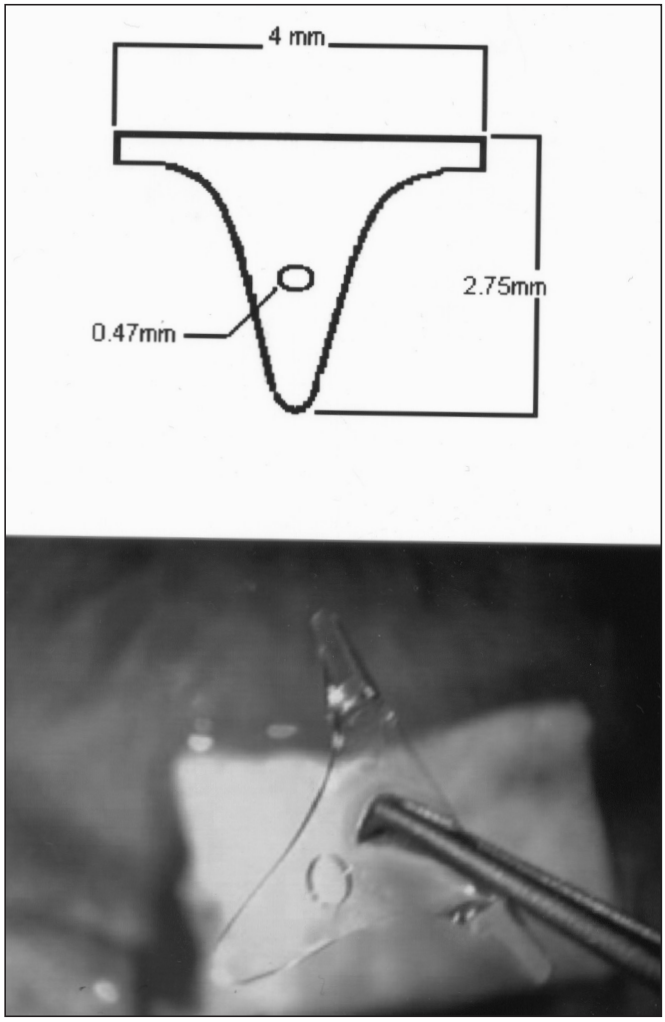

Fig. 1 - *Dimensions of T-Flux implant in mm.*

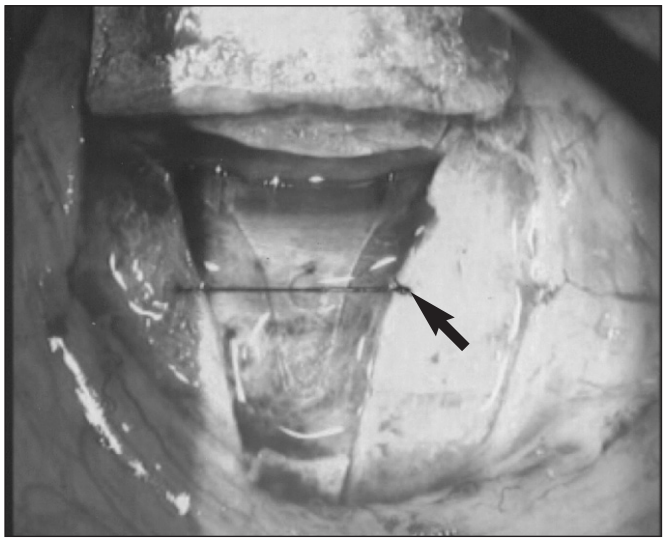

Fig. 2 - *Black suture is visible through the central hole to anchor it to sclera.*

non-degradable, biocompatible, and resistant to fibrosis (3). To date literature on T-flux implant in nonpenetrating glaucoma surgery has been insufficient. Hence we aimed to determine the success rate and complications of T-flux in external trabeculectomy.

METHODS

Thirty-five eyes in a consecutive series of 35 patients (30 male, 5 female) with medically uncontrolled primary open angle glaucoma (POAG) underwent external trabeculectomy with T-Flux implant (ETTF) over a period of 1 year (2003–2004) in our department. The mean age was 67 years. The indications for surgery by the examining surgeon (A.M.) were 1) uncontrolled intraocular pressure (IOP) defined as two successively high measurements 1 month apart with high risk of glaucoma progression, 2) worsening of visual fields, and 3) progression of glaucomatous optic neuropathy. Exclusion criteria were an unwillingness to participate, only eye, advanced lens opacities, and any previous eye surgery. After obtaining approval from the ethical committee of Cork University Hospital, the patients were enrolled in this interventional case series. Informed consent was obtained from all patients. Preoperatively all patients had an examination comprised of Snellen best-corrected visual acuity (BCVA), autorefraction, slit-lamp biomicroscopy, IOP measurement with the Goldmann tonometer, gonioscopy, visual field testing (Humphrey 32-2 program automated field analyzer), fundus examination with the indirect ophthalmoscope, and optic disc assessment with 78 D lens.

Postoperative examination included serial Snellen BC-

TABLE I - PREOPERATIVE AND POSTOPERATIVE IOP AFTER ETTF

Time	Mean IOP	p value mmHg
Preoperative	32.88	
Postoperative		
1 day	6.28	0.001
1 week	8.32	0.001
1 month	15.04	0.001
3 months	15.44	0.001
6 months	16.00	0.001
12 months	15.44	0.001

IOP = Intraocular pressure; ETTF = External trabeculectomy with T-Flux

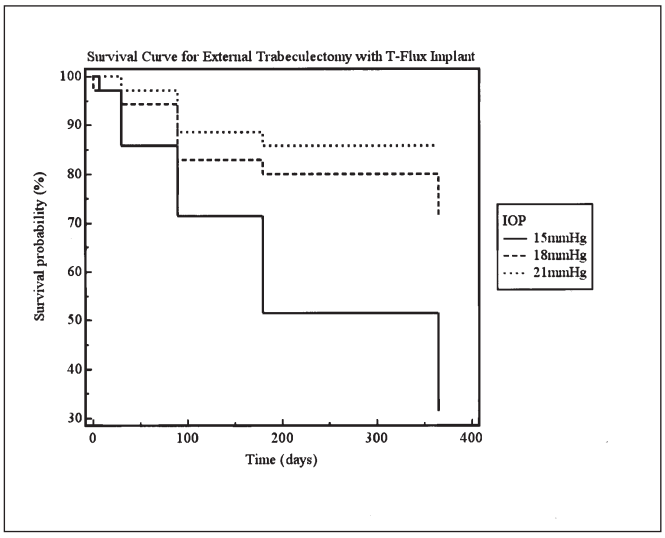

Fig. 3 - *Kaplan-Meier survival curve of external trabeculectomy with T-Flux.*

VA, autorefraction, IOP, and slit-lamp biomicroscopy and fundal examination at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months. Visual field testing using the Humphrey 32-2 program automated field analyzer was performed postoperatively at 6 and 12 months. Visual field defects were classified as early, moderate, or severe based on model of Hodapp et al (4), and progression of defects was judged according to the system of Budenz (5). All patients completed follow-up of 1 year postoperatively.

Complications considered were hyphema, hypotony, shallow/flat anterior chamber, choroidal detachment, and rapid onset of cataract.

One surgeon (S.K.G.) performed all ETTF procedures under peribulbar anesthesia.

A corneal traction suture was placed at 12 o'clock. The conjunctiva and Tenon capsule were opened in a fornix-based fashion superiorly and hemostasis was obtained with gentle wet-field cautery.

A 5x5 mm superficial one-third thickness limbal-based scleral flap was created. This flap was further dissected forward 1.0 mm into clear cornea. A deep triangular scleral flap of up to 90% thickness was then raised in the bed of original scleral flap. In order to dissect this flap, bluish choroid was visualized at the apex of the original scleral flap and the plane for dissection was selected just superficial to it. Anteriorly, the CS was un-roofed and the deep flap was advanced and excised at the corneal stroma. The external trabecular tissue was removed to enhance aqueous filtration. The location of CS was confirmed by injecting balanced salt solution into the canal with a blunt cannula (Roycroft) and observing the blanching of paralimbal conjunctival vessels. The T-Flux was inserted with its arms tucked in CS and sutured to sclera with one 10/0 nylon suture. The superficial scleral flap and conjunctiva were closed loosely over the T-Flux with 10/0 nylon sutures.

Three of 24 eyes were excluded from the study for the following reasons:

In Patient 1, a 31-year-old man with POAG, intraoperative failure to identify the CS led to trabeculo-Descemet perforation with iris prolapse and surgery was converted to conventional trabeculectomy with basal iridectomy.

In Patient 2, a 45-year-old man with POAG, no aqueous was observed to be percolating intraoperatively despite the removal of external trabecular tissue and the procedure was therefore converted to conventional trabeculectomy.

In Patient 3, a 70-year-old woman with POAG, on the first postoperative day after routine ETTF the eye was massaged with resultant iris prolapse. The patient was returned to the operating theater and surgery was converted to conventional trabeculectomy.

Postoperatively, all patients were treated with topical combination of dexamethasone 0.1%, neomycin sulphate 0.35%, hypromellose 0.5%, and polymyxin B sulphate 6000 IU/mL four times a day for 1 month, then three times a day for the second month and twice a day for the third month. Antimetabolites were not employed peroperatively or postoperatively. We used the following two strict criteria for successful IOP control:

Complete success: IOP <21 mmHg and 30% or greater reduction from preoperative baseline without antiglaucoma medications

Partial success: IOP <21 mmHg and 30% or greater reduction from preoperative baseline with one antiglaucoma medication

When a patient did not meet the above criteria at two consecutive visits, it was considered as a failure. Statistical analysis was performed by paired Student t-test and survival analysis was demonstrated using a Kaplan-Meier curve (Fig. 3).

RESULTS

Preoperative IOP (mean ± SD) of 32.88 ± 5.7 mmHg was observed to decrease significantly to 15.44 ± 2.1 mmHg over a follow-up period of 1 year. The difference between the preoperative IOP and the IOP at each postoperative visit was statistically significant (Tab. I).

The preoperative number of antiglaucoma medications (mean ± SD) per patient was 2.74 ± 0.61 as compared to 0.11 ± 0.32 postoperatively at 12 months (p=0.0001).

The BCVA was 0.39 ± 0.07 (mean ± SD) preoperatively and 0.41 ± 0.07 12 months postoperatively. The difference (p=0.257) was not statistically significant. Autorefractometric analysis revealed that T-Flux implantation did not induce clinically treatable refractive change. Visual fields remained stable over the follow-up of 12 months.

Eight eyes (25%, 8 of 32 eyes) in which the IOP reduction after 3 months postoperatively was considered insufficient underwent Yag laser goniopuncture. However, this intervention failed to control the IOP in 6 (75%, 6 of 8 eyes) patients and topical antiglaucoma medications were started. In two of these patients despite topical medications IOP remained uncontrolled and they underwent standard trabeculectomy.

There were few complications associated with surgery. Three eyes (8.5%) had microperforations with no iris prolapse so ETTF proceeded routinely. Ten eyes (28.5%) had microhyphema that resolved spontaneously.

There were no cases of hypotony, excessive postoperative uveitis, or choroidal detachment. No postoperative complications of the type that might occur after standard trabeculectomy were encountered.

DISCUSSION

The decision to perform surgery in patients with glaucoma represents a key point in the long-term management of the disease. The indication has been expressed as "A patient with glaucoma on maximum tolerated medical therapy who has had maximal laser benefit and whose optic nerve function is failing or likely to fail" (6).

Nonpenetrating filtration procedures are alternatives to trabeculectomy with the advantage of a lower risk of postoperative complications. They preclude the sudden hypotony and its complications (7-10) that occur after trabeculectomy by creating progressive filtration of aqueous humor from the anterior chamber to the subconjunctival space without perforating the eye.

The concept of nonpenetrating glaucoma surgery was initially conceived in the 1950s by Epstein (11), who noticed oozing of aqueous humor at the paralimbal sclera when dissecting a deep seated pterygium. He then performed deep sclerotomies at the paralimbal area overlying Schlemn's canal and achieved a short term lowering of IOP before scarring of the conjunctiva occurred.

External trabeculectomy can be defined as a technique of nonpenetrating glaucoma surgery, in which after removing deep scleral tissue and un-roofing the CS the external trabecular tissue (juxtacanalicular) is peeled off to eliminate the site of highest resistance to aqueous outflow in the juxtacanalicular trabecular meshwork to enhance the aqueous drainage without opening the anterior chamber. To prevent the inevitable late stage fibrosis of interscleral space many materials like collagen (12), Healon (13), and reticulated hyaluronic acid pieces (14) have been employed with varying success. Chiou et al (15) performed ultrasound biomicroscopy in patients who had undergone deep sclerotomy and collagen implantation. Their findings were consistent with IOP lowering by aqueous filtration through the thin remaining trabeculo-Descemet membrane to an area under the scleral flap, which was hypothetically kept open by the implant. The authors stated that the implant dissolved slowly, within 6 to 9 months, and was replaced by new autologous scleral tissues; a tunnel was left. Sanchez et al (16) compared the effectiveness of deep sclerectomy with and without a collagen implant and concluded that the implant increased the success rate. In contrast, Demailly et al (17) stated that a collagen device did not seem to improve the medium-term tonometric results. Although implants seem to have a role in enhancing filtration, their results are widely conflicting. Because of their absorbable nature these implants tend to lose their efficacy in the long term.

Theoretically, placing a non-absorbable implant could create a permanent intrascleral space by preventing adhesion between the scleral flap and the scleral bed. As a non-absorbable hydrophilic material the T-Flux has obvious advantages as an intrascleral stent. It may have a dual action by keeping the deep scleral space patent and work as a decompression chamber for the aqueous humor.

Dahan et al[1] reported that the IOP dropped 50% from an average preoperative value of 23.47 mmHg with 2.8 antiglaucoma medications to 11.78 mmHg without any medication, after nonpenetrating glaucoma surgery and T-Flux implantation. In our series the mean IOP was signifi-

[1] Dahan E, Raviner E, Mermoud A. Non-penetrating glaucoma surgery with and without the T-Flux non-absorbable hydrophilic implant; 1997-2000. First International Congress on Non-Penetrating Glaucoma Surgery; February 1–2, 2001; Lausanne, Switzerland.

cantly lower throughout the follow-up period compared with the preoperative levels, and the mean reduction from the preoperative levels was 46.95% at 12 months postoperatively. Our rate of complete success (IOP <21 mmHg without medication) and partial success (IOP <21 mmHg with medication) was 82.25% and 94.28%, respectively, at 12 months postoperatively. However, we also noted that the mean IOP tended to increase during the study. This tendency must be followed up closely over the long term.

Mermoud et al (18) reported that 41% of 100 eyes had to undergo Nd:YAG laser goniopuncture after deep sclerectomy and collagen implantation. The success rate of the secondary procedure was 83% at the end of 2 years. Hamard et al (19) determined that goniopuncture had to be performed in more than one third of cases after deep sclerectomy and collagen implantation; it was affective in controlling the IOP in half the cases. In our series of patients, we had to perform Nd:YAG laser goniopuncture in 8 eyes (25%, 8 of 32 eyes). As the IOP did not decrease to acceptable levels thereafter, 6 patients (75%, 6 of 8 eyes) were started on topical antiglaucoma medication, and 2 of these patients underwent trabeculectomy.

Glaucoma filtration surgery can result in loss of visual acuity through an increase in lens opacification, maculopathy due to hypotonia, and "wipeout" (20). However, after deep sclerectomy it is uncommon to have a change in visual acuity (21). Overall our study showed that visual acuity over the postoperative period of 12 months remained stable. The development of cataract was not observed. Because of the short-term follow-up it is difficult to establish the fact but equally there is no reason to believe that incidence of cataract is higher with ETTF.

In this study the main complication observed was microhyphema in 28.5% of cases (10 of 35 eyes). Microhyphema was recorded more frequently in our early cases. We believe it is due to bleeding from the anterior perforating vessels during the dissection of scleral flaps, perhaps causing retrograde flow in AC. Wet field cautery was found to be generally unsuccessful to occlude these vessels so sodium hyaluronate (Healon) was injected in the vessel for hemostasis and that reduced the incidence of postoperative hyphema. Microperforation was experienced in 8.5% of cases (3 of 35 eyes), but in the absence of iris prolapse ETTF was proceeded routinely. These cases followed the same postoperative course as other cases.

In this study a significant drop of IOP and number of antiglaucoma medications with few peroperative and postoperative complications was observed. It is clear that deep sclerectomy with a nonabsorbable implant has some disadvantages. The procedure is more technically challenging as deep scleral dissection is performed under high microscopic magnification and therefore necessitates a long learning curve. Also, the cost of the implant is a major problem but comparing the cost of glaucoma medications it might prove cost effective in the long run.

To prove the efficacy of T-Flux in different categories of patients with glaucoma, controlled prospective studies comparing this technique with other nonpenetrating filtration procedures and standard trabeculectomy are necessary.

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Reprint requests to:
S. Jungkim, MD
Department of Ophthalmology
Cork University Hospital
Cork, Ireland
sjungkim@hotmail.com

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