"To assess the efficacy & safety of Trans-ciliary Filtration(TCF) by Fugo Plasma Blade for un-controlled Glaucoma"

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ABSTRACT

Purpose: *To find out how effective and safe Trans-ciliary Filtration with a Fugo-Plasma Blade is in providing a long term IOP control in different varieties of Glaucoma.*

Material and Methods: *A prospective interventional study was conducted at a tertiary care centre from Jan 2013 till July 2015. Trans-ciliary Filtration by Fugo Plasma Blade was performed by a single surgeon (SI) on 52 consecutive eyes from age 6 months to 55 years. All cases were referred because IOP was uncontrolled on triple anti-glaucoma medication .The mean follow-up after TCF was 1 year.*

Results: *In 48 eyes, IOP remained below 15 mm without the addition of any anti-glaucoma medication up to 1 year follow-up. This was a success rate of 80.76%. In 2 eyes with neovascular glaucoma, the bleb failed due to neo-vascularization and Cycle-Cryotherapy had to be performed. In 2 eyes with Buphthalmos, the IOP gradually crept up to 22 mm and they needed the addition of topical beta blocker drug.*

Conclusion: *TCF performed with the Fugo Plasma blade is a safe procedure with minimal complications, easy to learn and master and offers efficient long-term IOP control in various types of glaucoma except the neo-vascular.*

Key words: *Trans-ciliary Filtration, Glaucoma surgery, Trabeculectomy, Fugo-plasma Blade, Conjunctival lymphatics.*

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INTRODUCTION

Glaucoma is a major cause of blindness worldwide and the search for a perfect solution that would offer a long-term control continues. Newer medications and surgical techniques to lower the intra-ocular pressure (IOP) continue to be added to the armamentarium. For decades, the view prevailed that aqueous drains out from the eye via an anterior route involving the trabecular meshwork at the angle of the eye, into the Schlemm's canal and then via collector channels, out of the sclera into the subconjunctival space where it drains by diffusion. The posterior route, called the uveo-scleral outflow, has not been studied and described as concretely, the aqueous draining via diffusion into the suprachoroidal space via pores in the permeable sclera and then passes out to the orbit.

Lymphatic networks in the cornea, conjunctiva and sclera were discovered by Singh[1,2,3]. A network of corneal channels drain into a circular sinusoidal channel at the limbus, called the Lucid Interval or the Sinusoid of Singh, which is a large circular channel located anterolateral to the Schlemm's canal; this, in turn, drains into 30-40 channels at the limbus which lead to the limbal conjunctival lymphatics. It is now confirmed that about 50% of aqueous drainage is via this route. The uveoscleral outflow, which was previously assumed to be via diffusion or perforating channels out of the sclera, is now confirmed by Singh that these perforating channels are in fact lymphatics at the level of sclera, episclera and conjunctiva, all freely communicating with each other.

After the discovery of conjunctival lymphatics, it made sense to assume that any surgical technique which utilises cutting incisions and coagulation of tissues will damage these lymphatics, thereby creating areas of scarring and is liable to fail. To preserve these lymphatic networks, the need to devise a minimally invasive glaucoma surgical procedure arose. In 1989, Fugo plasma blade (Medisurg, Norristown, Pa) was invented by Richard Fugo[4,5], an ophthalmologist as well as a nuclear physicist. It was a solid state electronic system that operated on four rechargeable batteries. It focussed electromagnetic energy to a blunt metal tip and produced sufficient plasma field which would cut tissue not like a knife but ablated or erased tissue into a mist of water vapours producing a pristine incision. Since the cut tissue vaporised, there was a minimal necrotic debris, less tissue inflammation and the incision healed without scarring. At the same time, the plasma energy stimulated coagulation cascade and activation of platelets which secrete adrenaline and constricted blood vessels in the cut area. Hence a non-cauterizinghomeo-stasis was produced along the incision line, which became blood-less. Its workingwas analogous to an excimer laser. The blade was approved by the FDA, USA for capsulotomy, iridotomy, TCF and oculoplastic surgery in 2004.

Hence, a minimally invasive glaucoma surgery utilising the Fugo Plasma blade was

developed by Singh[6-7] in 1999. In this technique, a micro-tract, 200 microns diameter, was used to drain either the anterior or the posterior chamber of the eye into the sub-conjunctival space, and out via the undamaged conjunctival lymphatics. Tran-sciliary filtration (Singh's Filtration) was considered a revolutionary alternative to trabeculectomy, which is still considered the gold standard glaucoma surgery. The procedure was approved by FDA in 2004[8]. We conducted this study to find out the long-term efficacy of Trans-ciliary filtration in draining the aqueous out of the eye, hence maintaining an IOP around 15 mm and preventing glaucoma progression in both children and adults.

MATERIALS & METHOD

This is a prospective, interventional study performed at Mughal Eye Trust Hospital, Lahore, Pakistan, (a tertiary referral centre) from Jan 2013 till July 2015. In this, 35 consecutive cases (52 eyes) referred for advanced glaucoma which was uncontrolled on triple anti-glaucoma medication were included. They included 12 cases of bilateral congenital glaucoma(Buphthalmos) from age 6 months - 10 yrs (24 eyes), 11 young adults from age 12 - 25 years (22 eyes) with steroid-induced glaucoma in 18 eyes and juvenile glaucoma in 4 eyes and 12 adults from age 40 - 55 years (16 eyes, only 4 cases had a bilateral glaucoma) with Chronic open angle glaucoma (COAG) in 10 eyes, chronic angle closure glaucoma in 4 eyes and neovascular glaucoma (NVG) in 2 eyes, as shown in Table 1. After a thorough history and ophthalmic examination, including best corrected visual acuity, IOP measurement, fundoscopy and Gonioscopy, Visual field testing and OCT were performed in all adults and co-operative children. 41 cases (78.84%), already had failed glaucoma surgery (trabeculectomy) performed elsewhere. In all cases, the topical anti-glaucoma medication as well as the oral acetazolamide were continued till the day of surgery except Latanoprost which was stopped in all cases at least 1 week prior to surgery. Any adult patient on blood thinning medication like aspirin was stopped 1 week prior to surgery. TCF by Fugo Plasma Blade was performed by a single surgeon (SI).

All patients were followed up meticulously on the first and third post-op day, then weekly for a month and then two monthly for 2 years. At each visit, their visual acuity and IOP were recorded; slit-lamp examination was performed by the surgeon to note the state of the draining bleb, Seidel's test to note bleb-leakage, status of the cornea, anterior chamber depth and any intraocular inflammation, fundus examination to note choroidal effusion and status of the optic disc. They were given a combination of mild steroid-antibiotic eyedrops 4 times a day for two weeks and NSAID eyedrops for a month which were tapered and stopped after further two weeks.

Method:

In children, the procedure was performed under general anesthesia while in adults, a retrobulbar block was given. In all cases, the exact attachment of ciliary body was marked at the start of procedure by a fibre-optic light. This was placed at the anatomical limbus at 9'o clock, and with the light of microscope turned off, trans-illumination seen through the thinned sclera of the limbus till the true attachment of the ciliary body was marked as an indentation with a pair of blunt forceps, as the intended site for a sclerostomy to be made later after retracting the conjunctiva. A traction suture with 4/0 silk was passed at 3 and 9'o clock at the limbus to retract the eyeball downwards. A 3 mm incision was made in the conjunctiva of the upper fornix with the Fugo Blade 100 micrometer tip, 6-8 mm from the marked site for the sclerostomy. The conjunctiva was held by the assistant with a pair of non-tooth forceps while the surgeon excised the tenon overlying the site for sclerostomy with the Fugo blade. Any bleeders at that site were ablated with the Fugo Blade.

A rectangular sclerostomy, parallel to the limbus and 1 x 4 mm was made with a 200 micron Fugo Blade tip at the marked site as shown in Fig 1. Any blood vessels encountered in that area were closed with the Fugo blade. A hole was made into the ciliary body through the sclerostomy with the 200 micron tip till the aqueous was seen to seep freely through the hole into the sclerostomy. Any bleeding from the ciliary body was controlled by water gently sprinkled at that site with a cannula or a sponge soaked in adrenaline placed for a minute. This stopped the bleeding.The conjunctiva was closed with a running 7/0 vicryl suture. The bleb was noticed to form immediately intra-operatively as soon as the conjunctiva was closed as seen in Fig 2 and 3.Then, 0.5 cc of Mitomycin C (0.02%) was injected with a blunt cannula into the sub-conjunctival space, before tying the final knot of the conjunctival suture. A sub-conjunctival injection of dexamethasone + gentamicin was given in the lower fornix. An eye pad was lightly placed on the eye for 24 hours.

RESULTS

When the dressing was removed on the first post-operative day (Table 2), all eyes remained white and showed a minimal reaction in the anterior chamber only in 4 eyes; in the remaining 48 eyes, the anterior chamber remained quiet. A mild hyphaema was seen in 2 earlier cases which cleared up in 4 days. In all remaining eyes, it was not seen as the blood vessels were meticulously coagulated with Fugo blade intra-operatively. Anterior chamber was deep in all except 5 eyes, where it was well-formed

but shallow due to an over-draining bleb though no bleb leakage was noted (Seidel negative). On the third post-operative day, choroidal detachment was detected in these 5 eyes. Hence they were managed with a pressure dressing for 48 hours and a bandage contact lens later for the next one week. The choroidal detachment gradually settled.

No bleb leakage or post-operative bleb infection was noted in any case. Cystic blebs were formed in 15 eyes (Fig 4) but their IOPs remained at 12-15 mm. Out of the 52 eyes, the procedure failed in 2 cases with end stage neovascular glaucoma. In these adults, neo-vessels grew over the sclerostomy and blocked it. Hence to control the IOP, cyclo-cryotherapy was performed one month after the initial TCF. In 2 children with bilateral buphthalmos, IOP was controlled in one eye but in the other, sclerostomy site got gradually partially closed and IOP crept up to 22 mm which was controlled with topical beta-blockers. This was still regarded as a partial success as they were on triple AGT pre-operatively with the IOP of 34 mm prior to TCF. In the remaining 48 eyes, the IOP remained below 15 mm without any AGT on 1 year follow up. This was considered as a success rate of 96%.

The visual acuity (Table 3) improved from hand movements to counting fingers in 11 eyes with buphthalmos and opaque corneas pre-operatively. In children with clear corneas, it improved from HM to 6/24 in 13 eyes. In the young adult group, the 5 eyes that had developed choroidal effusion, IOP gradually stabilized at 10-12 mm and visual acuity gradually improved from counting fingers to 6/9. In 2 adult cases with neovascular glaucoma, VA reduced from hand movements to NPL due to TCF failure and uncontrolled IOP. In the same group, 2 cases with pre-operative advanced glaucoma and a cup: optic disc ratio of 0.9, visual acuity reduced from 6/60 to NPL. In the remaining 24 eyes, VA remained stable during the one year follow up period.

Table1: Age of Patients and the type of Glaucoma

Age	No of cases	No of Eyes	Type of Glaucoma
6 months-10yrs	**12**	**24**	Buphthalmos
12 - 25 yrs	**11**	**22**	Steroid Induced=18 eyes Juvenile Glaucoma= 4 eyes
40 - 55 yrs	**12**	**16**	COAG = 10 eyes Chronic Angle Closure= 4 eyes Neo-vascular= 2 eyes
Total	**35 cases**	**52 eyes**	

Table 2: Post-operative result following TCF

Parameters	1 wk	1 month	6 months	1 year
IOP	< 10mm in all cases	<15 in 48 eyes >15 in 4 eyes	<15 in 50 eyes, in 2 needed AGT	<15 in 50 eyes, (96%)
Corneal edema	nil	2 eyes with NVG	nil	nil
AC Depth	Shallow in 5 eyes	deep in all eyes	deep	deep
AC Reaction	+ in 4 eyes	nil	nil	nil
Hyphema	2 cases, mild	nil	nil	nil
Cystic Bleb	nil			
Over-draining Bleb	5 eyes, (9.6%)	nil	nil	nil
Bleb Leakage	nil	nil	nil	nil
Choroidal Effusion	5 eyes, (9.6%)	nil	nil	nil
Hypotony	5 eyes, (9.6%)	nil	nil	nil
C:D ratio	no view in 11, reduced in 5, same in 36 eyes	no view in 11, same in 41 eyes	no view in 11, same in 41 eyes	no view in 11, same in 41 eyes
Need for AGT	nil	4 cases	2 cases	2 cases, (3.8%)

Parameters	1 wk	1 month	6 months	1 year
Further Need for surgery	nil	cyclocryo 2 cases, (3.8%)	nil	nil

Table 3: Comparison of Pre and Post-op Visual Acuity

Pre-op	Post-op			
Visual Acuity	1 wk	1 month	6 months	1 year
NPL	n= 0	n= 4 eyes (NVG+ end stage COAG)	n= 4	n= 4
HM, n= 26 eyes	n= 26			
FC		n= 24 eyes	n= 11	n= 11
6/24			n= 13	n= 13
6/9, n=26 eyes		n= 24 eyes	n= 24	n= 24

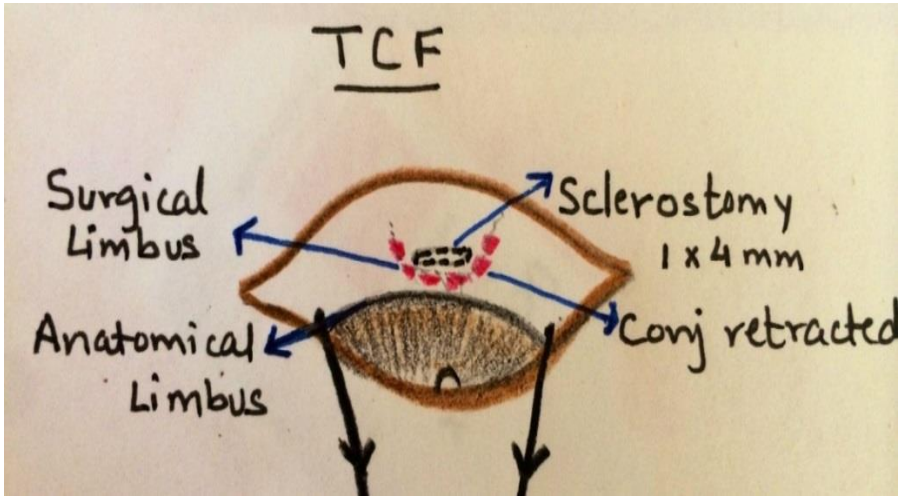

Fig 1: A diagrammatic representation of the sclerostomy site

Fig 2: A 5 years old girl with Buphthalmos, had bilateral failed Trabeculectomies, on triple AGT, still raised IOPs

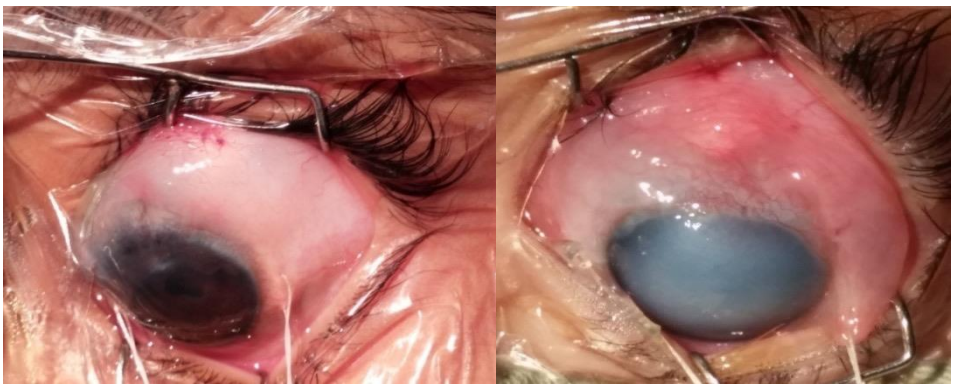

Fig 3: Bilateral TCF performed at the same time; blebs form as aqueous starts draining intra-op. In the left eye, the limbus has extended far backwards due to constantly raised IOP so site of TCF is also far back towards the fornix

Fig 4: 1 year post-op pic following a bilateral TCF in 40 years old patient showing cystic blebs

DISCUSSION

In the original procedure of Transciliary Filtration described by Singh[7-11], the posterior edge of the surgical limbus lying over the anterior corneo-scleral trabeculae was noted. A point1.5 mm posterior to it was marked with the blunt tip of a forceps at the level of pars plicata of the ciliary body. A 300 micron or 500 micron Fugo blade tip was chosen to be used at high power and intensity. The conjunctiva was pushed towards the limbus with a blunt sapphire knife till it reached the marked point on the sclera. The activated Fugo blade was passed through the conjunctiva, the sclera and the ciliary body to reach the posterior chamber till aqueous was seen draining. 0.1 ml to 0.2 ml of Mitomycin C (MMC) 0.02% was deposited under the conjunctiva and the conjunctival opening was sutured. Hence the whole procedure was performed in a single step and tenon overlying the scleral opening was not dissected. This small opening was found to close by either hematoma or proliferation of tenon.

In this study, we decided to modify the technique: the tenon was dissected overlying the intended sclerostomy, a large rectangular sclerostomy was made parallel to the limbus i.e.1 x 4 mm long instead of only 200-500 microns, all blood vessels in the area were ablated to make it a blood-less field and avoid hematoma blocking or closing the hole into the ciliary body. This was also noted in the study by Dow et al[12] who performed TCF in 200 eyes using the Fugo blade and achieved an 85% success. They found out that a 200 - 500 micron sclerostomy closed after some time while a larger sclerostomy remained patent. Mitomycin C was instilled into the sub-conjunctival space in all cases as they were on anti-glaucoma therapy for years which is known to promote fibroblastic activity. Also 78.8% of our cases already had a failed trabeculectomy. In paediatric and juvenile glaucoma, the tenon is known to be highly reactive and proliferates resulting in blocking of a track draining the aqueous. Hence tenon overlying the sclerostomy was meticulously excised with the Fugo Blade.

The hole into the ciliary body has to be made with the Fugo blade tip directed downwards; an anteriorly misdirected track might open into the anterior chamber while posterior misdirection of the Fugo blade tip can result in vitreous show/prolapse. The aqueous flows outwards through the tract which extends from the posterior chamber of the eye, through the hole in the ciliary body and the sclerostomy into the sub-conjunctival space. The aqueous then drains via the conjunctival lymphatic network thus lowering the intraocular pressure (IOP). As the flow of aqueous is directed outwards from the posterior chamber into the sub-conjunctival space,

the flattening of anterior chamber of the eye is prevented by the backward movement of iris-lens diaphragm due to a lower IOP in the posterior chamber and reduced force vectors at the back of the iris. Hence anterior chamber shallowing or flattening is avoided though it is usually encountered in the conventional trabeculectomy.

In uncontrolled congenital or Juvenile glaucoma, the scleral coat is stretched due to a constantly raised IOP and the attachment of ciliary body is pushed far backwards from the anatomical limbus. Hence it is very important to mark the exact site of the ciliary body which was done in all our cases by transillumination with a fibre-optic light. By this modification, accidental vitreous tap or prolapse was avoided in all cases.

Since no iridectomy was performed and there was minimal tissue trauma, hence a minimal inflammatory reaction or hyphema was noticed post-operatively in all cases. This is in contrast to a conventional trabeculectomy where hyphema is a common problem as well as marked inflammation post-operatively even in best surgical hands. This was similar to the study conducted by Thomas Dow[12] ·As in our study, the eyes remained quiet post-operatively in all his cases and the vision stabilised in a week or two. Similarly, Atwal[13] claimed a success of 92% with TCF performed in 300 cases as compared to 70% with standard trabeculectomy. He also did not have any shallowing of the anterior chamber or hyphema in any case of TCF.

We injected 0.5 cc mitomycin C (0.02%) into the sub-conjunctival space in all eyes at the end of surgery. This was done because they all had advanced glaucoma; they all had been treated with triple anti-glaucoma medication and more than 50% cases had failed glaucoma surgery performed elsewhere. We did have cystic blebs in 15 adults but no bleb leakage was seen in any case. Mitomycin can be avoided in virgin eyes in which no glaucoma surgery has been performed and in whom IOP is not being controlled by one anti-glaucoma drug only.

Post-operative hypotony was seen in 5 cases (9.6%) due to over-draining bleb and it lasted one month post-operatively. Choroidal detachment was seen in these 5 eyes which got settled in 3 eyes spontaneously in one week post-operatively. Only in two eyes (3.8%), it persisted and was managed with pressure dressing of the eye for two days followed by wearing a bandage contact lens for a week. Both these cases were high myopes. After one month post-operatively, their vision stabilised to the pre-operative level. Both these cases developed cystic blebs but bleb leakage was not seen in any case as confirmed by a negative Seidel's test at each follow-up visit. No bleb infection was seen in any case either. TCF was not repeated in any case.

As regards visual acuity shown in Table 3, 11 eyes with buphthalmos had opaque corneas. Even in these cases, vision improved from PL only or Hand Movements to Finger Counting at 2 feet. The 3 infants started following and fixing light while 8 children were able to recognize colours and walk without feeling their way. 2 adults with neovascular glaucoma and Hand Movement vision, became NPL one month post-operatively. 2 adult cases with fully cupped discs (end-stage COAG) band Hand Movement vision, also became NPL due to washing out of visual fields by post-operative hypotony. VA remained stable to the pre-operative level in 24 eyes (46%) while it improved single line in 13 eyes (25%). Hence overall visual improvement was seen in (11+24+13=48 eyes) 92%. This was similar to a study conducted by Kent[14].

Our two cases of neovascular glaucoma failed because of re-growth of fibrovascular tissue into and over the sclerostomy. They were the only cases in which TCF had failed (3.8%). This was also seen in the study by Atwal et al[13] though Singh had recommended TCF for neovascular glaucoma. In our 2 cases of buphthalmos, who already had failed trabeculectomy, the IOP gradually crept up to 22 mm instead of the initial 45 mm prior to performing TCF, despite triple anti-glaucoma medication. Hence they were assumed to be a partial success. Our overall success of keeping the IOP below 15 mm after one year follow-up was found to be 96%.

CONCLUSION

Since the discovery of conjunctival lymphatics as the major draining conduits for aqueous, any surgical procedure that prevents or spares them should work. Hence TCF performed by Fugo Plasma blade is found to be a safe and a very simple surgical technique whichefficiently controls IOP in all types of glaucoma except the neo-vascular variety. It is very easy to learn and master and is associated with excellent long term results with minimal post-operative complications.Although no large trials comparing trabeculectomy to TCF have yet been published, surgeons who have extensive experience with TCF believe it has significant advantages over trabeculectomy, the current gold standard surgery.

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