

Dissertation on

**A CLINICAL STUDY ON THE OUTCOME
OF MEHTA VALVE IMPLANT**

Submitted in partial fulfillment for

**M.S. OPHTHALMOLOGY
BRANCH - III**

**Regional Institute of Ophthalmology
Madras Medical College & Research Institute,
Chennai – 600 003**



**THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY
CHENNAI – 600 003**

TAMIL NADU

MARCH 2009

CERTIFICATE

This is to certify that **Dr.V.Sharmila Devi**, Post Graduate student in ophthalmology, Regional Institute of Ophthalmology, Government Ophthalmic Hospital, attached to Madras Medical College, Chennai, carried out this Dissertation titled, **A CLINICAL STUDY ON THE OUTCOME OF MEHTA VALVE IMPLANT** by herself under my guidance and direct supervision, during the period April 2006–March 2009. This dissertation is submitted to the **Tamil Nadu Dr. MGR Medical University, Chennai** in partial fulfillment of the award of **M.S Degree in Ophthalmology**.

Prof.Dr.M.S.Rajarathinam, M.S., D.O.,
Chief, Glaucoma Clinic
Regional Institute of Ophthalmology
Govt. Ophthalmic Hospital
Egmore, Chennai - 600 008

Prof.M.Radhakrishnan M.S.,D.O.,
Director and Superintendent,
Regional Institute of Ophthalmology,
Govt. Ophthalmic Hospital,
Egmore, Chennai - 600 008

Prof.T.P.Kalaniti, M.D.,
Dean, Madras Medical College &
Government General Hospital,
Chennai - 600003

ACKNOWLEDGEMENT

My sincere thanks and gratitude to **Prof. Dr. T.P. Kalaniti, M.D.**, Dean, Madras Medical College for permitting me to utilize the clinical material of this hospital.

I express my sincere thanks to **Prof. Dr. M. Radha Krishnan, M.S., D.O.**, Director RIO GOH Madras Medical College Chennai, for his Valuable guidance and constant support at every stage.

I have great pleasure in thanking my teacher **Prof. Dr. V. Velayutham M.S., D.O.**, Retired Director & Superintendent & Chief Glaucoma clinic. With his vast experience he has guided me throughout the study and made the completion of the study a reality.

I am extremely grateful to Glaucoma clinic Chiefs' **Prof. Dr. M.S. Rajarathinam M.S.**, & **Prof. Dr. K. Maragatham, M.S., D.O.**, for their guidance and support.

I wish to thank **Dr. N. Jayanthi, M.S., D.O.**, **Dr. Rajini, M.S.**, **Dr. N. Sharmila, M.S.**, **Dr. R. Muthiah, M.S.**, for their unwavering support.

I am thankful to all the professors and assistant professors who have guided me.

I am also grateful to all my patients, without whose cooperation this study would not have been possible.

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INTRODUCTION

Glaucoma drainage devices are important tools in the management of Refractory glaucomas. It was introduced by Molteno in 1969 to treat Refractory glaucomas. They were referred to as Setons previously because solid structures with shaft such as threads, wires or hairs were placed in the wound to form a patent drainage fistula.

Newer drainage devices use tubes that drain aqueous out of the eye in to posteriorly placed external reservoirs. The GDD differ according to size, shape & materials from which the external component & the tube are constructed.

However one of the most important fundamental design difference is whether the device has an open unobstructed drainage tube or one that contains a pressure regulating valve. Baerveldt, Molteno & Schocket are examples of open tube implants. Ahmed, krupin & Mehta have a flow restricting valve mechanism.

In this study we describe the outcome of Mehta valve implant in 25 cases of Refractory glaucoma.

AQUEOUS HUMOR

Aqueous humor is secreted by the nonpigmented ciliary processes. It is derived from the plasma within the capillary network of the ciliary process.

MECHANISM OF AQUEOUS HUMOR FORMATION

1. Active transport secretion: - 70%

An energy dependent process that selectively moves a substance against its electrochemical gradient across the cell membrane. Transports water soluble substances by Na^+ k^+ ATPase pump. Site of active transport is considered to be the nonpigmented epithelial cells.

2. Ultrafiltration

It is the movement of substance along a pressure gradient. Colloid osmotic pressure of tissue spaces is high. So it favours movement of water from the plasma in to the ciliary stroma.

3. Diffusion

It is the energy independent movement of substances across the membrane of ciliary epithelium along its concentration gradient.

AQUEOUS HUMOR OUTFLOW AND ANATOMY OF ANTERIOR CHAMBER ANGLE STRUCTURES

AQUEOUS HUMOR OUTFLOW

The ciliary epithelium produces the aqueous humor which enters the posterior chamber, passes through the pupil into the anterior chamber and leaves the eye by two main routes:

(a) **Conventional or canalicular system**-accounts for 83% to 90% of aqueous outflow. It consists of the following:

1. Trabecular meshwork
2. Schlemm's Canal
3. Intrasceral or collector channels and
4. Episcleral and conjunctival veins

(b) **Unconventional or uveoscleral and uveo-vortex system**-Accounts for 5- 15% of aqueous outflow.

ANATOMY OF THE ANGLE STRUCTURES

1. **Scleral spur** - On gonioscopy it appears as thin prominent white line that is the posterior portion of the scleral sulcus. It may be obscured from view by dense uveal meshwork. It represents the location for attachment of the corneoscleral meshwork anteriorly and the ciliary body (longitudinal muscle) posteriorly.

2. **Trabecular Meshwork** — It is a sieve like structure in the angle of the anterior chamber which converts the scleral sulcus into a circular channel called schlemm's canal and is divided into three portions.
 - (a) **Uveal meshwork** - It is the innermost portion arranged in rope — like trabeculae that extend from iris root to the schwalbe's line. The intertrabecular spaces are relatively large and offer little resistance to the passage of aqueous (25 —75 mic m openings).
 - (b) **Corneoscleral mesh work** — It forms the middle portion which extends from the scleral spur to Schwalbe's line and consists of trabecular sheets perforated by elliptical openings (5-50 mic. m in diameter)

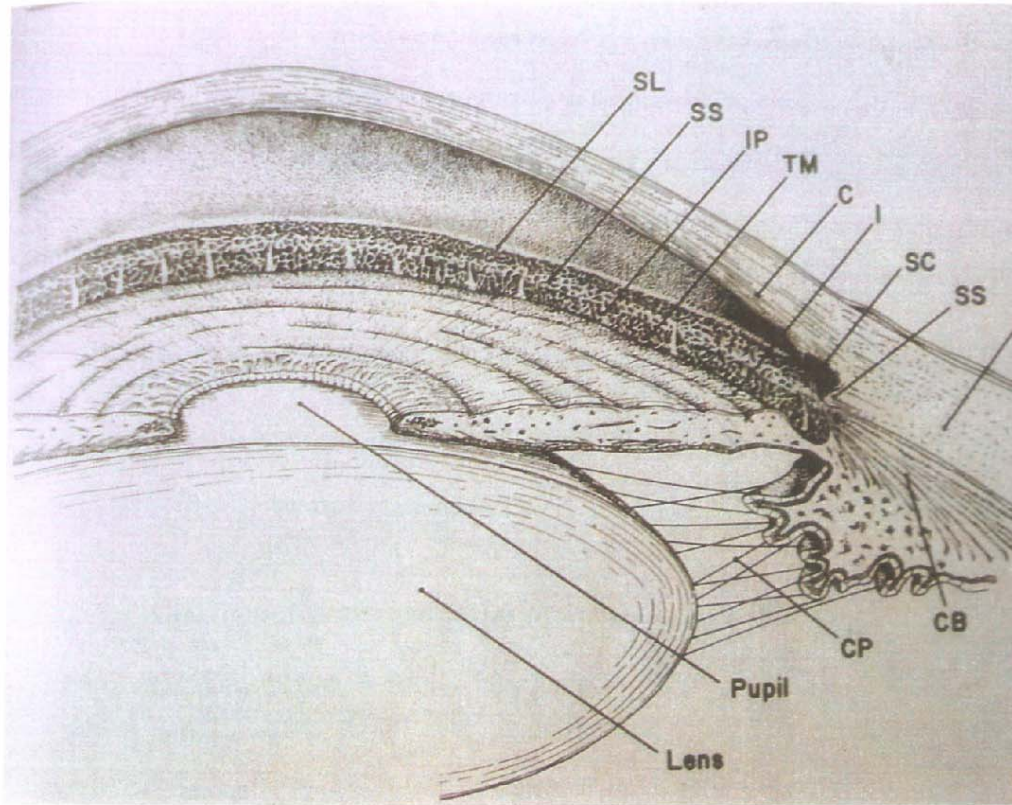
 - (c) **Juxta Canalicular tissue** — It is the outermost portion which consists of connective tissue lined on either side by endothelium. Outer layer comprises the innerwall of Schlemm's Canal, while inner layer is continuous with the remainder of the trabecular

endothelium. It offers the major proportion of resistance to aqueous outflow.

Gonioscopically, the trabecular meshwork consists of the following two parts:

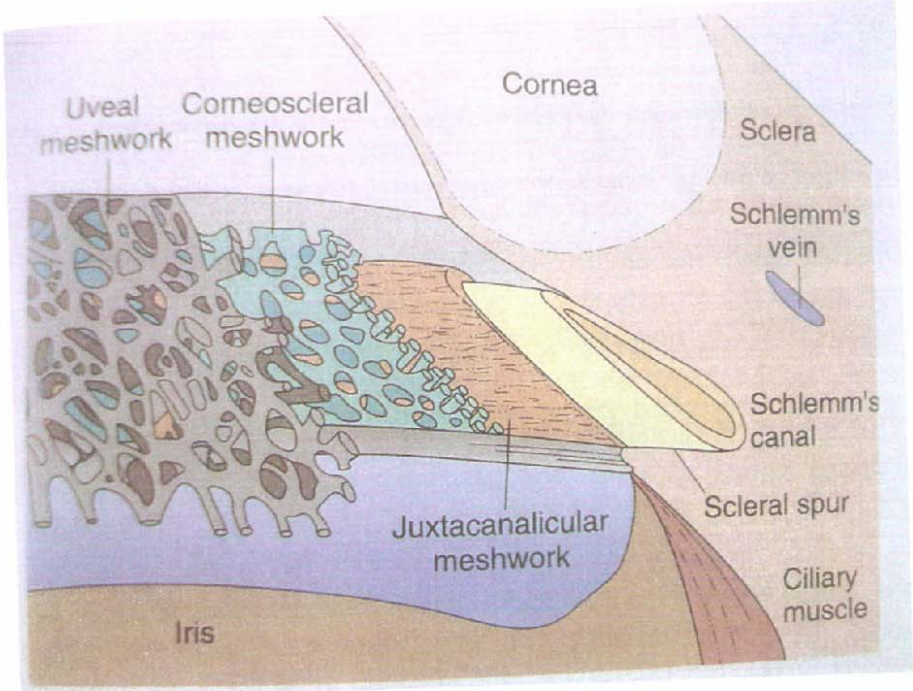
- (1) The anterior nonfiltering, nonpigmented part lies posterior to the schwalbe's line.
- (2) The posterior, filtering pigmented part lies adjacent to the scleral spur.
- (3) **Schlemm's Canal**-It is an endothelial lined circular channel that runs circumferentially around the globe with a diameter of 190- 370 mic. m. Its outer wall contains the openings of the collector channels.
- (4) **Collector Channels**: They arise from the outer wall of the Schlemm's canal and drain into intrascleral, episcleral and conjunctival venous plexus. **Schwalbe's Line**-Located at the termination of Descemet's membrane. It consists of a circumferential ring of collagenous fibres and basement membrane material. It marks the forward limit of the anterior chamber angle structures and serves as the anterior attachment site for the trabecular mesh work.

ANGLE OF ANTERIOR CHAMBER

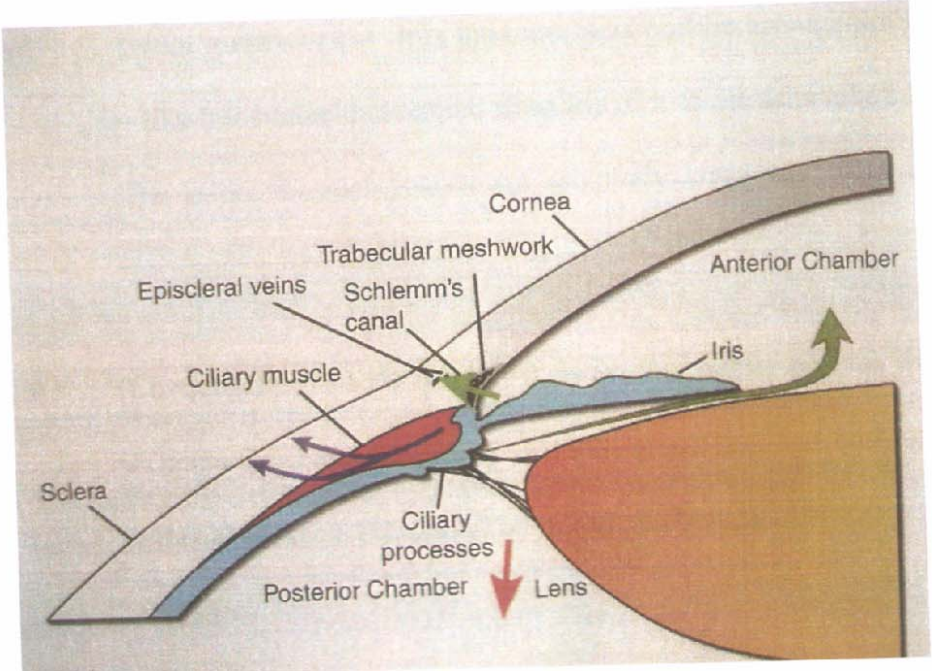


- SL - SCHWALBE'S LINE
- SS - SCLERAL SPUR
- IP - IRIS PROCESS
- TM - TRABECULAR MESH WORK
- C - CORNEA
- I - IRIS
- SC - SCHLEMM'S CANAL
- S - SCLERA
- CB - CILIARY BODY
- CP - CILIARY PROCESS

ANATOMY OF ANGLE STRUCTURES



AQUEOUS HUMOR CIRCULATION AND DRAINAGE



PATHOPHYSIOLOGY OF DRAINAGE IMPLANTS

All modern implants have the same basic design which typically consists of a silicone tube that extends in to the anterior chamber to a plate, disc or encircling element beneath the conjunctiva or tenons.

The edge of the external plate has a ridge through which distal end of the tube inserts on to the upper surface of the plate. The plates have large surface area & promote the formation of filtering bleb posteriorly near the equator.

The mechanism by which the drainage implants controls the IOP relates to a fibrous capsule that forms a filtering bleb around the external portion of the draining device.

The bleb histology has been studied in the rabbit model. After insertion of the device thin collagenous capsule surrounded by granulomatous capsule is present at one month. The granulomatous reaction resolves after four months. Capsule thickness remains relatively stable & the collagen stroma becomes less compact.

The fibrous capsule matures over time & becomes thinner over time. Microcystic spaces within thick layer of connective tissue in the

bleb may serve as channels of aqueous drainage. All surface of the fibrous Capsule contribute to filtration.

There is a direct relationship between the surface area of the implant & the filtering capacity of the surrounding capsule. At the same time reduction of the bleb diameter decreases capsular tension on the bleb, capsular fibrosis & thickness which increases the effectiveness of the filtering surface.

The failure of the filtering bleb after surgery may occur due to the increased thickness of the fibrous capsule around the implant.

AQUEOUS DRAINAGE DEVICES

- SETONS
- SHUNTS
- VALVES

SETONS

Non hollow linear shaft prevents wound apposition. Allows bulk flow by surface tension.

Horse hair

Tantalum wire

Gold wire

T- tube

SHUNTS

They are passive tubular structures

Molteno

Baerveldt

Schocket

White pump shunt

Molteno Single Plate



Molteno Double Plate



VALVES

Valves allow unidirectional flow. The valves available are

Krupin Denver

Ahmed glaucoma valve

Optimed pressure regulator

Joseph valve

Mehta valve

HISTORICAL REVIEW & IMPLANT DESIGNS

MOLTENO IMPLANT

In 1969 the Molteno implant was used to treat Refractory glaucomas. It's a prototype drainage implant & it consists of a single plate of thin acrylic with a diameter of 13mm & an area of 135sq mm. A Silicone tube with an external diameter of 0.62mm & internal diameter of 0.3mm connects to the upper surface of the plate.

A double plate Molteno combines two plates one of which is attached to the silicone tube in the anterior chamber while a second tube connects

the two plates giving a surface area of 270sq mm. Success rates with the double plate Molteno implant rose when compared to single plate.

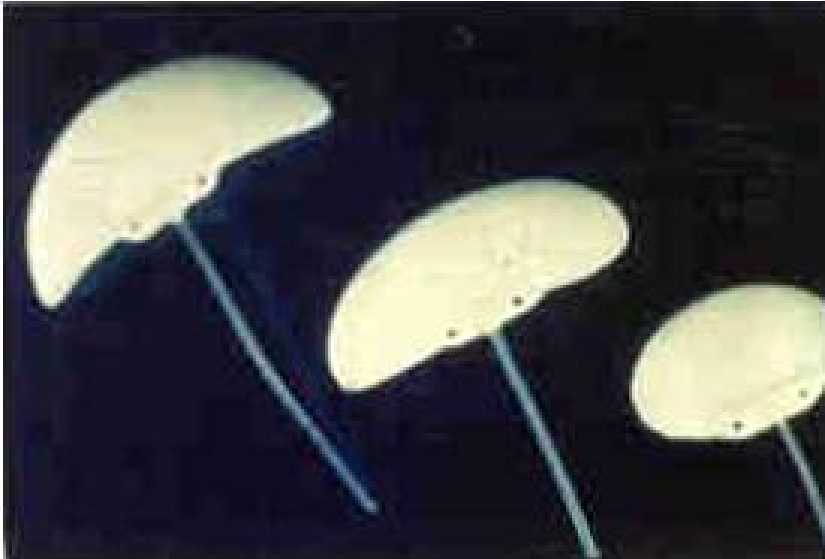
Molteno's key discoveries

- Implant to be made of non reactive synthetic material, with poor fibroblastic adherence
- Its essential to establish a potential space for aqueous pooling
- Bleb should be away from limbus at the equator.

VARIATION OF MOLTENO TECHNIQUE

- One-plate or two-plates
- One-stage or two-stage procedures
- Fibrosis suppression using medications
- Tube placement under scleral flap or donor graft
- Suture occlusion of tube internally or externally

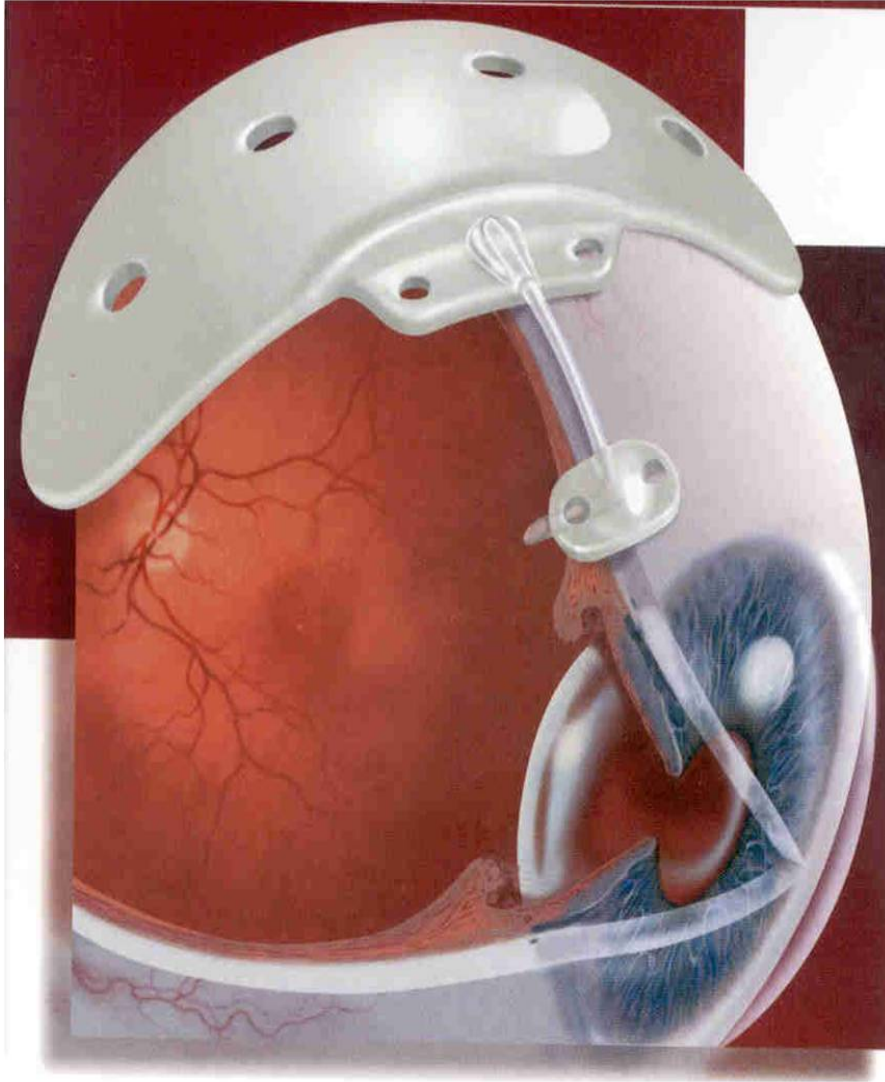
BAERVELDT IMPLANT



SCHOCKET TUBE SHUNT



BAERVELDT PARS PLANA IMPLANT



BAERVELDT IMPLANT

The unique feature of this implant is the large surface area of the plate. It works on the dose response between surface area & IOP. A Silicone tube is attached to a soft silicone plate.

THREE SIZES AVAILABLE :

- ◆ 200sq mm (13 x 20 mm)
- ◆ 350sq mm (14 x 32 mm)
- ◆ 500sq mm (17.5 x 36 mm)

However the 350sq mm implant is the preferred size & its safer & more effective than the 500sq mm implant.

The plate has fenestrations that allow growth of fibrous tissue through the plate serving to reduce the height of the bleb & secures the implant in place.

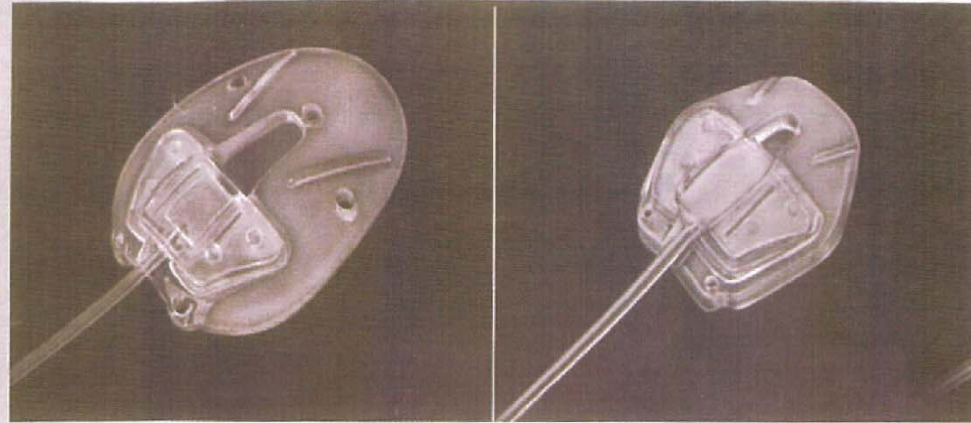
SCHOCKET TUBE SHUNT

Schocket developed a technique in which a silicone tube is extended from the anterior chamber through a 360 degree encircling silicone band as used in retinal detachment repair.

Modifications include insertion of the tube into a band extending for only 90 degrees beneath two recti or in to the pre-existing encircling band.

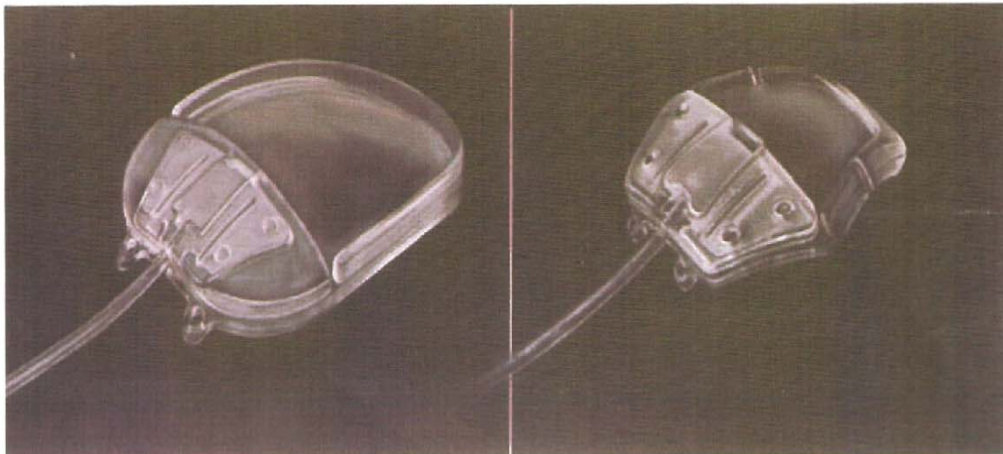
Though the shunt has a larger surface area than the Molteno implant, comparative studies show that the Molteno implant had a lower final IOP.

AHMED GLAUCOMA VALVE



Model FP7
Ahmed™ Glaucoma Valve
(Silicone)

Model FP8
Ahmed™ Glaucoma Valve
Pediatric Size (Silicone)



Model S2
Ahmed™ Glaucoma Valve
(Polypropylene)

Model S3
Ahmed™ Glaucoma Valve
Pediatric Size (Polypropylene)

FLOW RESTRICTED DRAINAGE DEVICES

AHMED GLAUCOMA VALVE

In this valved implant design silicone tube is connected to a silicone sheath valve which is held in a polypropylene body. The body of the most commonly used S2 model has a surface area of 184sq mm (16*13mm) & is 1.9mm thick. It works on the venturi effect.

The valve mechanism consists of 2 thin silicone elastomer membranes 8mm long & 7mm wide. It allows one way regulation of flow with IOP between 8mm Hg & 10 mmHg in the postoperative period.

The critical site for pressure drop is at the capsule surrounding the implant. Ahmed implant as with other implants has a hypertensive phase which is a transient phase of low capsule permeability seen at 4 to 8 weeks postoperatively.

The S2 model is made of polypropylene & the FP7 model is made of silicone. Silicone appears to cause less inflammation. Special modifications are available with pars plana clip for pars plana insertion.

Two trials investigating the effectiveness of adjunctive mitomycin (MMC) with the Molteno and Ahmed implants found no evidence of benefit with MMC.

ADVANTAGES:

- Immediate IOP reduction
- Reduced incidence of Hypertensive phase post operatively
- Unique pressure sensitive valve to prevent excessive drainage & chamber collapse
- Single stage implantation
- Eliminates drainage tube ligature sutures, Rip-cord & occlusion sutures.

OTHER DRAINAGE DEVICES

The Joseph tube with slit valve in its side is calibrated to open between 4 & 20mm Hg attached to 9mm wide silicone rubber strap. The other shunts available are Optimed glaucoma pressure regulator & White pump shunt that may be activated by touching or blinking.

OPTIMED GLAUCOMA PRESSURE REGULATOR

Made of PMMA & Silicone. Has 2 parts

1. Inlet tube
2. Pressure regulator component

Overall length 17.78mm

Width 5mm

Outflow pressure 10mm Hg

A variety of new stents & shunts are now available for refractory glaucomas. They are

1. Express miniature glaucoma shunt from Optanol
2. Mini catheter from iScience
3. iStent from Glaukos
4. Deeplight Gold microshunt from SOLX

EXPRESS SHUNT

Optonol's Ex-Press shunt developed in Israel is an effective, long-term alternative to traditional glaucoma surgery and can significantly improve the quality of life of glaucoma patients by providing possible relief from life-long dependency on drug therapy.

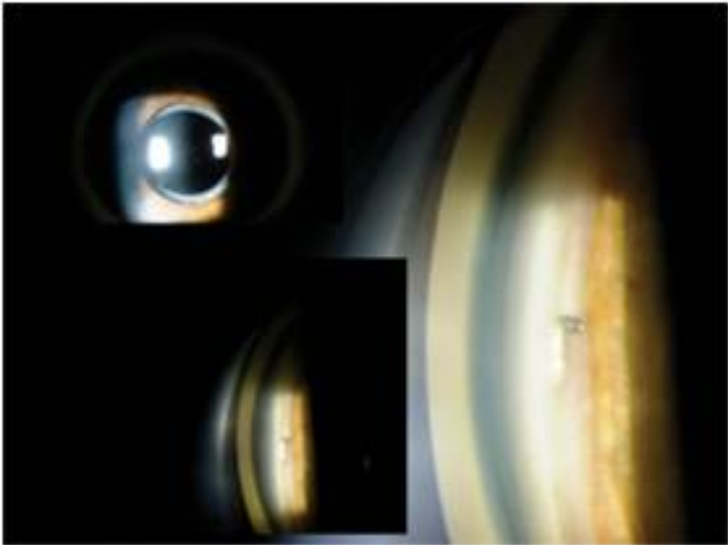
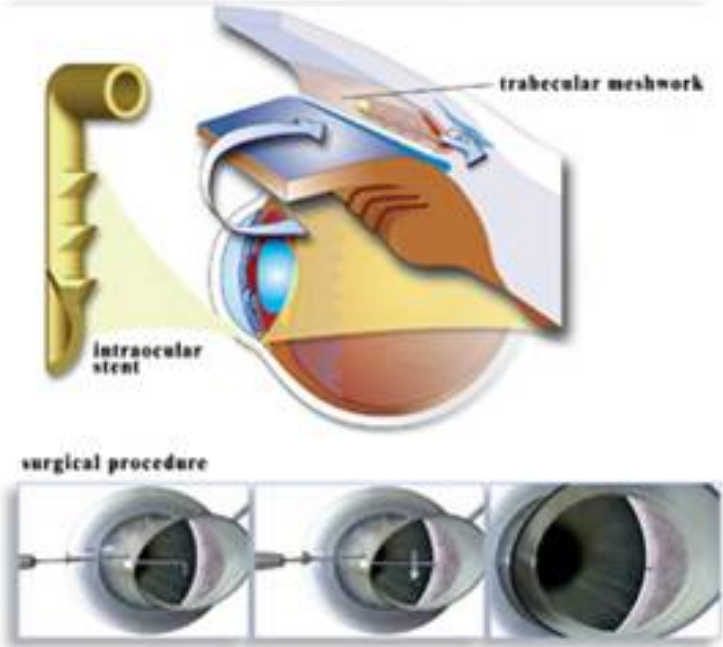
The FDA-approved shunt is a miniature glaucoma drainage device, just the tiny spike at the end of the needle. A simple, short procedure inserts the shunt at the edge of the colored part of the eye, the limbus. The microscopic conduit works by bypassing the blocked trabecular meshwork allowing aqueous to drain from the AC into the intrascleral & Subconjunctival spaces where it is absorbed by the blood vessels.

The 3-mm long, 400 micron diameter implant has received both Food and Drug Administration approval and CE approval for marketing in Europe. Before its introduction into the US market, the device had been implanted in more than 1,200 human patients since 1997 in worldwide clinical trials and in commercial use in Europe.

2. i Science mini catheter

The minicatheter is inserted into the canal of Schlemm in a procedure similar to viscocanalostomy.

GLAUCOS iSTENT



3. Glaucos istent

The istent from Glaucos Corporation is a small spike like implant that is inserted across the anterior chamber into the trabecular meshwork.

It is designed to allow aqueous to enter the canal of Schlemm. The device is very small with a width of 80 microns & a length of 1mm.

A gonioscope is used to view the angle while moving the istent across the anterior chamber. There are some practical difficulties as the stent has to be placed correctly in the Schlemm's canal

4. SOLX Deep Light Gold Microshunt

The 24 carat deep light gold microshunt from SOLX is designed to lower IOP in a procedure without a bleb. The implantable device reduces IOP by taking advantage of the natural pressure differential between the anterior chamber & the suprachoroidal space (SOLX literature).

The ultra thin device is inserted into a 4mm wide incision that connects the anterior chamber to the suprachoroidal space. The shunt is biocompatible, inert, rests permanently in the suprachoroidal space & can eliminate the formation of scar tissue according to company literature.

BIFURCATABL TRABECULAR SHUNTS

The claims about the shunt:

A trabecular shunt for transporting aqueous humor in an eye, comprising an elongated tubular element having an inlet section and an outlet section; wherein the outlet section comprises two bifurcatable elements, the bifurcatable elements configured to be positioned within a Schlemm's canal of the eye, wherein at least one of said two bifurcatable elements comprises a shape-memory material, the shape-memory material having a preshape and a shape-transition temperature, wherein the shape memory material conforms to its preshape when the shape-memory material is heated to above the shape-transition temperature; and an external heat source that is adapted to heat the shape-memory material to above the shape-transition temperature.

The method may further comprise placing the trabecular shunt inside a delivery apparatus, wherein the two bifurcatable elements are self-bifurcatable in two opposing directions when the trabecular shunt is deployed from the delivery apparatus.

The trabecular shunt may include a pressure sensor for measuring the pressure of the anterior chamber of an eye of a patient. The pressure

sensor may further include an electromagnetic (e.g., radiofrequency) transmitter, for wirelessly transmitting pressure measurements to a pressure receiver outside the patient's body.

Outcome of glaucoma drainage devices

The following data are derived from the long term follow ups of study populations in which “success” was typically defined as lower end cut off of 5-6mmHg & high end of 21-22 mmHg with or Without medications.

In Trials with Molteno implant success rates were 73-74% with a minimum follow up of 18 months & 57% with a mean follow up of 43-44 months. Survival analysis in a retrospective study showed that failure was most common in the first post-operative year & significant risks for failure were pseudophakia & Neovascular Glaucoma. Postoperative IOP tended to be lower after double plate than after single plant implantation.

With Shocket type implants success rates were 81% with a 17.5 month mean follow up but fell to 30% at 36 months in one study.

Reported success rate with Baerveldt implants were 93% & 88% for 350 sqmm implant & 500sqmm implant respectively.

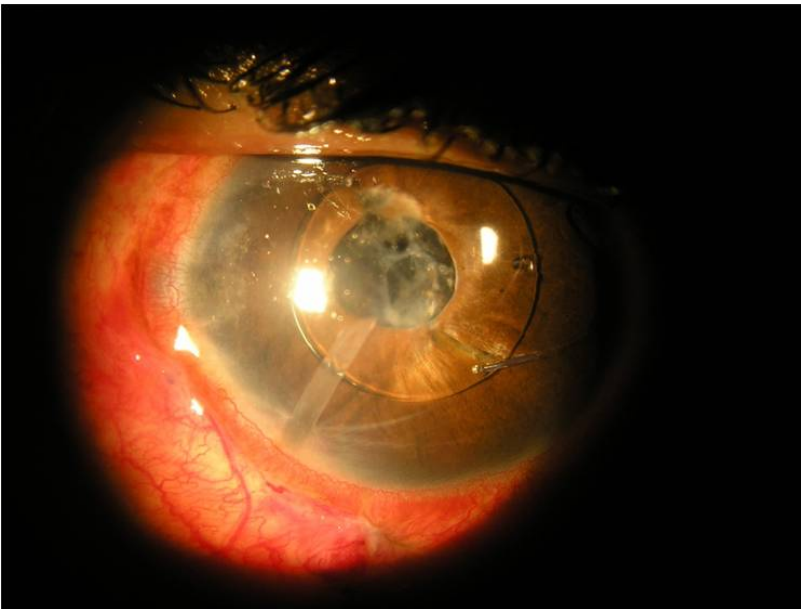
Studies with Krupin valve revealed a success rate of 66% after 12 months & 80% success rate after 25 months.

Studies with Ahmed valve reveals success rates of 77-88% at 1 year of follow up & 75% success rates at 2 years of follow up. However in paediatric population success rate is somewhat lower.

BLEB AFTER IMPLANT PROCEDURE



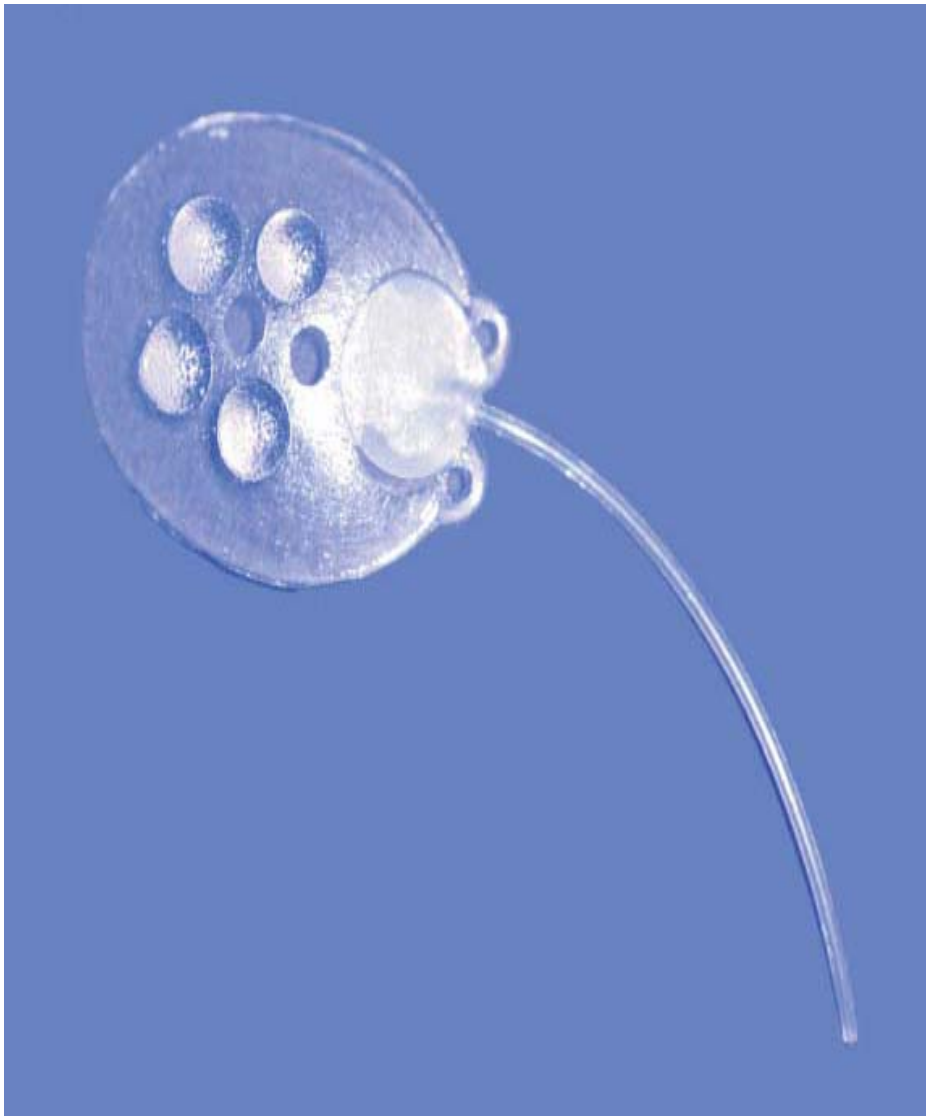
AGV IN PSEUDOPHAKIC GLAUCOMA



COMPARISON OF IMPLANT DEVICES

Device	Ahmed S2	Ahmed FP7	Molteno D1	Baerveldt BG 103 250	Baerveldt BG 101 350	Mehta
Surface area(mm ²)	184	184	133	250	350	
Side to side(mm)	13	13	13	22	32	15
Front to back(mm)	16	16	13	14	15	17
Implant profile(mm)	1.9	0.9	1.65	0.84	0.84	
Single insertion	quad yes	yes	yes	yes	yes	yes
Plate Material	Rigid polypropylene	Smooth silicone	Rigid polypropylene	Smooth silicone	Smooth silicone	Smooth silicone
Drainage tube	valved	valved	open	open	open	Valved
Fixation holes	suture yes	yes	yes	yes	yes	Yes
manufacturer	New world medical	New world medical	Molteno oph, ltd	Advanced med optics	Advanced med optics	Surgiwear

KEIKI MEHTA VALVE



KEIKI MEHTA “BP VALVE” GLAUCOMA SHUNT

INTRODUCTION:

Keiki Mehta “BP valve” glaucoma shunt has been developed by Surgiwear in association with Dr. keiki R. Mehta world renowned Ophthalmic surgeon. It is a very simple & effective device which has no high sounding mechanics or valves. It has just three parts a tube, a membrane valve & a button, all made of medical grade silicone. It has following important features.

A. “BP Valve” or body pressure valve.

The valve regulating the flow does not have any opening pressure of its own. It is being pressed by body’s own tissues. When the pressure of fluid in eye is more than pressure of body tissues, the valve will open & allow flow of fluid. Thus the fluid pressure inside the eye is maintained at the level of body pressure.

B. “Peaks on button” there are multiple peaks on the button. These peaks keep conjunctiva and Tenon’s capsule away from button to facilitate distribution of fluid around. These peaks allow fibrous growth & hence it prevents plate migration. The fluid can pass beyond the button also, because there is no limiting ridge

around. Thus effectively it has a large absorption area for the fluid to get absorbed.

- C. Soft & flexible button with rough upper surface. The button body is soft so easy to implant. The rough top surface creates large surface area & prevents sticking of valve with button body.

PRESENTATION

The glaucoma shunt is available sterilised ready to use in three sizes:

1. Regular size
2. Small size
3. Large size.

Depending upon size of the eye ball & severity of problem the size is selected.

INDICATIONS

Indications of GDD:

Drainage implant surgery is reserved for patients in whom trabeculectomy with adjunctive anti-metabolite has either failed or is thought to have a very low chance of success or in whom still there is a reasonable potential for vision.

1. Young patients- in children with JRA & Uveitic Glaucoma.
2. Intractable Neovascular glaucoma.
3. Glaucoma associated with Uveitis.
4. Severe Conjunctival scarring.
5. Glaucoma in aphakia & pseudophakia
6. Patients with prior surgery such as vitreo retinal surgery & PKP.

YOUNG PATIENTS

Drainage implant surgery for childhood glaucoma is more problematic than in adults. Nevertheless success rates of 55-95% have been reported with no definitive advantage between Molteno, Baerveldt or Ahmed.

Drainage implant surgery may be especially useful in children with juvenile rheumatoid arthritis & uveitic glaucomas & glaucomas associated with Sturge-Weber syndrome.

An advantage of drainage implants over trabeculectomy with antimetabolites in Sturge-Weber is the reduced risk of expulsive haemorrhage associated with marked IOP reduction.

Complications in children include tube malposition, flat anterior chamber, tube obstruction by iris or vitreous, cornea tube touch, choroidal detachment, corneal oedema & corneal abrasion.

NEOVASCULAR GLAUCOMA

Drainage implants have been successful in some eyes with neovascular glaucoma, although the success declines with time. Glaucoma drainage implants have been reported to have better outcome in the eyes with neovascular glaucoma than cyclophotocoagulation.

UVEITIC GLAUCOMA

Ahmed valve implants have been shown to be a better alternative for high risk patients with uveitic glaucoma. Success may be enhanced by preop & long term postop immunotherapy.

SEVERE CONJUNCTIVAL SCARRING AND PREVIOUS OCULAR SURGERY

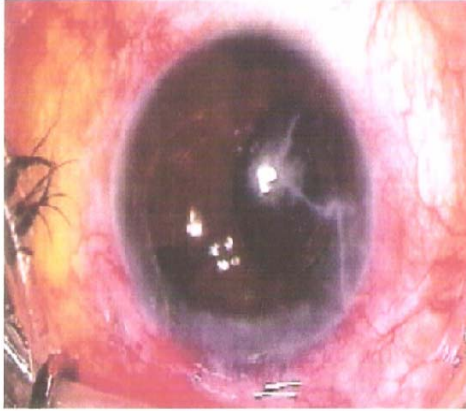
A failed trabeculectomy, especially when the conjunctiva is scarred down in both superior quadrants, could be an indication for a drainage implant procedure. Schocket implants have been used in association with pars plana vitrectomy in eyes with vitreoretinal disorders.

ANIRIDIA

Molteno implants & the Ahmed valve have been used in these patients. These are the general indications of GDD. Mehta valve implant is indicated in Neovascular, Congenital & uveitic Glaucoma.

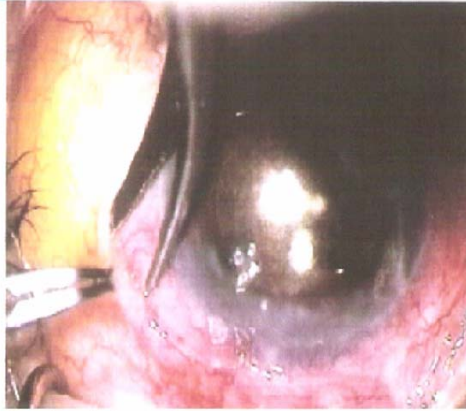
Keiki Mehta "BP Valve" Glaucoma Shunt

1



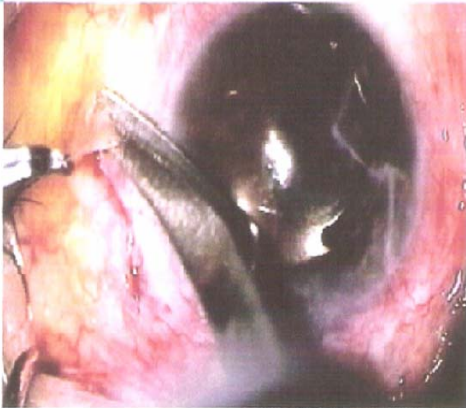
It is a case of uncontrolled glaucoma with multiple trabeculectomies with anterior chamber IOL

2



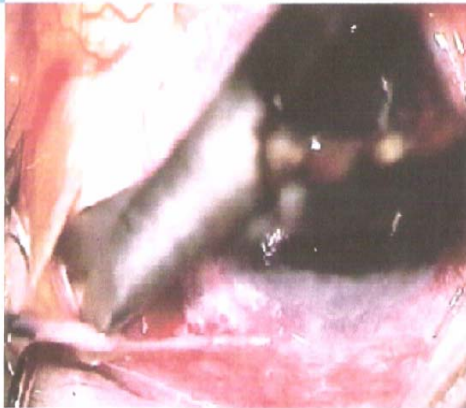
An incision is given in either upper outer or upper inner quadrant.

3



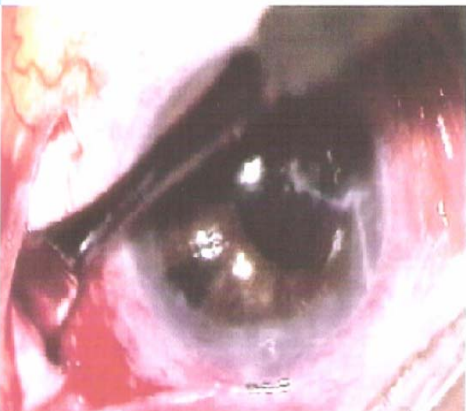
Conjunctiva in and Upper inner quadrant is being cut and opened up.

4



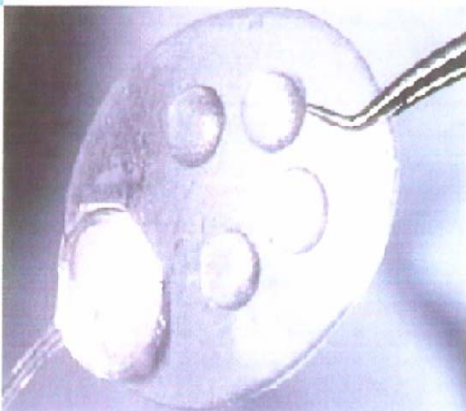
A pocket is created under conjunctiva & Tenon's capsule with curved corneal scissors.

5



Curved blunt spatula is used to further clear the pocket.

6



Keiki Mehta Glaucoma Shunt is flushed with saline using 27 gauge cannula.

Keiki Mehta "BP Valve" Glaucoma Shunt

7



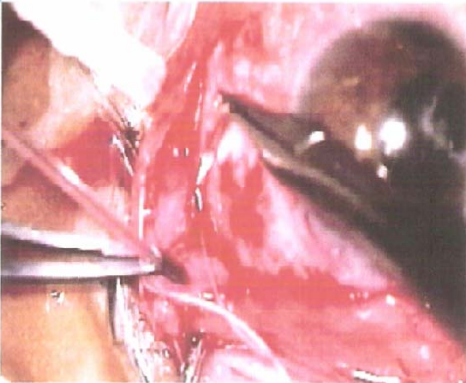
Patency of system is checked. Fluid should flow out freely from the valve

8



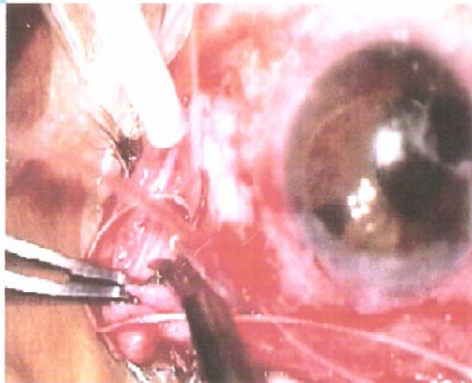
Glaucoma shunt is inserted into the pocket created under conjunctiva & Tenon's capsule.

9



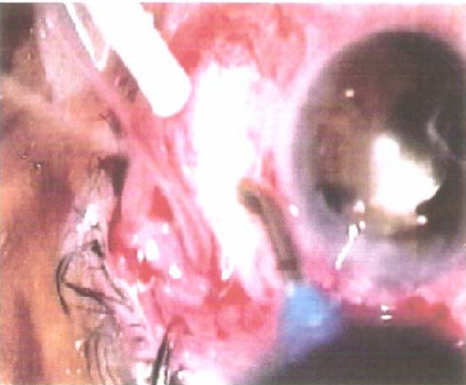
The valve is sutured in place using 6/0 non absorbable suture. The position of valve should be 10 mm behind limbus.

10



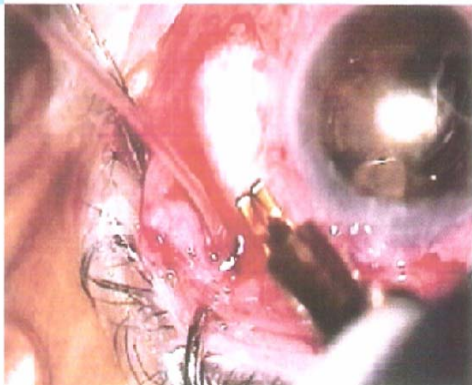
The needle is passed through the eyelets present in the shunt (not shown in the picture)

11



Bleeding points are secured using light cautery.

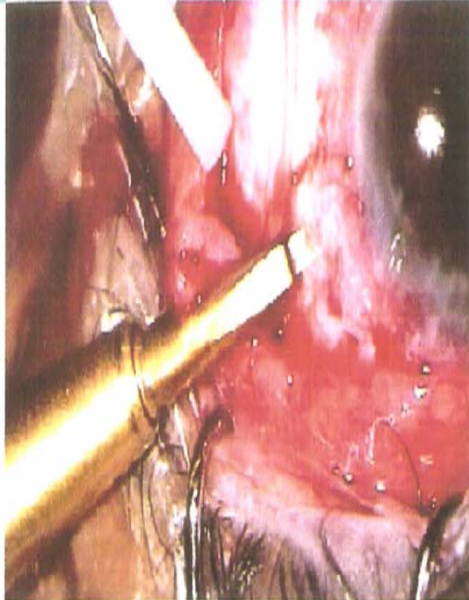
12



Graded micrometer knife is used to make two cuts 35 micron deep into sclera to bury the tube under it.

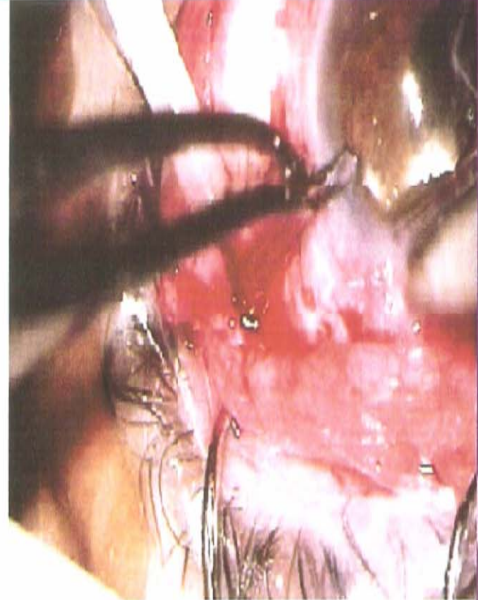
Keiki Mehta "BP Valve" Glaucoma Shunt

13



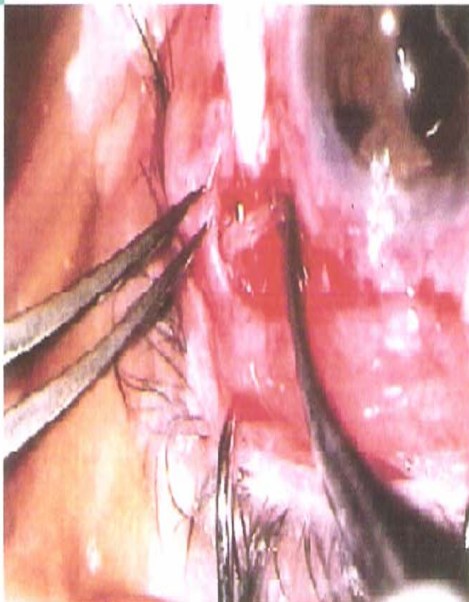
1.2 mm diamond knife is used to create a passage through the sclera through the cuts. same knife is used to enter into ant. chamber

14



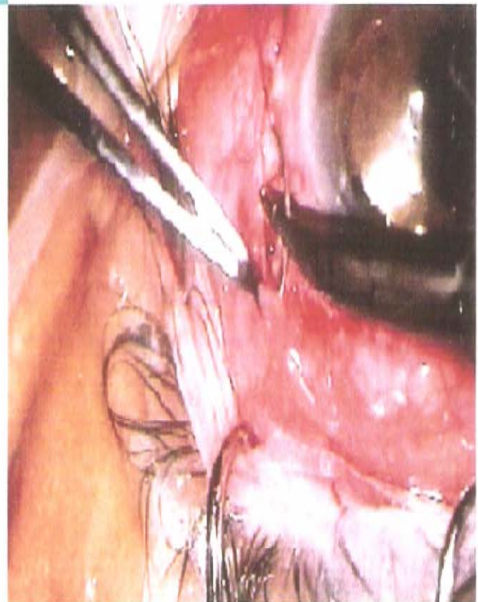
Length of tube is cut in an oblique fashion Length should be just sufficient to enter into the anterior chamber.

15



The tube end is pushed through the passage created. The end of tube should be visible in the anterior chamber.

16



The conjunctiva is closed using absorbable suture.

SURGICAL TECHNIQUE OF MEHTA VALVE IMPLANT

1. Priming of the valve is done by injecting saline through a 27 gauge needle into the tube. This is done to expel the air bubble in the tube & the patency of the shunt is also checked by flushing the tube.
2. A fornix based incision is given either in supero nasal or supero temporal quadrant & conjunctiva is opened.
3. A pocket is created under conjunctiva & tenons with curved corneal scissors.
4. A curved blunt spatula is used to further clear the pocket.
5. A glaucoma shunt is inserted into the pocket created under the conjunctiva & tenons.
6. The valve has two eyelets & it is sutured in place using 10-0 monofilament nylon.
7. A graded micro metre knife is used to make two cuts deep into sclera to bury the tube & 1.2mm diamond knife is used to create the passage through the sclera into the anterior chamber.

8. Length of the tube is calculated & it is cut with the bevel facing up. Length should be sufficient to enter in to the anterior chamber.
9. The tube is pushed through the intrascleral tunnel. The end of the tube should be visible in the anterior chamber.
10. Conjunctiva is closed using absorbable suture.

OTHER MODIFICATIONS OF BASIC TECHNIQUE

Sometimes the conjunctiva is scarred at the limbus, making conjunctival dissection impossible without destroying much of the conjunctival tissue. In this case, the initial conjunctival incision may be made approximately 8mm from the limbus to create a limbal based conjunctival flap. Another option is to use the inferotemporal or a superonasal quadrant.

Sometimes occlusion ligatures like releasable sutures can be tried. Biodegradable stents like collagen lacrimal plugs or 4-0 chromic sutures also have been evaluated but they have been less satisfactory because they do not always resolve.

A clear corneal graft tied with 8-0 nylon can be used instead of pericardium or scleral graft to cover the outer portion of tube.

Instead of preserved tissue an autologous partial thickness scleral patch graft crafted from the sclera adjacent to the tube has been described.

No complication has been described with this technique but the risk of perforation to the globe exists.

Some use stent occlusion with longitudinal slits in the tube to provide early IOP control.

In a retrospective study implantation of AGV with the use of MMC achieved lower postoperative IOP with fewer glaucoma medications. However at the present time there does not appear to be significant benefits from application of antimetabolites in conjunction with drainage implant.

COMPLICATIONS

The complications associated with aqueous shunts can be categorised as those associated with the reduction of IOP, with the functioning and placement of the tube, with the episcleral plate and the response to surrounding tissues to it, and with the intraocular surgery per se.

Complications associated with reduction of IOP

HYPOTONY

Flat anterior chamber has been reported following insertion of valved and nonvalved aqueous shunts. Until the fibrous capsule has developed around the aqueous flow the open non valved tube implants provide very low resistance to flow and hypotony in early post op course. The best way to prevent this postop complication is by temporarily obstructing the tube lumen.

Techniques include suture ligation of the tube, temporary occlusion of the tube lumen with a stent, 2 stage implantation or use of a valved implant. If early post op hypotony happens with flat AC then injection of dense viscoelastic in to the AC & close observation may be helpful.

If hypotony persists then removal of the tube from the AC is recommended to prevent corneal decompensation, Repositioning can be done later.

Treatment of Early Postoperative Hypotony

Most early postoperative hypotony is self-limited and will resolve spontaneously without treatment. However, intervention is warranted when there is lens-cornea touch or when there is evidence that the hypotony will be prolonged if no intervention is made.

Identify and repair any bleb leaks which result in significant hypotony associated with a flat chamber. A small leak may be observed if the chamber is adequately maintained allowing time for spontaneous closure.

Deepen the chamber with viscoelastic through the paracentesis if there is lens-cornea touch. This procedure can be repeated daily until the IOP begins to rise and the chamber stabilizes (usually at the end of week two).

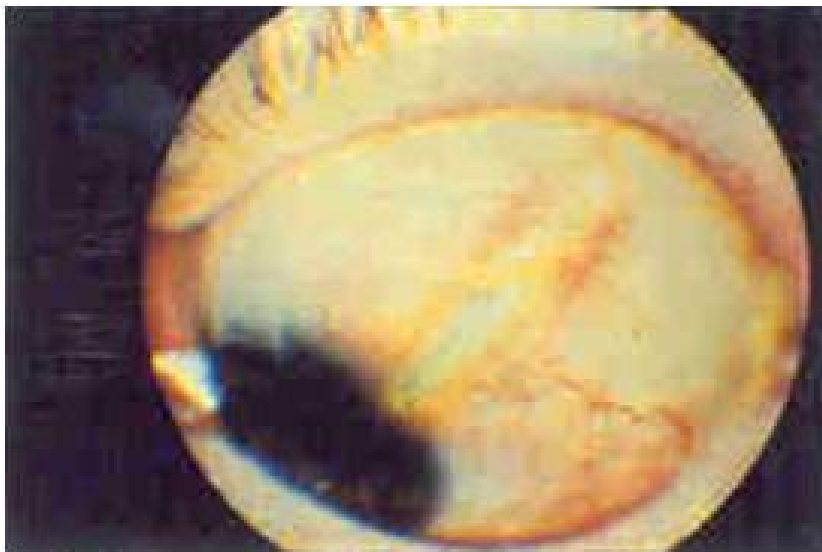
Drain large choroidals if there is lens-cornea touch. This will deepen the chamber and expedite the return to a normal IOP.

COMPLICATIONS

TUBE OCCLUSION



TUBE EXPOSURE



Elevated IOP

Elevated IOP can be present in the early or late postop period. Within the first 7-10 days there is a hypotensive phase followed by a second hypertensive phase associated with formation of fibrous capsule. The IOP reduction & stabilisation occurs in the next 3-6 months. Elevated IOP in the early post op period may be due to obstruction of the tube by fibrin, blood, iris, vitreous membranes. This is been observed in 11% of case after the AGV implant.

Iridectomy at the site of the tube ostium has been recommended to prevent iris plugging the tube ostium. Nd YAG laser membranectomy was effective for reopening blocked glaucoma tube shunts but the risk of recurrence is high. Another technique is to irrigate the tube with BSS using a 30 guage cannula through a paracentesis incision. Intracameral injection of TPA is done to resolve fibrin clot.

Late IOP elevation inspite of the tube being patent is due to excessively thick fibrous capsule. Needling revision can be done in such cases. It is been reported that topical steroid therapy can cause IOP elevation despite the presence of a drainage implant.

Treatment of Early Postoperative Hypertension

Observation for first 48 hours if not severe. The IOP will frequently come down spontaneously as viscoelastic, blood, fibrin, or other occlusive material is cleared from the anterior chamber.

If the IOP is unacceptably high, the addition of digital massage or antiglaucomatous medications may be useful. This will allow time for an absorbable suture ligature to dissolve or for bleb encapsulation to occur allowing removal of the tube occluding (stent) suture.

Remove the occluding (stent) suture; if this is done during the first week, the chance of severe hypotony, shallow chamber, and related complications is increased.

If the end of the tube is occluded by vitreous, iris, or fibrin. The Nd: Yag laser may be used to clear the obstruction. In some cases, a return trip to the operating room may be necessary. This is particularly common if there is a large anterior hyphema in the early post-operative period which is associated with significant IOP elevation.

MIGRATION, EXTRUSION & EROSION

Tube migration may occur after glaucoma shunt procedures. If the tube is not adequately secured to the sclera it may migrate posteriorly out of the anterior chamber, which may require repositioning of the tube & securing it to the sclera with additional 9-0 prolene sutures.

Extrusion of the implant was the most common reason for repeat surgery in children. The tube may need to be repositioned when it is blocked by cornea, iris, or vitreous. Avulsion of an implant after blunt trauma may force the tube against the cornea, causing corneal melting & requiring explantation of the implant.

Erosion of the silicone tube through the overlying conjunctiva is a recognised complication of the aqueous shunts. A partial thickness scleral flap does not prevent erosion of the tube. The tube & fistula site should be covered with preserved sclera, dura, fascia lata, or pericardium.

If a scleral graft is too thick, it may elevate the limbal conjunctiva enough to produce dellen formation.

Solvent preserved cadaver pericardium offers several advantages, including availability, lower cost, uniformity in size & tissue quality & enhanced sterility. Tissue sterilisation is achieved through the treatment

with organic solvents followed by low dose radiation, which inactivates bacteria, fungi & viruses including HIV.

ENDOPHTHALMITIS

Endophthalmitis may develop after needling of implant. Recurrent *Propionibacterium acnes* endophthalmitis has been reported after molteno tube revision.

Tube reinsertion in to the anterior chamber resulted in recurrence of the infection. Early postoperative endophthalmitis, following placement of an implant, may be successfully treated by immediate removal of the implant & surgical management of the infection, with subsequent placement of a new implant.

In the late post-op period exposure of the tube seems to be a major risk factor for these infections. Surgical revision with a patch graft in all cases in which there is an exposed tube is indicated to prevent this potentially devastating complication.

CORNEAL DECOMPENSATION & GRAFT FAILURE

Tube-cornea touch is a cause of corneal decompensation. When the tube-corneal contact is seen, removal of the tube from the anterior chamber, shortening of the tube, & subsequent reinsertion may be

necessary. Corneal problems may be secondary to the underlying ocular condition or to the drainage itself. Phosphorylcholine polymer coating of the glaucoma drainage devices was suggested to reduce the rate of corneal endothelial failure.

DIPLOPIA & OCULAR MOTILITY DISTURBANCE

Implants with larger plates, especially when implanted in the superonasal quadrant, can interrupt extraocular muscle function & cause strabismus & diplopia. While the complication is usually associated with the larger plates, such as the 350 sqmm Baerveldt implant & the Krupin valve with disc, it may also occur with smaller plates, such as the single-plate or double-plate Molteno implants, especially in children.

Corrective measures may require removal of the implant, replacement with a smaller plate design or transfer to the superotemporal quadrant, which usually relieves the implant.

PART-2

AIM OF THE STUDY

To measure the outcome of Mehta valve implant in 25 cases (26 eyes) of intractable glaucoma inserted using a modified surgical technique that eliminates the need for a donor scleral graft.

The main outcomes included

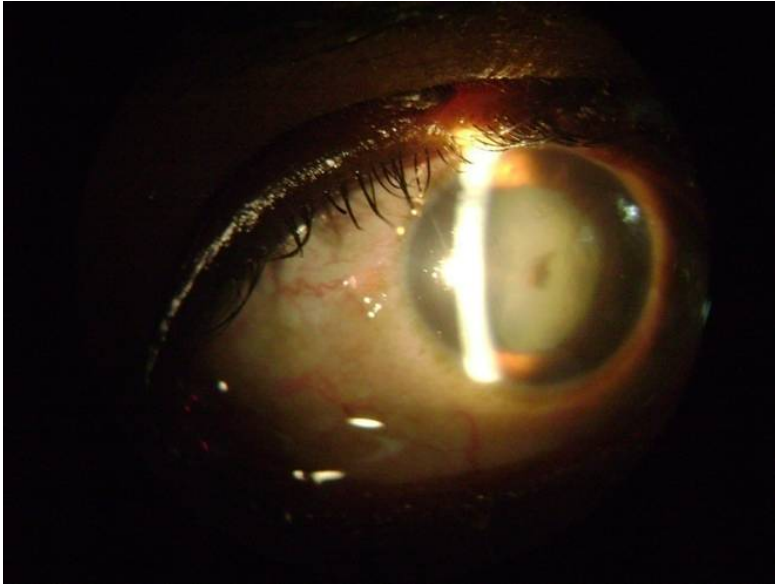
1. Analysis of intraocular pressure control following surgery & comparison with the preoperative baseline IOP
2. Frequency of intraoperative and postoperative complications.
3. Success rate of the procedure at a follow up of 6months, 1year, 18 Months & 2years

INCLUSION CRITERIA

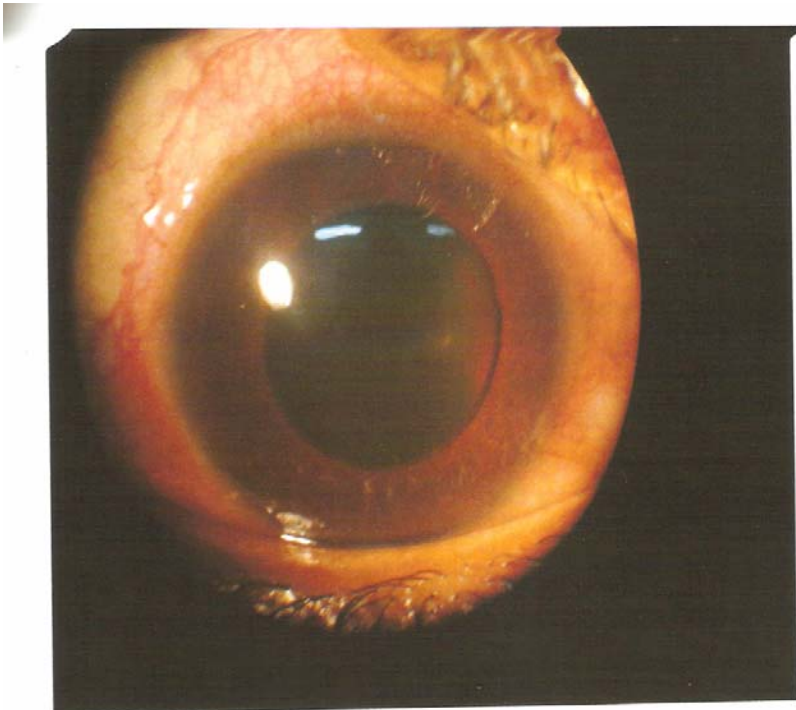
Patients between the ages of 30-70 yrs were taken. One patient alone was in the paediatric age group.

Patients with Glaucoma uncontrolled on maximum tolerated medical therapy & were considered at high risk of failure for trabeculectomy or had previously failed trabeculectomy were taken.

POST INFLAMMATORY GLAUCOMA



NEOVASCULAR GLAUCOMA WITH NVI



MATERIALS AND METHODS

A total of 26 eyes of 25 patients diagnosed as refractory Glaucoma attending the Glaucoma service of GOH between August 2006 & October 2008 were enrolled in this study.

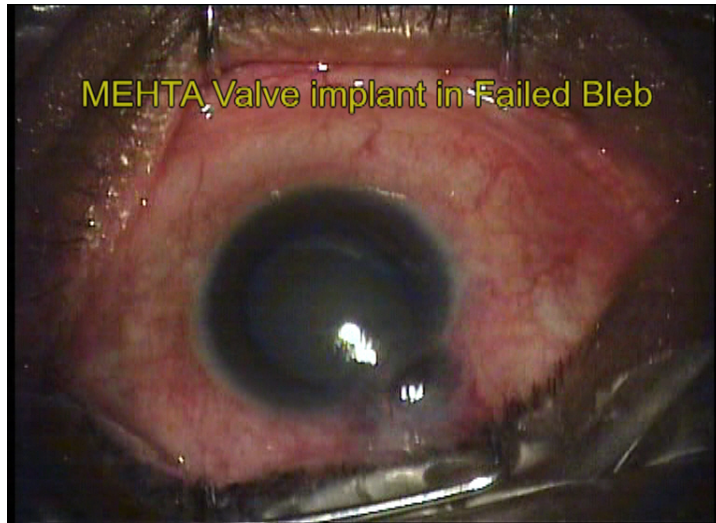
Of the 25 cases 18 cases were neovascular glaucoma, 2 were cases of post-traumatic Glaucoma, 2 were cases of post traumatic glaucoma with failed trabeculectomy, 2 cases were postinflammatory glaucoma & 1 case of post PKP glaucoma.

All the patients included in this study were advised to come for regular follow up visits in our clinic. Diagnosis of glaucoma was mainly based on changes in the optic discs and intraocular pressure (By Applanation tonometry) & Gonioscopic findings.

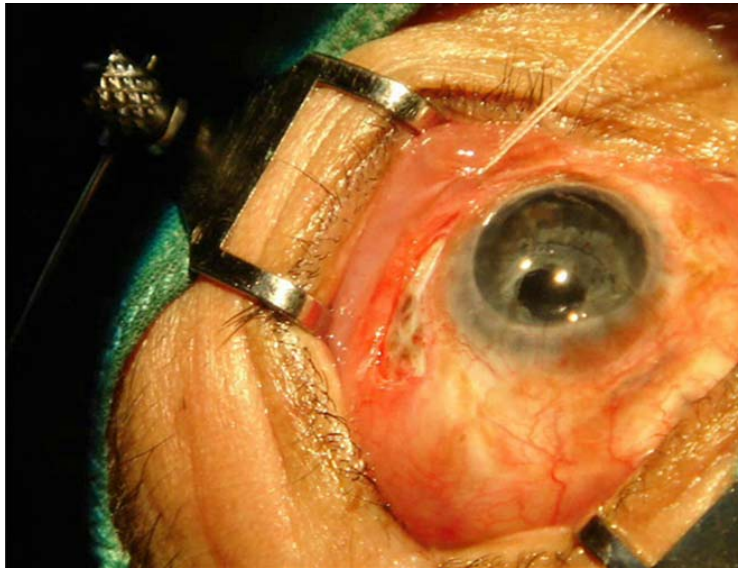
All the surgeries were performed by single surgeon. Indications for valve insertion included intraocular pressure not controlled by medical therapy or other forms of surgery—namely, cycloablation and trabeculectomy.

Implant used was Keiki Mehta BP valve Glaucoma shunt developed by surgiwear in association with Dr. Keiki.R.Mehta. The Glaucoma shunt is available sterilised ready to use in 3 sizes: 1.Regular size, 2. Small size, 3.Large size.

INTRA OPERATIVE PICTURES



IMPLANT PROCEDURE IN POST PKP GLAUCOMA



SURGICAL TECHNIQUE OF MEHTA VALVE IMPLANT

1. Priming of the valve is done by injecting saline through a 27 gauge needle in to the tube. This is done to expel the air bubble in the tube & the patency of the shunt is also checked by flushing the tube.
2. A fornix based incision is given either in supero nasal or supero temporal quadrant & conjunctiva is opened.
3. A pocket is created under conjunctiva & tenons with curved corneal scissors.
4. A curved blunt spatula is used to further clear the pocket.
5. A glaucoma shunt is inserted in to the pocket created under the conjunctiva & tenons.
6. The valve has two eyelets & it is sutured in place using 6-0 prolene.
7. Intrasccleral tunnel is created about 3mm from limbus using 18 gauge needle & the needle is used to enter the anterior chamber
8. Length of the tube is calculated & it is cut with the bevel facing up. Length should be sufficient to enter in to the anterior chamber.

9. The tube is pushed through the intrascleral tunnel. The end of the tube should be visible in the anterior chamber.

10. Conjunctiva is closed using absorbable suture.

In the original surgical technique described by Dr. Keiki Mehta a graded micro metre knife is used to make two cuts 35 micron deep in to sclera to bury the tube & 1.2mm diamond knife is used to create the passage through the sclera in to the anterior chamber.

But here the Surgeon used an intra scleral tunnel using an 18 guage needle to insert the tube.

All cases were done without patch graft& tube was secured in the intrascleral tunnel. This eliminated the complications associated with the patch graft.

Definition of Success:

A Postoperative IOP between 8mmHg & 21mmHg without medications was termed successful. Qualified success was defined as an IOP between 8 & 21mmHg with additional topical medications.

Failure was defined as persistent IOP >21mmHg, hypotony <8mmHg, a requirement for cyclodestructive procedure or further glaucoma surgery.

A transient elevation of IOP was permitted if the mean IOP for a 6 month period was less than 21mmHg. If it remained elevated the time of failure was taken as the first date the elevation was recorded.

Demographics of study population:

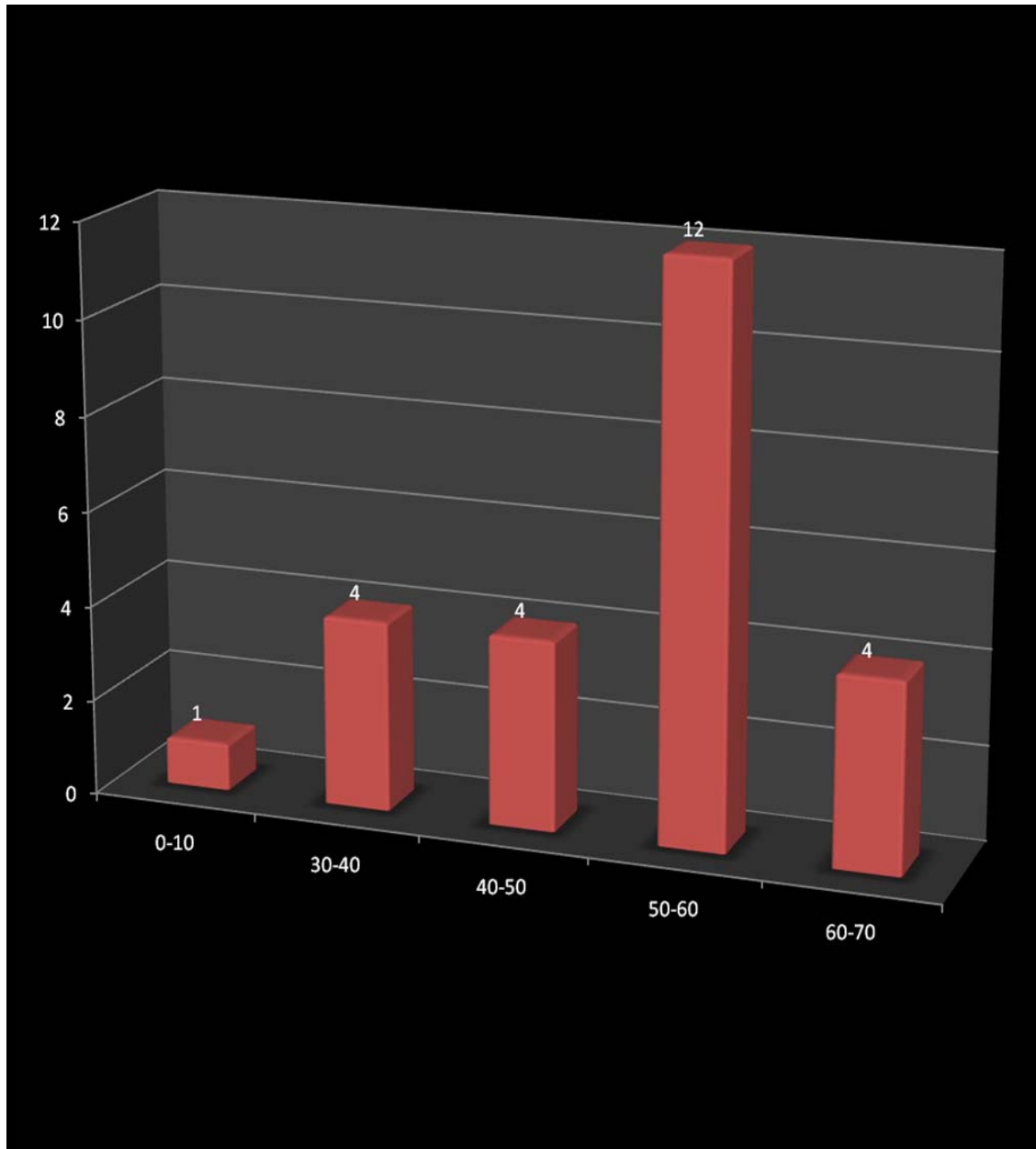
NUMBER	NO
Patients	25
Eyes	26
AGE	No- %
0-10	1- 4%
30-40	4- 16%
40-50	4- 16%
50-60	12- 48%
60-70	4- 16%
Pre-op IOP	
20-30	1
30-40	17
40-50	8
Diagnosis	No of eyes
Neovascular Glaucoma	18
Post-traumatic Glaucoma	2
Post PKP Glaucoma	1
Post traumatic Glaucoma	2
Post inflammatory Glaucoma	3

Previous Glaucoma Surgery	
Total	3
Type of previous Glaucoma surgery	
Trabeculectomy	2
Cyclocryotherapy	1

AGE DISTRIBUTION

Age in years	No of cases	%age
0-10	1	4
30-40	4	16
40-50	4	16
50-60	12	48
60-70	4	16

AGE DISTRIBUTION

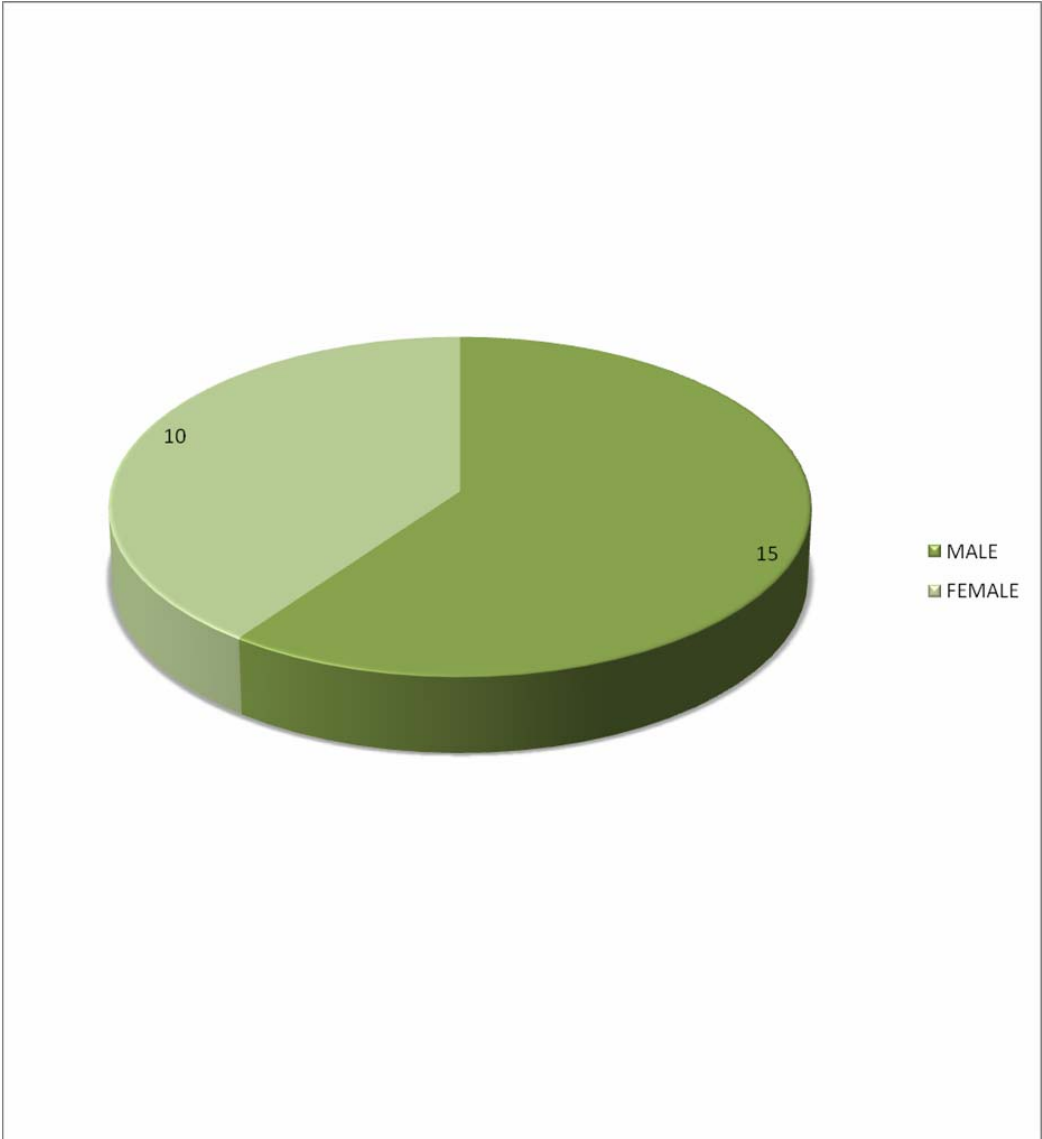


GENDER DISTRIBUTION

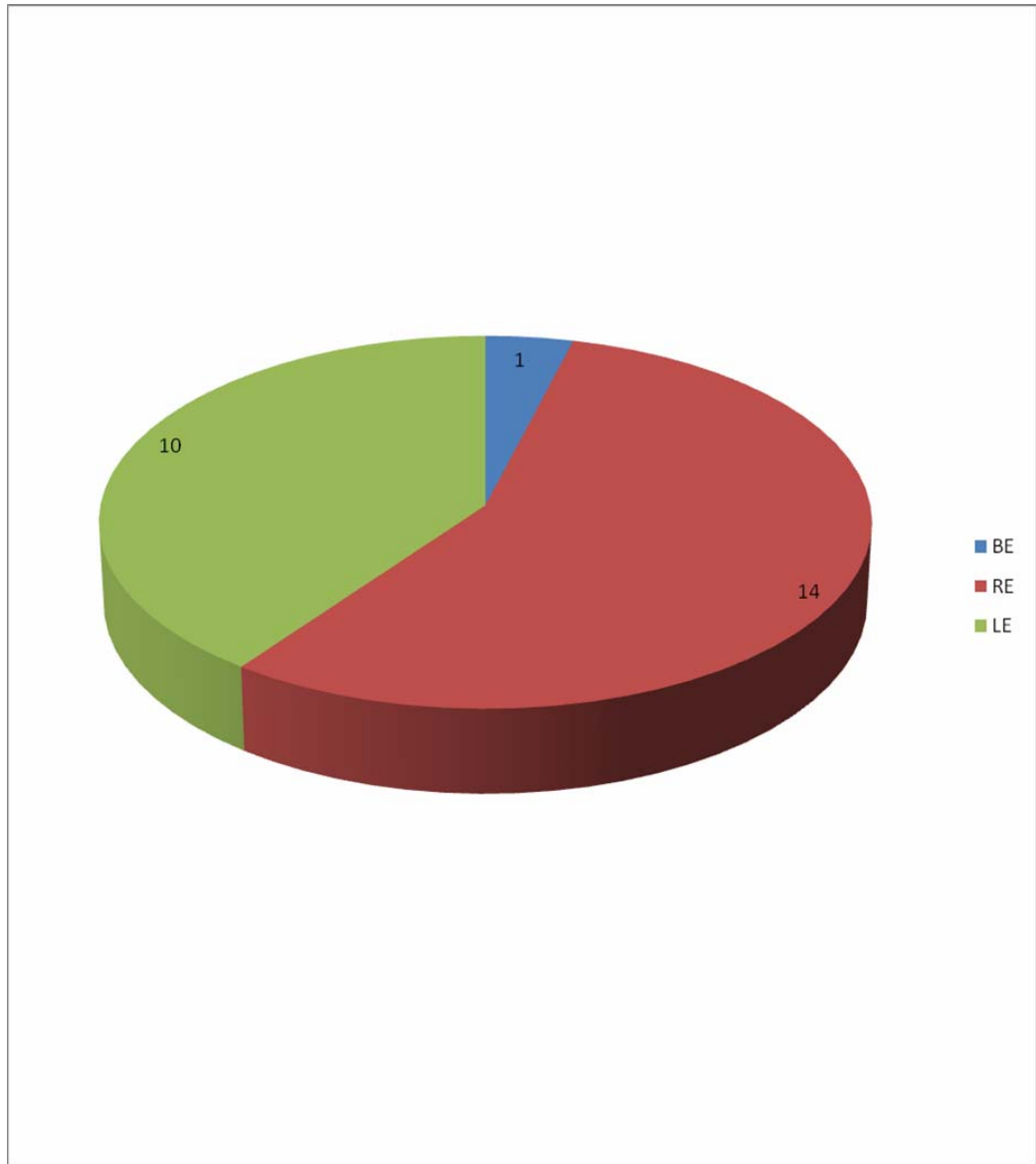
SEX	No of cases	% age
MALE	15	60
FEMALE	10	40

LATERALITY

Laterality	BE	RE	LE
No.	1	14	10
% age	4	56	40

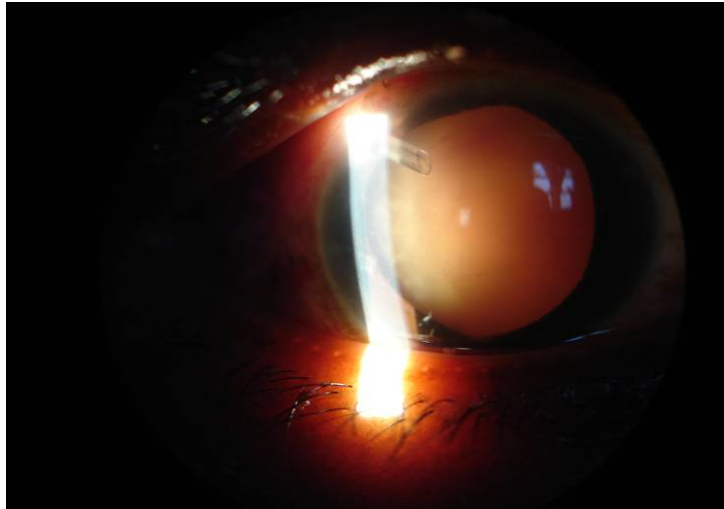


GENDER DISTRIBUTION

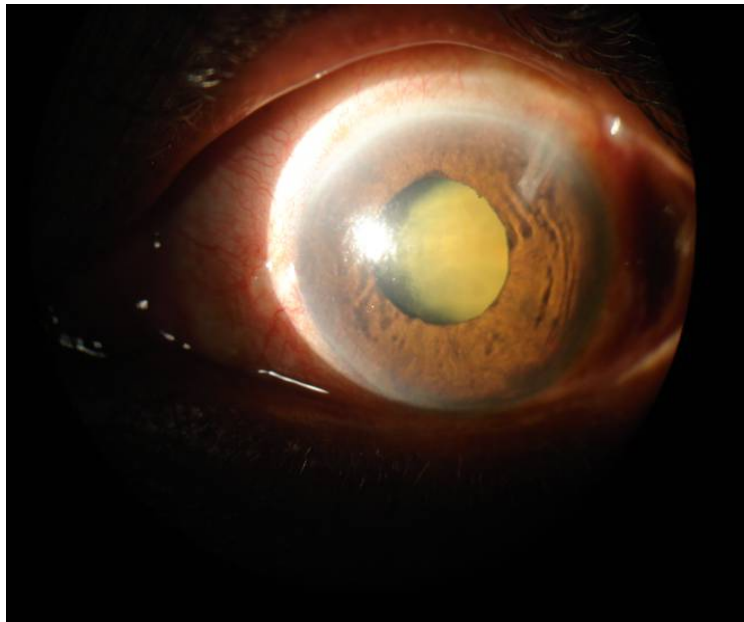


LATERALITY

**MEHTA VALVE IMPLANT IN A CASE OF POST
TRAUMATIC GLAUCOMA**



MEHTA VALVE IMPLANT IN A CASE OF NVG



RESULTS

Mehta valve implantation was done in 26 eyes of 25 patients during the 2 year study period between September 2006 & October 2008.

The male to female ratio was 2:1 & the mean age was 48.06(range 10-64 yrs).

The mean pre-operative IOP was 37.4mmHg.

Of the 26 eyes operated 18 were cases of Neovascular glaucoma. 1 was a case of post PKP glaucoma, 2cases were of post traumatic glaucoma, 2 were cases of failed trabeculectomy &2 (3eyes) were cases of post-inflammatory glaucoma.

In the immediate postoperative period IOP was recorded by Non Contact Tonometry.

21 patients had immediate postoperative IOP well within the desired range.

3 patients had minimal hyphema in the immediate postoperative period & the IOP was not recordable immediately but 1 week later the IOP was within the desired range.

1 patient had a persistent shallow anterior chamber with high IOP. The patient was taken up for surgical revision & the intumescent cataract was removed. The patient's IOP remained stable throughout the period of follow up.

Out of the 14 patients who had to come for followup after 18 months only 12 patients came for regular followup.

Out of the 12 cases one paediatric case of postinflammatory glaucoma had tube erosion & the valve was explanted.

The average follow up for all eyes ranged between 6mths to 2years. Four eyes were reviewed for 2 years. For three eyes the follow up was only for six months. Not all eyes were reviewed at every follow up period.

At the time of last follow up 23 eyes were considered successful. Of the 3 eyes that failed 1 eye was a Paediatric post inflammatory glaucoma, 1 eye was neovascular glaucoma & the other one was post traumatic glaucoma with failed trabeculectomy.

3 cases who had significant cataract were taken up for cataract surgery through clear corneal incision at a later date. There was no displacement of the tube or spike in IOP following surgery.

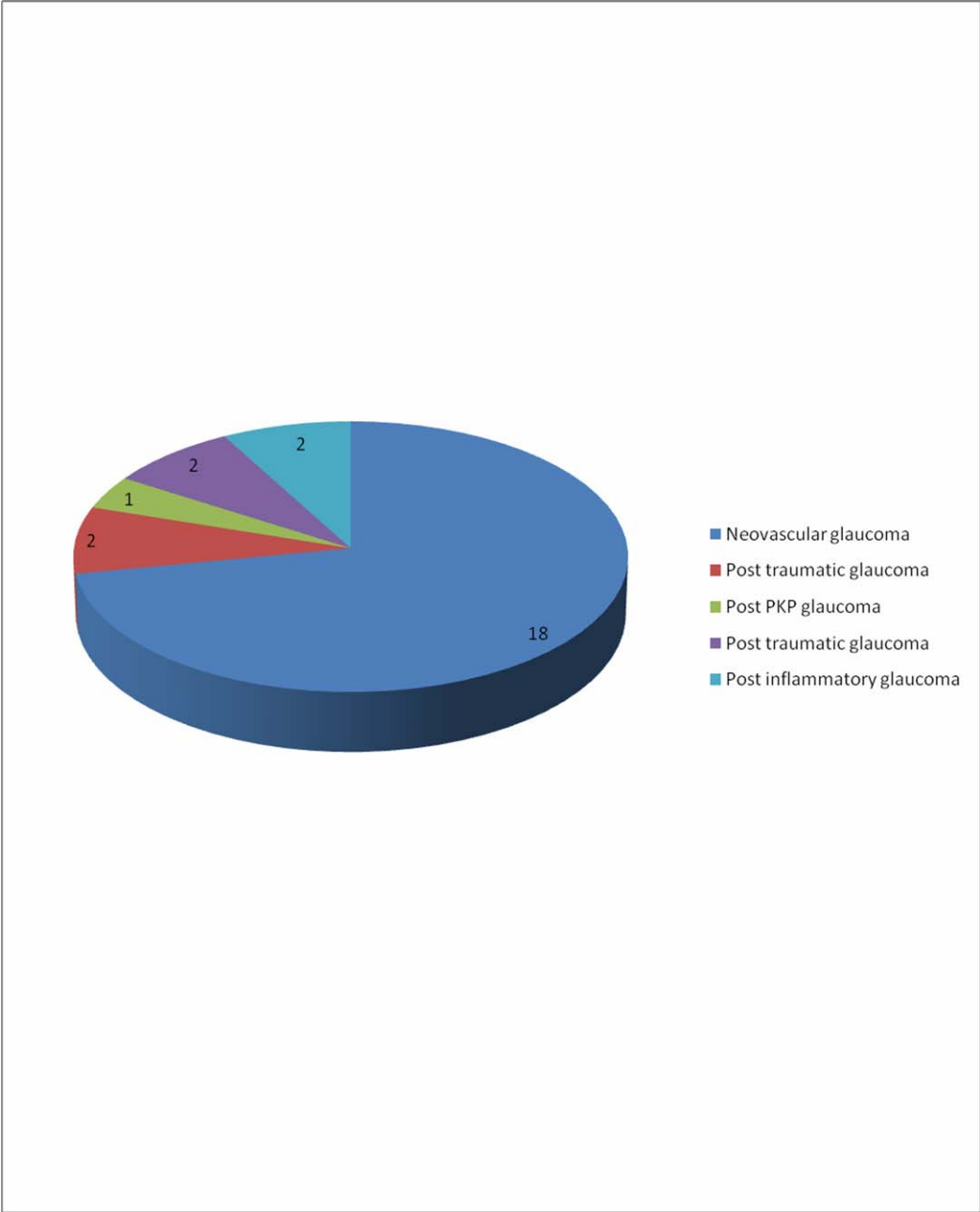
VISUAL OUTCOME

At the patient's last follow up visit, the visual acuity outcomes defined as a change of 1 or more Snellen lines was improved in 20%, an improvement in 1 metre observed in 20% & was unchanged in 60%.

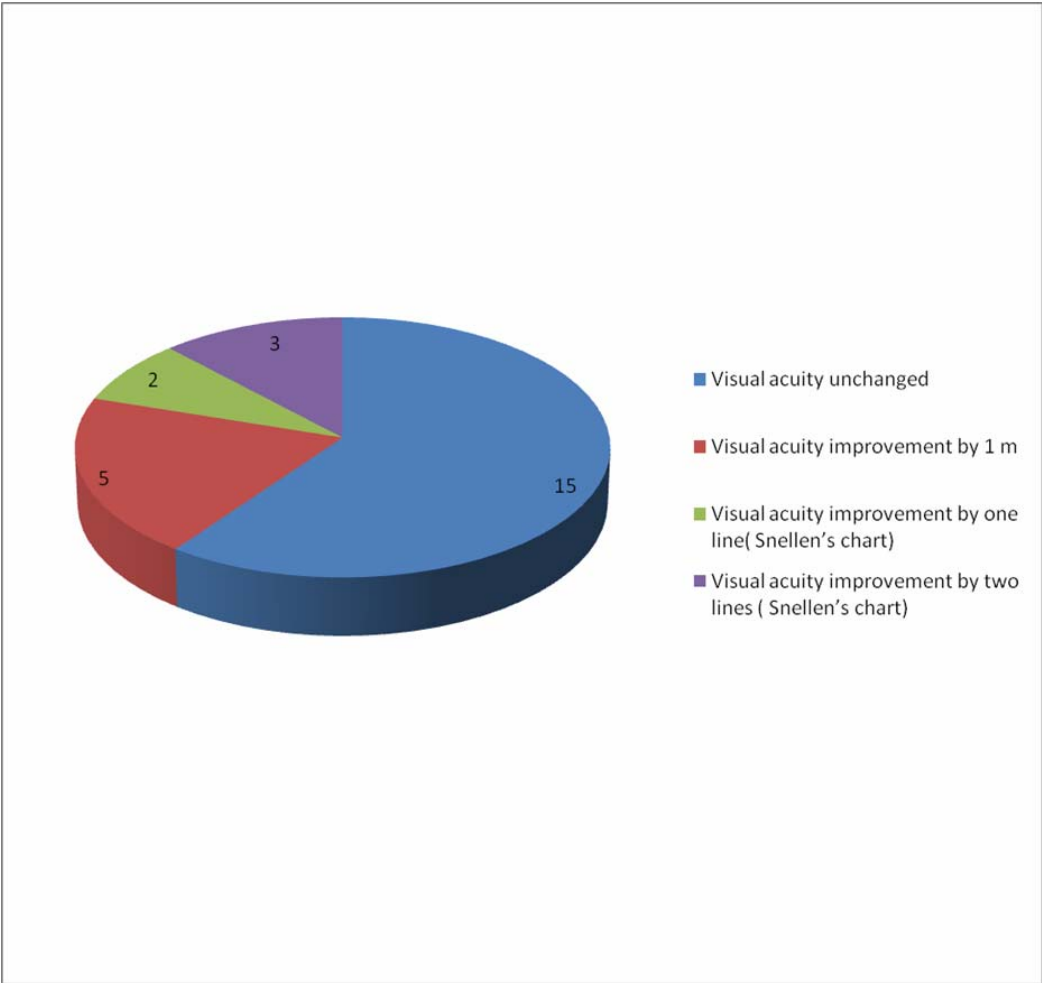
GLAUCOMA DIAGNOSIS	No. of Patients
Neovascular glaucoma	18
Post traumatic glaucoma	2
Post PKP glaucoma	1
Post traumatic glaucoma	2
Post inflammatory glaucoma	2

VISUAL OUTCOME

Post-op BCVA	No. of patients
Visual acuity unchanged	15
Visual acuity improvement by 1 m	5
Visual acuity improvement by one line(Snellen's chart)	2
Visual acuity improvement by two lines (Snellen's chart)	3

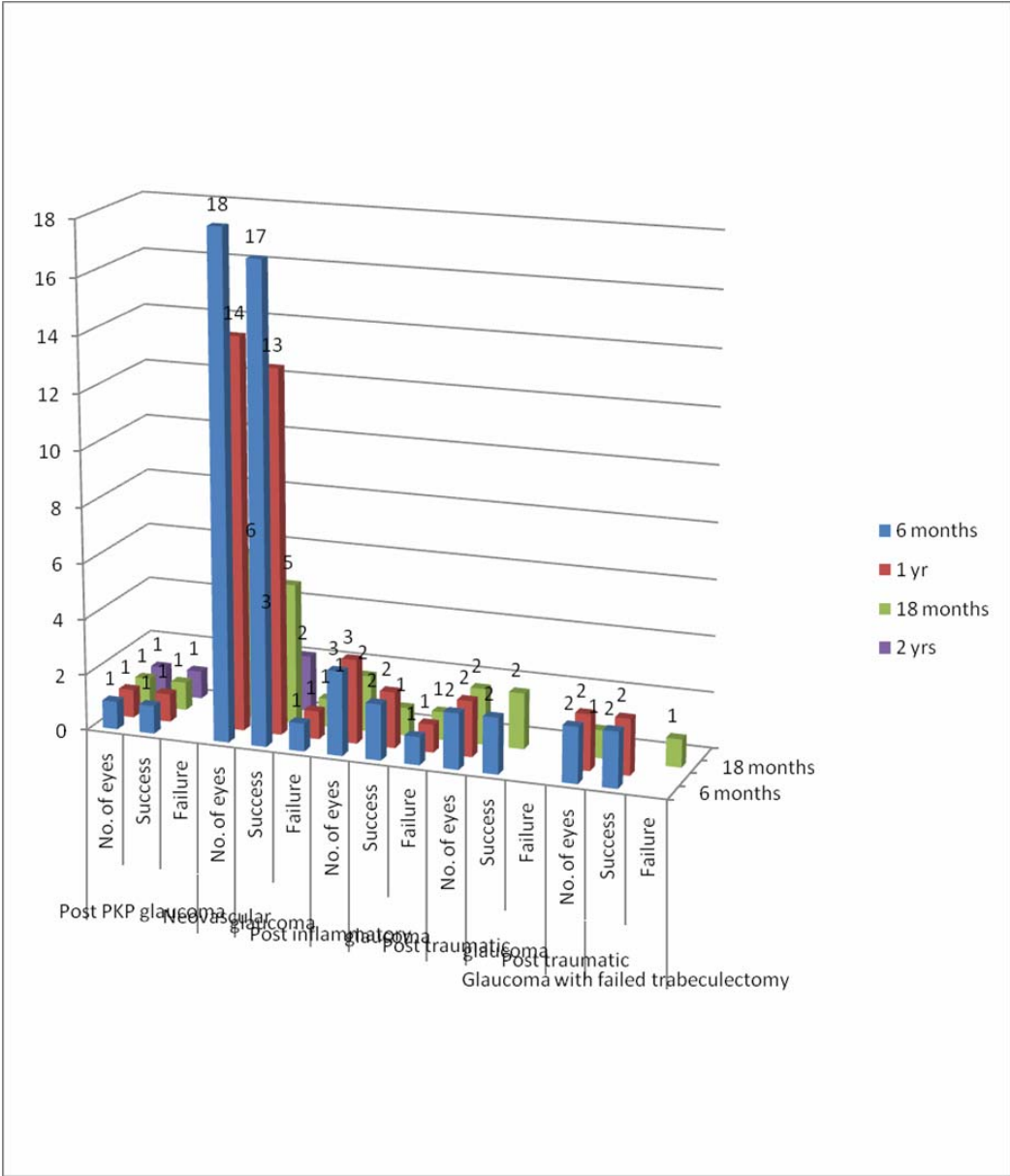


GLAUCOMA DIAGNOSIS



VISUAL OUTCOME

Glaucoma diagnosis	Follow up				
		6 months	1 yr	18 months	2 yrs
Post PKP glaucoma	No. of eyes	1	1	1	1
	Success	1	1	1	1
	Failure	-	-	-	-
Neovascular glaucoma	No. of eyes	18	14	6	3
	Success	17	13	5	2
	Failure	1	1	1	1
Post inflammatory glaucoma	No. of eyes	3	3	2	-
	Success	3	2	1	-
	Failure	0	1	1	-
Post traumatic glaucoma	No. of eyes	2	2	2	-
	Success	2	2	2	-
	Failure	-	-	-	-
Post traumatic Glaucoma with failed trabeculectomy	No. of eyes	2	2	1	-
	Success	2	2	-	-
	Failure	-	-	1	-



POST OPERATIVE FOLLOWUP

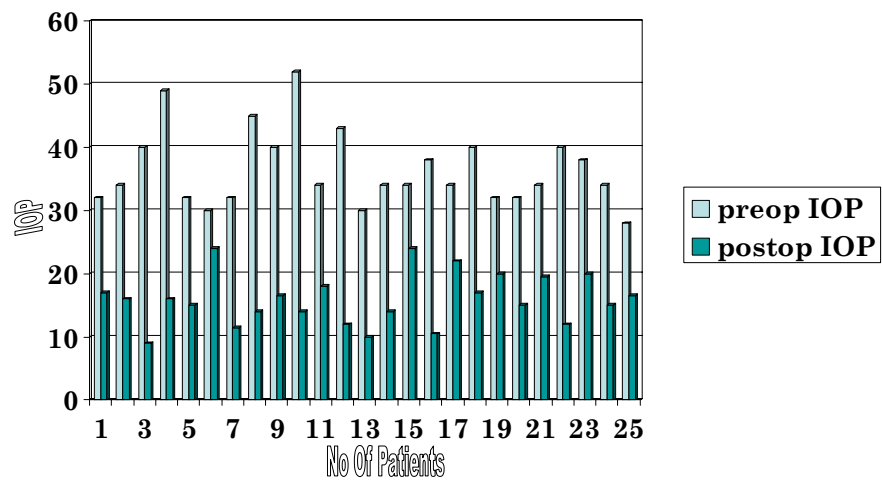
Complications

There were no intraoperative complications.

4 pts with NVG had post op hyphaema which resolved with conservative management.

Another patient who was diagnosed as RE NVG with mature cataract required surgical revision as the AC was very shallow postoperatively with high IOP. The cataract was removed through clear corneal incision and AC was reformed. The patient had stable IOP through out the period of follow up.

A paediatric patient diagnosed as a case of postinflammatory glaucoma underwent Mehta valve implantation in BE. He had erosion of tube through conjunctiva in RE after 15months & the shunt was explanted.



Comparison of Pre operative and post operative Intraocular pressure

DISCUSSION

Trabeculectomy despite recent modification and use of antiproliferative agents still fails to control intraocular pressure in some cases of refractory glaucomas. Remaining surgical options include cyclodestructive & drainage implant procedure.

Since the introduction of Molteno implant there has been a rapid advancement in the drainage devices used & improvement in the surgical techniques.

Studies with Ahmed valve reveals success rates of 77-88% at 1 year of follow up & 75% success rates at 2 years of follow up. However in paediatric population success rate is somewhat lower.

In the study group there was a significant reduction in the mean IOP following surgery which was sustained over the duration of follow up & was associated with the decrease in the number of glaucoma medications required.

There were no intra-operative complications. Only one case had displacement of the tube & conjunctival erosion. The partial thickness of the scleral tunnel used in this technique proved sufficient to prevent conjunctival dehiscence & tube exposure. The implant was secured nicely

between the two recti and hence extra ocular muscle function was not interrupted post operatively and there was no strabismus.

Using strict definition of success our qualified success rates are 96% for the first 6 months 90.9% for the first 1 year & 75% for the first 18 months.

Only 4 cases were followed up for 2 years & the success rate for the 2 year follow up period was 75%.

The mean pre-operative IOP was 37.4mmHg. The mean post-operative IOP at 1 year was 16.04, 17.7 at 18 months & 16.8 at 24 months including the failures.

Longer follow up is necessary to examine the long term course of the success rate. However previous studies suggest that longer follow up almost always leads to decrease of surgical success, whether the surgical procedure is glaucoma implant surgery, trabeculectomy or cycloablation.

CONCLUSION

In terms of IOP control Mehta implant was found to be good in patients with uncontrolled complicated glaucoma cases. The fall in IOP was sustained over the period of follow up.

It is a valved implant & hence it prevents post operative hypotony by providing resistance to the flow & therefore regulating the pressure within the desired range.

All cases were done without patch graft & tube was secured in the intra scleral tunnel.

In conclusion, Mehta valve implant is a simple & an effective device & it could be a good treatment option in intractable glaucomas. Nevertheless longer follow up is necessary to examine the long term course of the success rate.

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PROFORMA

SL.NO:

NAME:

GLAUCOMA CLINIC NUMBER:

AGE:

DATE :

SEX:

AFFECTED EY : PRESENT / ABSENT

HYPERTENSION : PRESENT / ABSENT

OCULAR EXAMINATION : DATE OF SURGERY:

Vision:

IOP by applanation:

POST OP PERIOD

Conjunctiva:

Cornea:

FOLLOW UP

AC:

IOP

Iris:

BCVA

Pupil:

Any Complication

Lens:

Gonioscopy:

Field:

Fundus:

B- Scan:

Diagnosis(Type of Glaucoma) :

INDEX TO MASTER CHART

1. BCVA : Best corrected visual acuity.
2. IOP : Intra Ocular Pressure.
3. PH : Pin Hole.
4. RE : Right Eye.
5. LE : Left Eye.
6. NVG : Neo Vascular Glaucoma.
7. PDR : Proliferative Diabetic Retinopathy.
8. ADED : Advanced Diabetic Eye Disease.
9. JCA : Juvenile Chronic Arthritis.

MASTER CHART

NO	NAME	AGE	DIAGNOSIS	PREOP BCVA & IOP (mmHg)	POSTOP BCVA & IOP (mmHg) 6month, 1 yr, 18 mon, 2yr
I	Madhava prabhu	52	Post PKP Sec.Glaucoma	6/60 with PH 6/36 IOP 32	6/36 with PH 6/18 16,18,18,16
2	Mohan	40	BE PDR with NVG LE	PL IOP 34	PL 16,17,17,19
3	Kumar	30	Penetrating injury with LE Glaucoma	CFCF IOP 40	1/60 8,10,9
4	Satyamoorthy	47	RE NVG	PL IOP 49	PL 16,17,17
5	Siva	56	LE NVG	5/60 IOP 32	6/60 NIG NIP 14,16,15,20
6	Kantha	60	RE NVG	6/60 NIP IOP30	6/36 NIP 20,21,22,30
7	Chinthamani	55	BE PDR with LE NVG	HM IOP 32	HM 12,11
8	Penicillammal	60	RE Mature CataractwithNVG	PL IOP45	PL 15,16,16 Vn 6/60 (post cat. surg.)
9	George Clive	44	RE NVG	5/60 with PH 6/60 IOP 40	6/60 with PH 6/36 20,17,15,14
10	Beevi	60	RE immature Cataract with NVG	PL IOP 52 Post cataract surg	Shallow AC IOP 40 6/60, IOP 14
11	Dayalan	60	LE NVG	HM IOP 34	1/60 20,16
12	Sundaram	58	BE PDR With LE NVG	5/60 NIP IOP43	6/60 NIP 11,12,12
13	Sivaji	30	Blunt injury RE with Resolved Vit Hg. With Glaucoma	PL IOP 30	PL 9,10,10
14	Kuruvammal	64	RE NVG	4/60 IOP 34	6/60 14,14

15	Ashiq	10	BE – JCA with Pan-Uveitis with post infl Glaucoma BE	1/60 NIP BE IOP 34 RE 30 LE	1/60 NIP 12,20,24, 12,12,14
16	Duraisamy	59	LE ADED with NVG	HM IOP 38	HM 12,10
17	Kondaiah	44	Post traumatic glaucoma with failed trabeculectomy	6/60 IOP34	6/36 14,20,30
18	Mariammal	65	NVG RE	PL IOP 40 Post cataract surg	6/60 21,17
19	Raja	30	Post infl. glaucoma	6/60 IOP 32	6/24 21,20
20	Subramani	56	LE NVG	6/60 IOP 32	6/60 14,16
21	Chandrasahsan	45	Post traumatic glaucoma with failed trabeculectomy	5/60 NIP IOP 34	6/36 NIP 22,17
22	Senthamarai	58	BE PDR with LE NVG	HM IOP 40	HM 12, 11 (3, 6 months)
23	Kuruvammal	60	LE NVG	HM IOP 38	HM 20,20 (3, 6 months)
24	Baby	60	RE NVG	6/60 IOP 34	6/36 14,16 (3, 6 months)
25	Muniammal	60	RE NVG	PL IOP 28	PL IOP 16, 17 (3, 6 months)

LIST OF FEW SURGERIES PERFORMED

SL No	Name	Age	Sex	IP/OP NO	Diagnosis	SURGERY
1.	Raman	53	M	68004	LE-Mature cataract	LE-ECCE/PCIOL
2.	Mani	57	M	413926	LE-Nuclear Cataract	LE-SICS/PCIOL
3.	Kumar	62	M	65837	RE-Immature Cataract	RE-ECCE/PCIOL
4.	Vimala	73	F	424520	RE-PACG	RE-Trabeculectomy
5.	Kantha	52	F	413348	RE-Immature Cataract	RE-SICS/PCIOL
6.	Ganesan	65	M	426626	LE-Secondary angle closure Glaucoma	LE-Combined Surgery
7.	Komala	35	F	411184	LE-Conjunctival tear	LE-Conjunctival Suturing
8.	Pushpa	18	F	69004	RE-Pterygium	RE-Excision/Autograft
9.	Natarajan	27	M	41234	LE-Rupture Globe	LE-Corneoscleral suturing
10.	Thangaraj	61	M	416599	RE-Panophthalmitis	RE-Evisceration
11.	Valli	28	F	64287	RE-Lower lid Chalazion	RE-Incision and curettage
12.	Kesavan	73	M	68905	LE-Pterygium	LE-Pterygium Excision/Autograft
13.	Ganesh	45	M	56432	RE-Chronic dacrocystitis	RE-DCT
14.	Thulasi	62	F	62346	RE-Nuclear Cataract	RE-ECCE/PCIOL
15.	Rajesh	43	M	65749	RE-Chronic dacrocystitis	RE-DCT
16.	Jagadambal	56	F	15281	LE-Immature Cataract	LE-SICS/PCIOL
17.	Kavitha	54	F	17865	LE-Immature Cataract	LE-SICS/PCIOL
18.	Hariharan	76	M	69045	LE-Chronic dacrocystitis	LE-DCT
19.	Ramanathan	34	M	564781	RE-Lowerlid granuloma	Excision
20.	Kulesekar	48	M	45367	RE-Pterygium	RE-Pterygium Excision/Autograft
21.	Kala	52	F	456390	RE-Immature Cataract	RE-SICS/PCIOL
22.	Ramiah	65	M	421184	LE-Mature cataract	LE-ECCE/PCIOL
23.	Chidambaram	64	M	60897	RE-Chronic dacrocystitis	RE-DCT