

**INDICATIONS AND OUTCOMES OF AHMED GLAUCOMA VALVE  
IMPLANTS IN KENYA**

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**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF  
DEGREE OF MASTERS IN MEDICINE (OPHTHALMOLOGY), UNIVERSITY OF  
NAIROBI**

**DECLARATION:**

THIS DISSERTATION IS MY ORIGINAL WORK AND HAS NOT BEEN PRESENTED FOR A DEGREE IN ANY OTHER UNIVERSITY.

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## **DEDICATION**

This work is dedicated to my family for their overwhelming support and encouragement throughout the years as I studied for this ophthalmology degree.

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**LIST OF ABBREVIATIONS:**

IOP-----Intraocular pressure  
OD -----Right eye  
OS----- Left eye  
AC-----anterior chamber  
LTP-----Laser trabeculoplasty  
NVG ---Neovascular glaucoma  
OAG ---Open angle glaucoma  
ACG----Angle closure glaucoma  
POAG--Primary open angle glaucoma  
GDD ---Glaucoma drainage device  
CCT ----Central corneal thickness  
BCVA --Best corrected visual acuity  
CAI-----Carbonic anhydrase inhibitors  
D -----Dioptres  
OHTS --Ocular Hypertension Treatment Study  
ONH ---Optic nerve head  
PGA----Prostaglandin analogues  
ON -----Optic nerve  
CIGTS--Collaborative initial glaucoma treatment study  
TET-----Trabeculectomy  
SD-----Standard deviation  
AGV----Ahmed glaucoma valve  
RD-----Retinal detachment  
PK -----Penetrating keratoplasty  
BGI-----Baerveldt glaucoma implant  
LogMAR-Logarithm Mean Angle of Resolution  
CDR ----Cup disc ratio  
VA-----Visual acuity



MSD ---Mean standard deviation

PSD ----Pattern standard deviation

HVF ----Humphrey's visual field

AKUH--Aga Khan University Hospital

KNH----Kenyatta National Hospital

SPSS ---Statistical Package for Social Scientist

## **ABSTRACT**

**Title:** Indications and outcomes of Ahmed glaucoma valve implants in Kenya.

**Objective:** To establish the indications, efficacy in control of intraocular pressure, complications and need for additional anti-glaucoma medication and surgery after Ahmed glaucoma valve implantation.

**Design:** Retrospective case series

**Setting:** The study was conducted in various institutions in Kenya where Ahmed valve implants are used as surgical therapy for control of intraocular pressure. These were: KNH, Kikuyu Eye Unit and Tenwek Mission Hospital.

**Subjects:** All adults and children who had undergone Ahmed glaucoma valve implantation between 2006 and 2012.

**Outcome measures:** This comprised of the mean intraocular pressure, use of additional anti-glaucoma drugs post-operatively, surgical complications and the need for additional surgery.

**Results:** A total of 50 records were reviewed. The male to female ratio was 3:2. Majority of the patients were in the 0 to 10 year age group. The age range was 2 to 83 years. The mean pre-operation IOP was 42.50 mm/Hg with a range of 21 to 63mm/Hg. Failed trabeculectomy was the most common indication of AGV implantation (20%). Four percent of all the patients had Ahmed valve surgery as the primary surgery. Paediatric glaucoma was the indication for surgery in 16% of the patients. There was a statistically significant reduction in the mean IOP after surgery throughout the follow-up period. On the first day after surgery the mean intraocular pressure reduced to **17.5mm/Hg** from a mean IOP of **42.50mm/Hg** before surgery. Sixty four percent of the patients were not on any glaucoma medication on the first post-operative day. The most common complication noted was hypotony, seen in four patients in the first day after surgery and in one patient in the first year of follow-up.

**Conclusion:** The most common indication for AGV use in Kenya was failed trabeculectomy. Other common indications were primary congenital glaucoma and neovascular glaucoma. Good IOP control was achieved with the AGV in patients who had uncontrolled glaucoma with the use of conventional medical therapy. There was a statistically significant reduction in the number of

anti-glaucoma medication used after surgery. Hypotony was the most common complication noted, whereas endophthalmitis was the most serious complication.

## **1.0 INTRODUCTION**

Glaucoma is an eye disease that leads to damage of the optic nerve. Left untreated, glaucoma can lead to permanent damage of the optic nerve, visual field loss and eventually progress to blindness. The loss of vision occurs gradually over a long period of time. Symptoms only occur when the disease is advanced. Once vision is lost, it cannot be recovered. Treatment is aimed at preventing further visual loss. Regardless of the IOP, the presence of glaucoma is defined by specific optic disc changes and characteristic visual field defects.

### **CLASSIFICATION OF GLAUCOMA**

Glaucoma is generally classified as primary or secondary. By definition, the primary glaucoma's are not associated with known ocular or systemic disorders that cause increased resistance to aqueous outflow or angle closure. Conversely the secondary glaucoma's are associated with ocular or systemic disorders responsible for decreased aqueous outflow.

Glaucoma can also be classified as open angle or closed angle. Open angle glaucoma is classified as primary when an anatomically identifiable underlying cause of the events that lead to outflow obstruction and IOP elevation cannot be found. Glaucoma is classified as secondary when an abnormality is identified which leads to outflow obstruction and IOP elevation. Childhood glaucoma is further divided into primary congenital or infantile glaucoma which is evident at birth or within the first few years of life. Secondary infantile glaucoma is associated with inflammatory, neoplastic, hamatomatous, metabolic or other congenital abnormalities. Primary juvenile glaucoma is recognized later in childhood or early adulthood.

## **1.1 EPIDEMIOLOGICAL ASPECTS OF GLAUCOMA**

Glaucoma is a leading cause of blindness worldwide. It is the second leading cause of blindness globally.<sup>1</sup> It was estimated in 2010 that 60.5 million people had OAG and ACG. This is expected to increase to 79.6 million by 2020 of which 74% will have OAG.<sup>2</sup> In 2010 women comprised 55% of OAG, 70 % of ACG & 55% of all glaucoma. It is also estimated that by 2020 Asians will represent 47 % of those with glaucoma and 87 % of those with ACG<sup>2</sup>. By 2010 bilateral blindness was present in 4.5 million people with OAG and 3.9 million people with ACG. This is expected to rise to 5.9 and 5.3 million people respectively by 2022.<sup>2</sup>

## **1.2 MANAGEMENT OF GLAUCOMA**

The role of glaucoma therapy is to preserve visual function by lowering the IOP below a level that is likely to produce further damage to the optic nerve. The treatment regimen which achieves this goal with the lowest risk, fewest side effects and least disruption of the patient's life, taking into account the cost implications of treatment should be the one employed. An individualized target IOP should be set based on the IOP at which damage is thought to have occurred, the severity of the damage, the life expectancy and associated factors. The aggressive target IOP is meant to minimize the risk of progressive glaucoma damage and vision loss. The target pressure range needs to be constantly reassessed and changed as dictated by IOP fluctuations, optic nerve changes and visual field progression. Consistently lower IOP results in a reduced risk of progressive glaucoma damage.

## **1.3 MEDICAL MANAGEMENT OF GLAUCOMA**

Several groups of ocular hypotensive agents are in use for the treatment of glaucoma. They include:

- Prostaglandin analogues
- Adrenergic antagonists (selective and non – selective )
- Parasympathetic agents (miotics )
- Carbonic anhydrase inhibitors
- Adrenergic agonists (selective and non – selective )
- Hyperosmotic agents
- Combined medications

Medical therapy is tailored to the individual needs of the patient. These drugs have different mechanisms of action and Vary in their potency of lowering the IOPs. In the OHTS, ocular hypotensive medication was found to be effective in delaying or preventing the onset of POAG in individuals with high IOP & no evidence of glaucomatous damage<sup>3</sup>.

## **1.4 SURGICAL THERAPY FOR GLAUCOMA**

Surgical therapy for glaucoma is usually undertaken when medical therapy is not effective, not appropriate, not tolerated, not properly utilized by a patient (poor compliance) or when the glaucoma remains uncontrolled with progressive damage.

Surgery is usually the primary approach for both congenital glaucoma & pupillary block glaucoma. In patients with POAG; surgery has traditionally been considered when medical therapy has failed.

Results from the Collaborative Initial Glaucoma Treatment Study (CIGTS) confirmed that initial surgical therapy achieved better IOP control than initial medical therapy. However early visual acuity loss was greater in the surgery group and the rate of cataract removal was also greater in the surgically treated group <sup>4</sup>.

Based on the CIGTS, most clinicians defer surgery after an attempt is made to treat with medical therapy. The surgical options available depend on whether the patient has open angle or angle closure glaucoma. Incisional surgery options for OAG include; Trabeculectomy with use of antifibrotic agents such as Mitomycin C, or 5 – Fluorouracil. Surgery options for Angle closure include; laser iridectomy or peripheral iridoplasty. Other procedures that lower IOP include:

- Aqueous shunt implantation
- Ciliary body ablation
- Cyclodialysis
- Visco canalostomy

## **1.5 AQUEOUS SHUNT IMPLANTS / GLAUCOMA DRAINAGE DEVICES**

These devices have a tube placed in the anterior chamber so that aqueous flows out through the device to an external reservoir on the sclera. They create an alternate aqueous pathway from the AC by channeling aqueous out of the eye through the tube to a subconjunctival bleb or to the suprachoroidal space. The tube is usually connected to an equatorial plate under the conjunctiva.

## **1.6 HISTORY OF GLAUCOMA DRAINAGE DEVICES**

In 1906 Rollet and Moreau attempted to drain fluid out of the AC into the subconjunctival space at the limbus by implanting a silk thread connecting the AC to the subconjunctival space. Other unsuccessful attempts were made by Epstein in 1959 who inserted a polythene tube and by Macdonald and Pearce in 1965 who inserted a silicone tube. Failure of these operations was attributed to excessive scar formation at the limbus.

In 1973 Molteno created an implant which would drain fluid away from the limbus. To increase the success rate, he then introduced the Molteno implant with a long silicone tube attached to a large endplate placed 9-10 mm posterior to the limbus.

In 1976 Molteno conducted a study where he described the operative technique of inserting the long tube implant. He then looked into the results and complications of the implants<sup>5</sup>. All the currently available GDDs are based on this concept by Molteno. Since the Molteno implant two major concepts have been introduced to modify the GDDs. The first approach was the introduction of a valve to offer resistance to outflow hence reducing the incidence of post-operative hypotony. In 1976 Krupin developed a pressure sensitive unidirectional valve which provides resistance to the flow of aqueous and therefore prevents hypotony.

In 1993 Ahmed introduced the Ahmed Glaucoma Valve which is a pressure sensitive unidirectional valve which is designed to open when IOP is 8 mm/Hg.

The second modification occurred after the realization that an increased surface area of the end plate increased the surface area of drainage and this subsequently resulted into lower IOPs. In 1981 Molteno introduced the double plate implant. Baerveldt on the other hand introduced a non-valved silicone tube attached to a large barium impregnated silicon plate.

In 1992 Freedman J et al conducted a study to look at the clinical experience with the Molteno dual chamber single plate implant which is a modification of the single plate Molteno implant.



The modified implant was found to have reduced post-operative hypotony. It also eliminated choroidal haemorrhage and reduced IOPs<sup>6</sup>.

## **1.7 CLASSIFICATION OF GLAUCOMA DRAINAGE DEVICES**

GDDs differ in their surface area, materials and flow resistance. However all drainage devices are made out of materials to which fibroblast cannot adhere. The materials used to manufacture these devices should be non-toxic, non-immunogenic and chemically inert. Elastomeric silicone is the most commonly used material but polypropylene and PMMA are also used. These materials have a high binding for plasma and interstitial fluid proteins such as albumin, fibrinogen and IgG.

GDDs are generally classified into:

- Devices with no resistance to aqueous flow
- Devices with resistance to aqueous flow
- Devices with variable resistance to aqueous flow

The GDDs with no resistance to aqueous outflow consist of a silicone tube attached to an end plate which acts as a surface for bleb formation. They lack valves to regulate the aqueous outflow. They rely on a fibrous bleb which is formed on the end plate to provide sufficient resistance to outflow and control the IOP. The size of the end plate; the surface area and the thickness of the fibrous bleb determine the amount of resistance in the device. A small surface area and a thick fibrous bleb will cause a great amount of resistance and therefore a lower IOP. These devices are associated with an increased incidence of over filtration since there is no resistance to aqueous outflow. These can lead to hypotony, shallow-flat AC and choroidal effusion. Various modifications have been put into place to reduce the complication of hypotony in non valved devices. A Suture can be passed through the lumen of the implant. Once the fibrous capsule around the plate is formed, the stent suture is removed. A suture can also be placed around the external aspect of the tube or slits created anterior to the suture therefore allowing immediate IOP control in the early post-operative period. Non-valved implants do not work until approximately six weeks after surgery when the sutures dissolve. Patients therefore continue with their glaucoma medication. Once the tube opens and the IOP reduces the medication is discontinued.

Examples of devices without resistance include:

- The single and double plate implant – in the double plate implant a second end plate is attached to the right or left of the original end plate therefore doubling the surface area.
- The Baerveldt implant – this implant was developed to provide easy placement of a large endplate in a single quadrant, it's usually placed under the rectus muscle and this has been found to promote fibrous encapsulation which can result to diplopia.
- The shocket implant – this is another non valved device which is not commonly used. One end of this implant is inserted into the AC and the other end is tucked under the rectus muscle with a retinal encircling band.
- The Express R 50 implant – comprises of a 3mm long tube with a penetrating tip with 3 side orifices and a spur like projection to prevent extrusion.

The GDDs with set resistance comprise of valved devices which as the name suggests offer resistance to aqueous outflow. They contain an internal mechanism to control the outflow of aqueous humor. They are designed so that fluid is not able to drain through the shunt unless a minimum IOP is reached. Once the threshold IOP is reached, the device allows aqueous humor to flow through it and control the patients IOP. This mechanism helps to prevent hypotony. The most commonly used valved devices are the Ahmed Glaucoma Valve Implant and the Krupin valve.

The AGV consists of a plate(s) made of silicone or polypropylene, a drainage tube and a valve. Polypropylene implants are radiation resistant. A study done by Ishida K et al, evaluated and compared clinical outcomes after the implantation of silicone and polypropylene plate AGVs. The success rate of the silicone implant was 94.2% and 83.2% for polypropylene at 12 months of follow-up and 82.4% and 56.7% at 24 months of follow-up. IOP reduction of 30% which was used as the success criterion was 89.5% and 71.7% for the silicone and polypropylene implants respectively at 12 months of follow-up. However tenons cyst complication was commonly seen with the polypropylene implant<sup>7</sup>. This study indicates that the material from which an implant is made plays a big role in determining the outcome. The silicone implant is commonly available and it is therefore used more than the implant made of polypropylene. The inlet cross section of the chamber is wider than the outlet hence resulting to a pressure difference between the AC and the bleb. It's designed to open when the IOP is 8 mm/Hg. When the IOP is too high the valve

opens letting fluid flow out of the eye through the drainage tube. The valve automatically closes when the pressure is normal again.

### **The Ahmed valve**



### **1.8 MECHANISMS OF FLOW THROUGH THE VALVE**

Aqueous humour from the AC flows through the tube into the trapezoidal chamber within the plate element. The plate allows the valve to open at a specific IOP. As the aqueous humor flows into the plate it increases the IOP. Once the IOP reaches the preset threshold of 8mm/Hg the valve opens lowering the IOP. Tension in the silicone membrane helps to reduce hypotony by closing after the pressure has reduced and reached the normal level again. The AGV is the commonly used GDD. It is preferred due to the low incidence of hypotony, increased success rates with all types of glaucoma, it requires a single staged implantation procedure, few sutures are needed and there is MRI compatibility.

## 1.9 INDICATIONS FOR THE USE OF GLAUCOMA DRAINAGE DEVICES

These devices are generally reserved for cases in which conventional filtering surgery has failed or is likely to fail. These devices are recommended as a last resort procedure. They should be considered in the following clinical settings:

- Failed trabeculectomy with antifibrotic. Trabeculectomy may fail in patients who have undergone previous eye surgery resulting into conjunctival scarring.
- Prolonged use of anti-glaucoma medication may have an adverse effect on the conjunctiva by leading to a proliferation of lymphocytes and fibroblasts which decreases the likelihood of successful filtration surgery.
- Patients with ocular surface disease such as acne rosacea are also at risk of failed filtration surgery due to conjunctival scarring and therefore failed blebs. These patients should therefore be considered for glaucoma drainage devices.

Various studies have been done to compare the outcomes of Trabeculectomy and GDDs. In the treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after 5 years of follow-up, the tube shunt was reported to have a higher success rate compared to trabeculectomy with MMC during 5 years of follow-up. The mean IOP in GDDs was 14.4 $\pm$ 6.9, for the TET group it was 12.6 $\pm$ 5.9 mm/Hg. The cumulative probability of failure during 5 years of follow-up was 29.8% for GDDs and 46.9% for TET. The rate of reoperation was 9% in GDDs and 29% in TET<sup>7</sup>. GDDs have also been useful for the treatment of Neovascular glaucoma (NVG). This type of glaucoma develops when new and abnormal blood vessels begin developing in the angle of the anterior chamber hence blocking drainage. This uncommon type of glaucoma is usually caused by proliferative diabetic retinopathy (PDR), central retinal vein occlusion (CRVO), or by conditions that lead to ischemia of the retina or the Ciliary body. Eyes with NVG are at increased risk of TET failure. These implants are therefore an alternative surgical procedure in NVG and are effective in those patients with visual potential<sup>8</sup>. GDDs give an improved mean IOP for these patients. However the visual outcomes may be poor and there is greater risk of surgical failure due to progression of the underlying disease.

Uveitic glaucoma is also an indication for the use of the tube shunts. This type of glaucoma is a common complication of uveitis. The pathogenesis may be acute in onset due to rapid onset inflammation resulting into obstruction of the intertrabecular spaces and high IOPs. It may also be chronic with repeated bouts of uveitis leading to fibroblastic inflammation and scar tissue

formation within the trabecular meshwork which obstructs aqueous outflow. The high IOPs in uveitic glaucoma may also be secondary to corticosteroids which are used for the treatment of uveitis.

Surgery for uveitic glaucoma is reserved for refractory cases not responding to maximal medical therapy and for cases of acute angle closure. Surgery is best avoided during the acute inflammatory phase. Treatment of inflammatory glaucoma is complicated. Conventional medical therapy with steroids may exacerbate the inflammation and further elevate the IOP. GDDs have been found to be effective in lowering IOP and reducing the number of antiglaucoma medication. Mike Bartolatz studied the long term results of AGV implantation for uveitic glaucoma where he found the valve to be a safe yet moderately successful procedure for uveitic glaucoma. The IOP reduction was found to be 25% and 74% of the patients' required anti-glaucoma medication after 4 years of followup<sup>9</sup>.

Post-Penetrating Keratoplasty glaucoma is an important cause of irreversible visual loss and graft failure. An increase in IOP at any time after PK leads to a significant endothelial cell loss with dire consequences as the endothelial reserve is already low. Post PK glaucoma is defined as an elevated IOP greater than 21mm/Hg with or without associated visual field loss or ON head changes. Pathophysiology of post PK glaucoma is multifactorial. It may be related to distortion of the angle with collapse of the trabecular meshwork, formation of peripheral anterior synechiae resulting into outflow obstruction, postoperative inflammation or the use of steroids. Risk factors for glaucoma in patients undergoing PK include; combined PK and cataract surgery, performance of vitrectomy during PK, adherent leukoma, perforated corneal ulcer, mesodermal dysgenesis or preexisting glaucoma. A Study by Karadag et al on the incidence of and risk factors for raised IOP after PK found the common risk factors to be pre-operative diagnosis of inflammatory disease, peripheral anterior synechiae, preoperative glaucoma and additional surgery combined with PK<sup>10</sup>.

Drainage implants are increasingly being used for the management of paediatric glaucoma which is often refractory to conventional medical and surgical therapy. The prognosis of paediatric glaucoma depends on early, accurate diagnosis, successful control of IOP, treatment of associated ocular abnormalities and prevention of amblyopia. The pathogenesis is thought to be due to trabecular dysgenesis as a result of the Barkans membrane or deposition of collagen leading to outflow obstruction. Coleman et al evaluated the AGV implant in paediatric glaucoma

cases and reported the cumulative probability of success at 12 and 24 months to be 77.9% +/- 8.8% and 60.6 +/- 13.7 respectively<sup>11</sup>.

Aphakic glaucoma is another indication for the use of tube shunts. This type of glaucoma develops months or years after cataract surgery in children and it's a major long term complication. The risk factors for aphakic glaucoma include; micro-cornea, early surgery, persistent fetal vasculature, congenital rubella, retained lens material<sup>12</sup>.

Kirwan et al found that the AGV alone or in combination with medical therapy is successful and safe in the management of aphakic glaucoma. In his study<sup>12</sup> of the children achieved IOP control of 15mm/Hg or less with a valve alone or with additional medical therapy<sup>13</sup>.

Elevated IOP is a frequent occurrence after trauma to the eye. It may occur early (acute) with or without hyphema or it may occur late (chronic) with or without angle recession. A study by Jitendra K S on the efficacy of AGV in cases of refractory glaucoma in Indian eyes comprised of 12 cases of refractory glaucoma secondary to trauma amongst other causes. The mean IOP reduced from 36.3 +/- 15mm/Hg to 19.6 +/- 9.2. None of the eyes had failure of the implant in terms of IOP control. The number of medication used also reduced significantly<sup>14</sup>.

Keratoprosthesis is a surgical procedure where a severely damaged or diseased cornea is replaced with an artificial cornea which is made of clear plastic and has excellent optical properties. This has found its use in patients with failed corneal transplant, patients with congenital birth defects or autoimmune disease. Glaucoma is a serious complication of Keratoprosthesis. GDDs have been useful in the control of glaucoma that is secondary to this surgery. A study by Netland PA found that IOP was controlled in 29 (81%) of the eyes while 9 eyes (25%) required additional medication<sup>15</sup>.

Glaucoma may occur after retinal detachment surgery. If it occurs directly after the operation it could be due to an encircling band, torsion of the Ciliary body or Ciliary block or serous detachment of the choroid from the use of diathermy. The use of silicone oil has also been shown to cause glaucoma after RD surgery; this may be as a result of pupil block. GDDs have become the primary operation in glaucoma after RD surgery<sup>16</sup>.

Iridocorneal Endothelial syndrome (ICE syndrome) is a unique disorder which involves irregular corneal endothelium which can lead to varying degrees of corneal edema, iris atrophy and secondary angle closure glaucoma. The altered endothelium is thought to migrate posteriorly where it contracts to give peripheral anterior synechiae which give angle closure. The drainage

devices have been mentioned as a successful surgical intervention although there is a paucity of literature to support this.

Epithelial ingrowth is also a cause of glaucoma. This is whereby the AC is infiltrated by an ingrowth of the epithelium therefore causing outflow obstruction. A study by Kuchlem et al found the main causes of epithelial ingrowth to be penetrating trauma (48 eyes), cataract surgery (123 eyes) and keratoplasty (21 eyes). Among the patients with epithelial ingrowth 43.1% presented with glaucoma<sup>17</sup>. GDDs have been mentioned as a surgical intervention for this cause of glaucoma however no study has been done on its effectiveness.

### **CONTRAINDICATIONS OF GLAUCOMA DRAINAGE IMPLANTS**

There are no known absolute contraindications for implantation of GDDs. The devices have a complicated postoperative course. Relative contraindications are for patients who are not able to comply with self-care in the post-operative period. Borderline corneal endothelial function is also a relative contraindication for anterior placement of a tube because it may worsen after glaucoma drainage implant surgery and result into chronic corneal oedema.

### **COMPLICATIONS OF GLAUCOMA DRAINAGE DEVICES**

The glaucoma drainage devices can be associated with various complications. The early postoperative complications are hypotony, flat AC and suprachoroidal haemorrhage. Hypotony and its related sequelae are more common with non valved implants. Valved implants reduce but do not eliminate hypotony.

Tube related problems may include blockage by blood, vitreous, fibrin, or iris. Obstruction of the tube may also arise from kinking. Retraction of the tube and anterior migration is commonly seen in children and may give rise to corneal decompensation. A posteriorly located tube may give rise to inflammation due to the tube rubbing on the iris. If the tube rubs on the anterior capsule of the lens, cataracts may arise. Migration or expulsion of the tube may occur if the tube is placed too anteriorly. Mahmut K et al evaluated the long term results and complications of AGV Implants. He found the most common complications were encapsulated cyst formation in 8 eyes (61.5%) and tube exposure in 4 eyes (30.8%)<sup>18</sup>.

Endophthalmitis has also been reported on the use of the GDD. It is thought to arise from erosion of the tube due to melting of the conjunctiva near the limbus that overlies the tube. This may be

secondary to poor patch graft preparation or placement. AL Torbak et al investigated the rate, risk factors, clinical course and treatment outcomes of endophthalmitis from GDD implantation. Endophthalmitis developed in 9 eyes (1.7%). The rate was five times higher in children than adults<sup>19</sup>.

An overhanging bleb may occur if the patch graft is too thick or the plate is too anterior, this may subsequently give rise to chronic dellen formation and ocular irritation.

Extra ocular muscle imbalance with diplopia has also been reported especially with inferior valve placement. Christmann L M et al did a study on motility disturbances after Molteno implantation. Vertical strabismus occurred in 3 patients and 2 children developed an inability to elevate the globe after the implants were placed superiorly. 1 adult could not depress the globe and had vertical diplopia<sup>20</sup>.

Hypertensive phase may occur in all types of GDDs although it is commonly seen with valved implants. It is more likely to occur between the first 6 weeks of surgery. During this phase the IOP may range from 30 to 50 mm/Hg. The higher incidence among valved implants is thought to be related to the biomaterial, shape and consistency of the end plate. The AGV endplate is also extremely rigid and it may have more micro motion in the post-operative period resulting in inflammation and raised IOP. Ayyala RS compared different biomaterials for GDDs and found that flexible biomaterials appeared to have less inflammation than rigid ones. Choosing a biomaterial with the least inflammation potential hence enhances the success rate of the GDDs<sup>21</sup>. Capsular fibrosis with scar tissue formation has also been attributed to cause raised IOP by restricting aqueous outflow. Ocular massage forces aqueous through the tube and into the reservoir, blunting the effect of the hypertensive phase. A study by Smith M et al found 50% of the patients achieved a 20% drop in IOP after massage<sup>22</sup>.

Statistics from the intermediate term and long term clinical evaluation of the AGV implant, found the early major complications to comprise of: transient hypotony (19.5%), shallow AC (14.5%), tube blockage (11.3%), haemorrhage (7.2%). The late major complication consisted of; encapsulated bleb (10.9%), tube exposure (5%), tube malposition (4.5%), corneal decompensation (2.3%), implant extrusion (1.4%)<sup>23</sup>.

Very few studies on these drainage implants have been done on African eyes. A Study by Kiage et al looked into the experience in East Africa. Out of the 25 cases that were identified for this study, 18 (72%) were paediatric eyes and 7 (28%) were adult eyes. The success rate during short



term follow-up was > 79%.The IOP decreased from a mean of 36.4 to 16.7mm/Hg and the glaucoma medication was lowered from a mean of 1.32 before surgery to 0.2 after surgery. The only major complication was an extruded infected valve in a child<sup>24</sup>.

A study by Kyoko Ishida et al compared the outcomes of Ahmed glaucoma valve implants between African Americans and white patients. Analysis of the results showed significantly lower success rates in African-American patients compared to white patients. The African – American patients also had a greater risk of surgical failure after AGV implantation compared to white patients<sup>25</sup>.

T. Giorgis looked at the clinical experience of tube shunt surgery in Ethiopian patients with refractory glaucoma. The success rate of IOP control was 76.9%. The IOP remained <18 mm/Hg with and without medication in 9 out of the 13 eyes that were included in the study. Three eyes required no medication until the last follow up period and the IOP was sustained at <15 mm/Hg. Three eyes had > 1 complication. Six eyes encountered hypotony, tube corneal touch, acceleration of cataract, flat AC, visual reduction and tube exposure<sup>26</sup>.

## **2.0 RATIONALE OF THE STUDY**

Glaucoma is a leading cause of blindness worldwide. The implication of the visual impairment that results from it affects the patients, their families and the entire society at large. This is due to the loss of self-reliance, and financial income, so that individuals, who were once independent, now become dependants. Not many studies have been done on AGV implants in Kenya. The only one done in East Africa by Kiage et al, looked at the short term outcomes of these implants and the sample size used was of 25 patients. Other studies done in non-African eyes have revealed a lot of information on the efficacy of these valves in the control of refractory glaucoma, as well as complications associated with the use of these valves, not much is known about the same on African eyes.

This study therefore aimed to look into both the short and long term outcomes of the AGV implants, as well as the complications associated with this method of surgical therapy for IOP control in Kenya. The outcomes of interest included IOP control, the need for additional anti-glaucoma therapy and the need for additional surgery for patients whose IOPs remained high post AGV implantation.

## **2.1 OBJECTIVES**

### **2.1.1 MAIN OBJECTIVE**

To determine the indications and outcomes of Ahmed Glaucoma Valve implants in Kenya.

### **2.1.2 Specific objectives**

1. To establish the indications for implantation of the AGV.
2. To establish the efficacy of the AGV in IOP control.
3. To establish the need for additional anti-glaucoma medication in patients with high IOPs post surgery.
4. To establish the complications associated with the use of AGV implants.

### **3.0 METHODOLOGY**

#### **3.1 *Study design***; retrospective case series.

Files from the registry of different hospitals where Ahmed glaucoma valves are used were reviewed. The data was collected using a structured questionnaire taking into consideration the age of the patients, sex, indication for AGV implantation, prior treatment regimen offered whether medical or surgical, pre-operative & post-operative VA, post-operative complications encountered with use of valves and the need for additional surgery. The patients' data on follow-up visits was also entered in a questionnaire.

#### **3.2 *Study-Setting***

The study was done in various hospitals where AGV implants are done. These were:

- Kenyatta National Hospital / Dental school
- Tenwek Mission Hospital
- Kikuyu Eye Unit

#### **3.3 *Study population***

The study population comprised of all patients both adults and children seen and treated in the facilities mentioned above and who had Ahmed valve implants used as a method of surgical treatment for glaucoma, from the year 2006.

## **INCLUSION CRITERIA**

Those included in the study comprised of:

- Adults who have had AGV implantation done.
- Children with AGV implants.

## **EXCLUSION CRITERIA**

The following were excluded from the study:

- Incomplete and lost records.
- Those below three months follow-up.
- Combined procedures such as: combined cataract and AGV implants.

### **3.4 OUTCOME MEASURES**

*Primary outcome measure:* This comprised of the **mean IOP**. The level of IOP on the first day, first month, third month, sixth month, first year and second year after the surgery.

*Secondary outcome measures:* These consisted of the following:

1. Change in mean number of glaucoma medication over time.
2. The proportion of surgical complications during the early (<30 days) and late (>30 days) post-operative period.
3. Number of additional surgical procedures required during the study period.

### **MATERIALS**

Data collection was done using:

- Patients records
- Questionnaires

### **3.5 PROCEDURE**

The file/card numbers of patients who have had AGV implants were identified from the theatre books after which the records clerks retrieved them from the records offices. Those that fulfilled the inclusion criteria were included in the study. A structured questionnaire was prepared for use in the data collection. The questionnaire comprised of the demographic details of the patient, the indications for AGV implantation, the use of any anti-glaucoma medication before and after surgery, previous surgical therapy for glaucoma including the type of surgery, the baseline VA, and complications of surgery. Each questionnaire was entered for each visit. Each patient record had a serial number that had a matching number on the questionnaire, where all the above-mentioned details were filled in. After every data collection day the information in the questionnaires was then entered into the computer. The data obtained was then analysed using the SPSS computer software, after which it was summarized and presented in the form of graphs and tables.

The following table gave a time window for follow-up visits; it was useful for data collection since patients may not have come for their post-operative reviews on the exact dates that had

been scheduled. The table gave the ideal, preferred and acceptable time period for all the follow-up visits<sup>27</sup>.

Follow-up visit	Ideal time	Preferred time	Acceptable time
DAY 1	1 day	1 day	1 -3 days
MONTH 1	30 days	23 – 37 days	15 – 59 days
MONTH 3	90 days	76 – 104 days	60 – 120 days
MONTH 6	182 days	161 – 203 days	121 – 270 days
YEAR 1	365 days	305 – 425 days	271 – 455 days
YEAR 2	730 days	670 – 790 days	638– 912 days

## **4.0 ETHICAL CONSIDERATIONS**

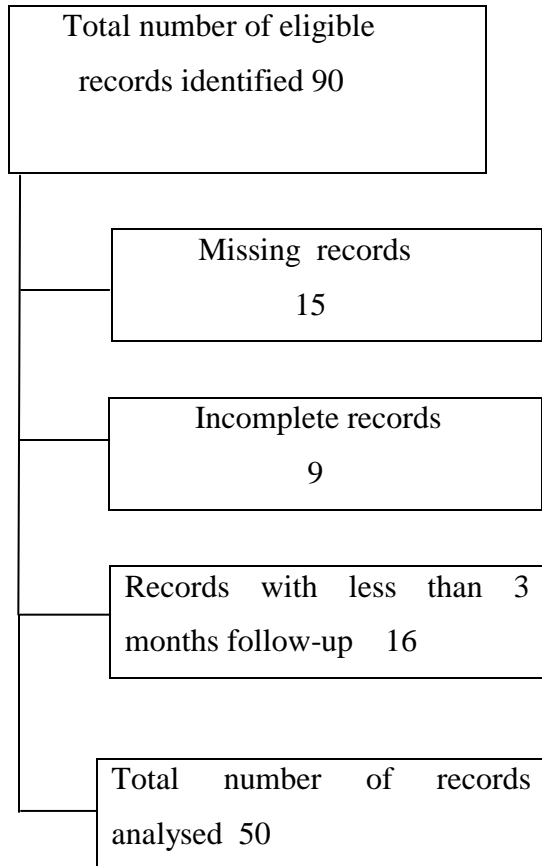
**4.1 Ethical Approval;** Approval for the study was sought from the KNH/UON Ethics, Research and Standards Committee prior to the commencement of the study. Approval from all the institutions where data was collected was also granted prior to the data collection process.

**4.2 Confidentiality;** All data collected was treated with confidentiality. The information filled in the questionnaires was only accessible to the investigator and the statistician. No medical record was carried away from the study setting for photocopying and the names of the patients and the clinicians were not recorded in the questionnaires.



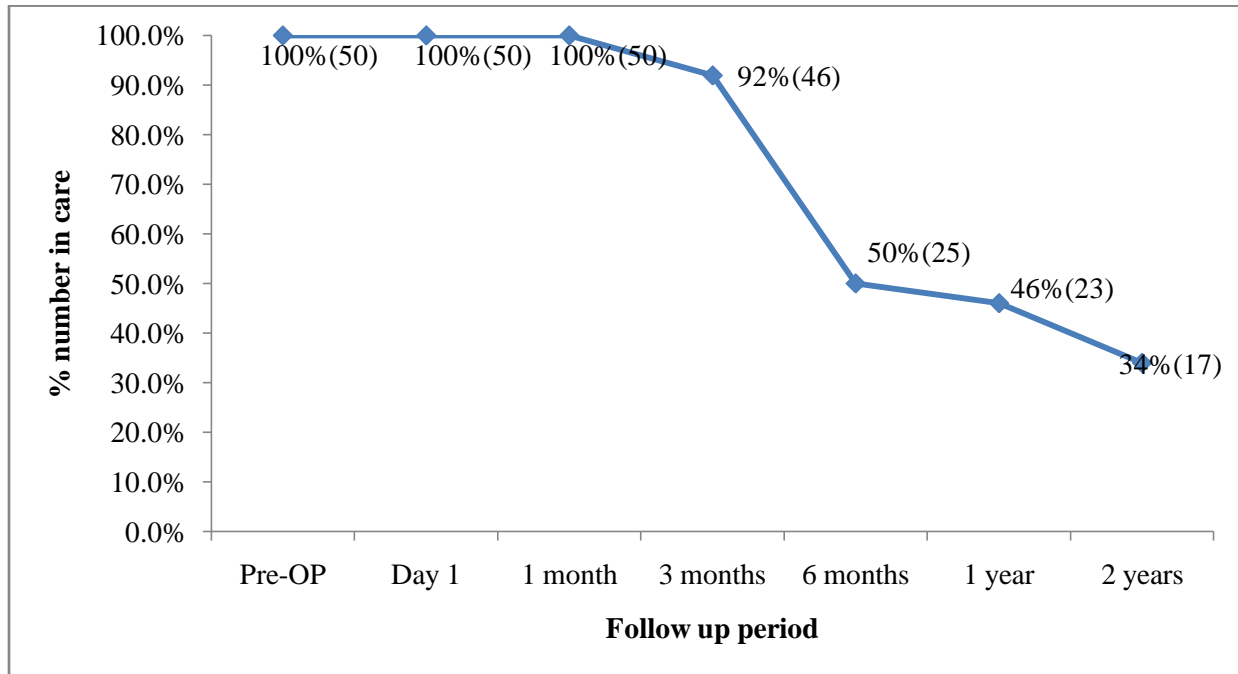
## RESULTS

**Figure 1: Flow chart of records seen**



A total number of 50 patient records were analysed. Two of the patients had bilateral AGV implantation. The data was collected from the year 2006 to 2012.

**Figure 2: patients' compliance to follow-up appointments**



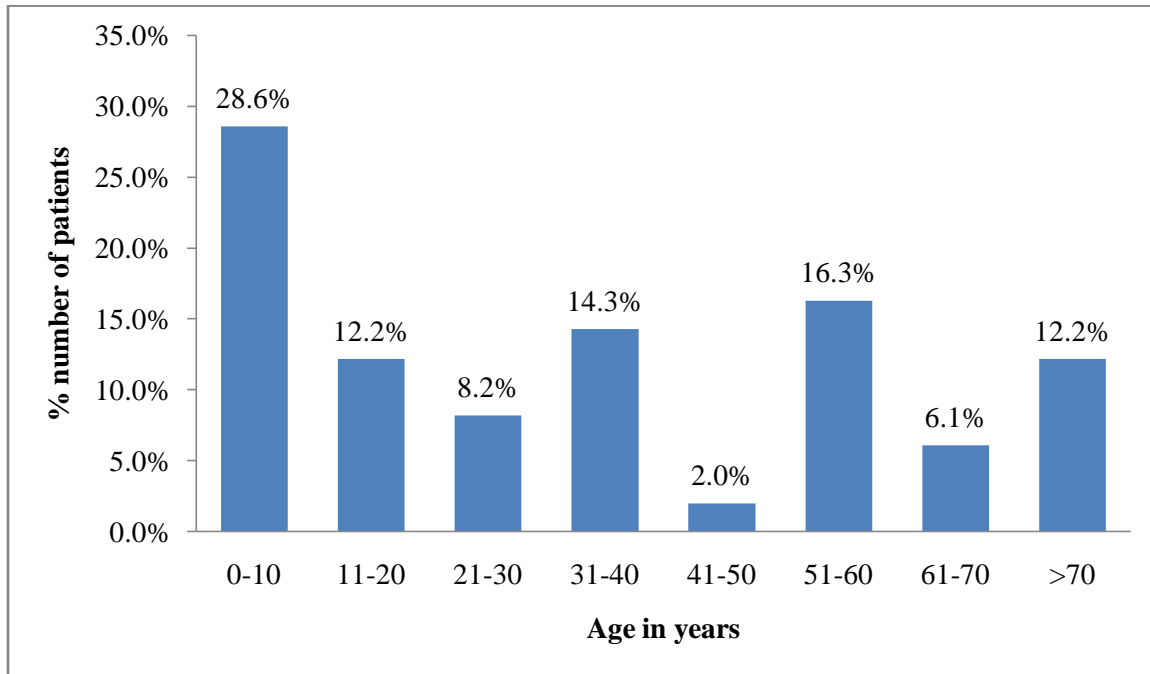
All the 50 patients attended their follow-up clinics until the first month post-operatively.

**Table 1: Baseline data**

<b>VARIABLE</b>	<b>FREQUENCY (%)</b>
<b>Sex</b>	
Male	30 (60%)
Female	20 (40%)
<b>RE</b>	24 (48%)
<b>LE</b>	26 (52%)
<b>Race</b>	
Africans	49 (98.0%)
Non- Africans	1 (2%)
<b>Prior surgical intervention</b>	
Trabeculectomy	12 (24%)
Trabeculectomy and trabeculotomy	1 (2%)
No prior intervention	37(74%)

Majority of the patients were male (60%), with a male to female ratio of 3:2

**Figure 3: Distribution by Age (n= 50)**



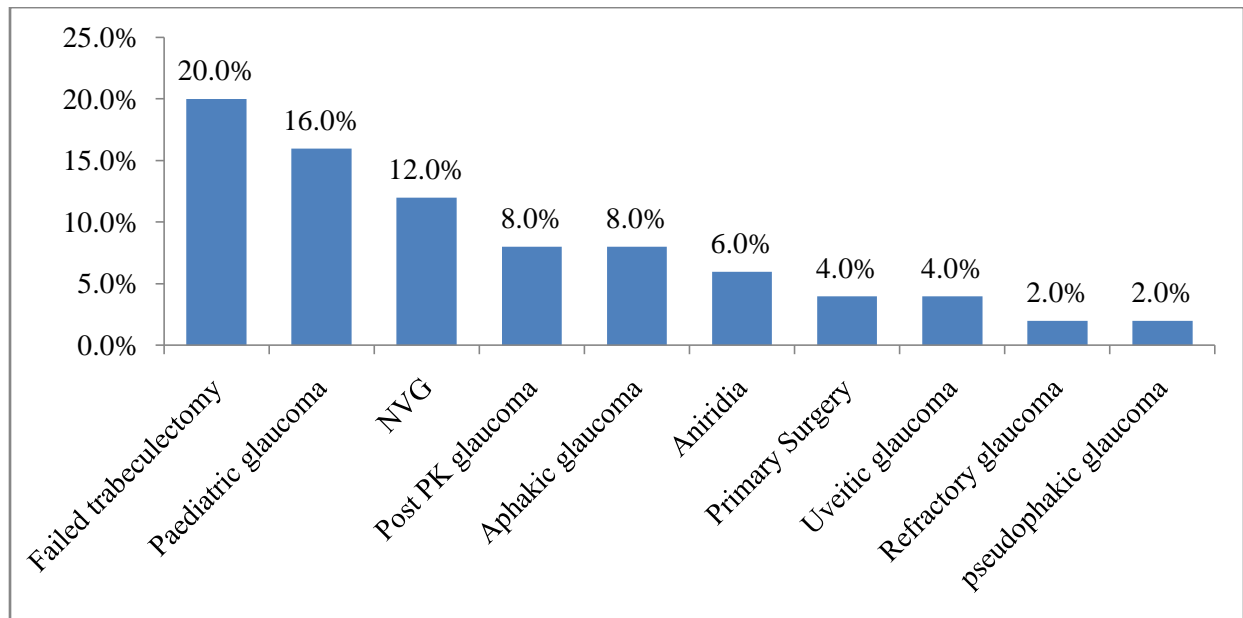
Majority of the patients with Ahmed glaucoma valve implants were between 0 – 10 years old (28.6%). The age of the patients ranged between 2-83 years. The mean was 34.5 and the median 34.0(7.5-56.5).

**Table 2:Pre-operation Visual Acuity (n= 50)**

<b>Vision (Log MAR)</b>	<b>Frequency (%)</b>
0 – 0.5	6 (12.0%)
0.5 – 1.0	7 (14.0%)
1.0 – 1.30	1 (2.0%)
1.30	11 (22.0%)
1.48	8 (16.0%)
1.78	8(16.0%)
HM	2 (4.0%)
Missing	7 (14.0%)

Most patients had a pre-operation presenting vision of less than 1.30 on Log MAR. Pre-operation visual acuity records were not seen in 7 of the patients.

**Figure 4: Indications for AGV implantation**



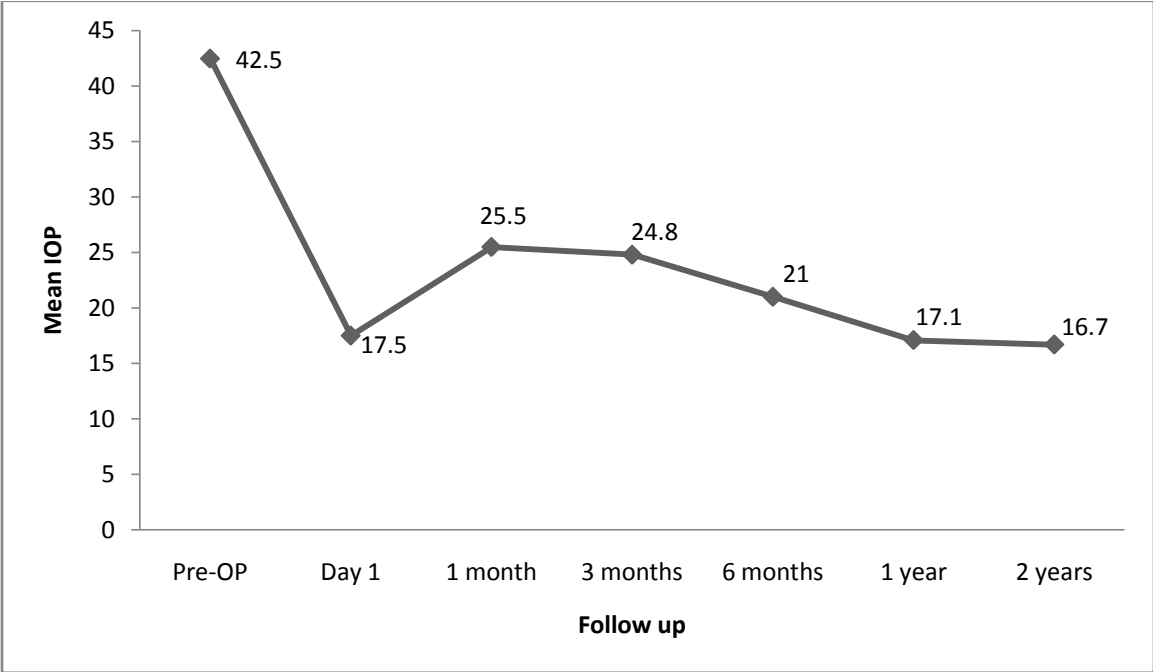
The most common indication for AGV implantation was failed trabeculectomy. AGV implantation was the primary surgery for POAG in 4% of the patients.

**Table 3:Pre-operation IOP (n =50)**

<b>Pre-OP IOP</b>	<b>Frequency</b>	<b>%</b>
21-30	8	16.0
31-40	13	26.0
41-50	13	26.0
>50	12	24.0
Not done	4	8.0

The mean pre-operation IOP was found to be **42.50** mm/Hg with a SD of 11.0 .The range was **21- 63** mm/Hg.Eight percent of the patients had no pre-operation IOP records.

**Figure 5: Reduction in mean IOP post- operatively**



The peak mean reduction of IOP was seen on the first post-operative day.

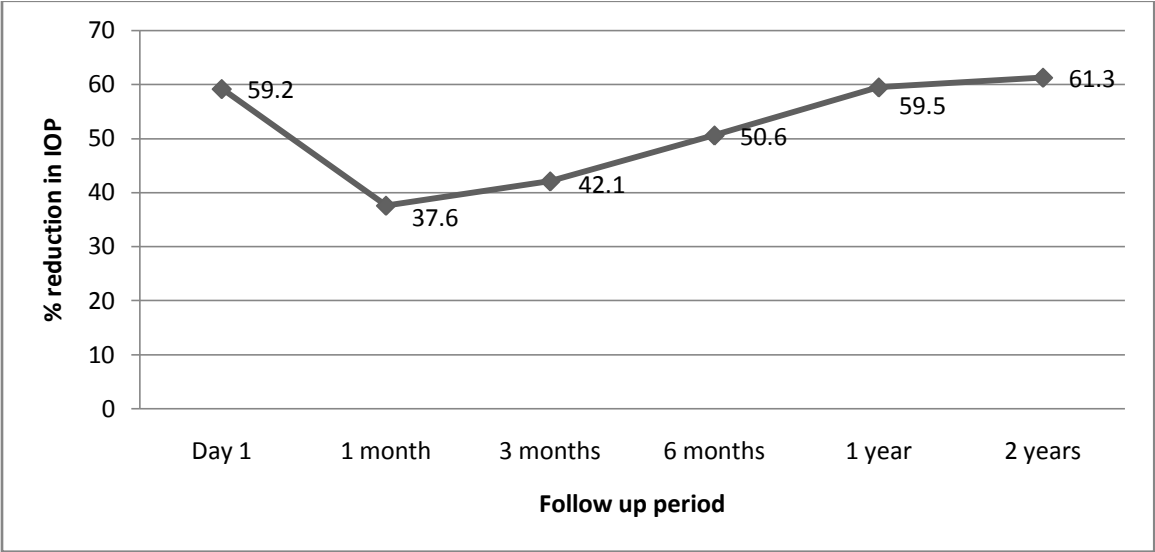


**Table 4: Comparison of the mean pre-op and post-op IOP**

FOLLOW-UP PERIOD	PRE - OPERATIVE MEAN	POST- OPERATIVE MEAN	P-VALUE
DAY 1 (n=33)	43.9 (11.5)	17.5 (13.3)	<0.001
MONTH 1 (n=45)	42.8 (10.9)	25.7 (11.8)	<0.001
MONTH 3 (n=38)	42.0 (11.5)	23.8 (10.6)	<0.001
MONTH 6 (n=24)	45.0 (11.5)	21.4 (7.6)	<0.001
YEAR 1 (n=22)	44.3 (11.9)	17.1 (7.8)	<0.001
Year 2 (n=14)	46.8 (13.7)	16.7 (7.2)	<0.001

There was a statistically significant reduction in the mean IOP post-operatively during all the follow-up periods.

**Figure 6: Percentage reduction in IOP from baseline**



The percentage reduction in IOP at month one was **37.6%**. There was a steady increase in the percentage reduction in IOP from baseline, with the maximum percentage reduction of 61.3% seen at two years of follow-up.

**Table 5: Pre-operation Anti-glaucoma drug use (N =50)**

	<b>Frequency (%)</b>
<b>Medications</b>	
Beta blockers only ( 1 drug)	18 (36.0)
Beta blockers + PGA (2 drugs)	5 (10.0)
Beta blockers + Oral CAI ( 2 drugs)	23 (46.0)
Beta blockers + PGA+ Oral CAI (3 drugs )	3 (6.0)
None	1 (2.0)

Majority of the patients (46%) were on combined Beta-blockers mainly Timolol and Oral Calcium Anhydrase Inhibitors (Acetazolamide) for IOP control.

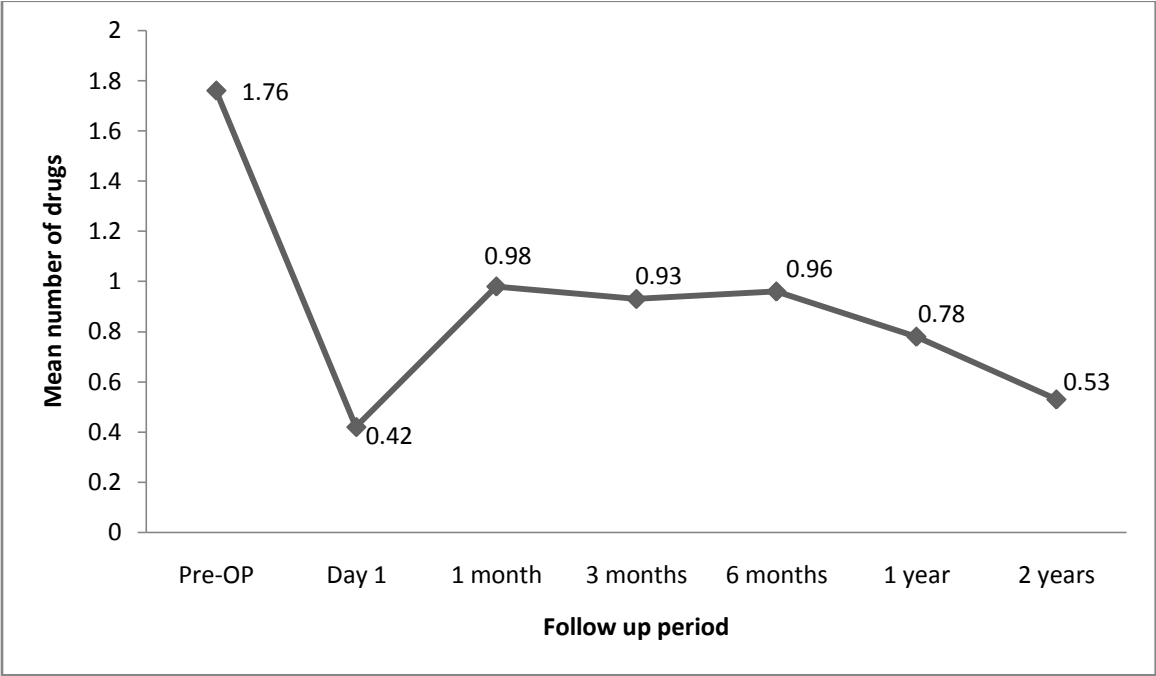
**Table 6: Post –operative use of anti-glaucoma medication**

	<b>Pre-OP n=50</b>	<b>Day 1 n=50</b>	<b>1 Month n =50</b>	<b>3 months N=41</b>	<b>6 months n=25</b>	<b>1 year n=23</b>	<b>2 years n=17</b>
<b>Drugs</b>							
0	1 (2.0)	32 (64.0)	11 (22.0)	10 (24.4)	8 (32.0)	8 (34.8)	10 (58.8)
1	18 (36.0)	15 (30.0)	29 (58.0)	24 (58.5)	12 (48.0)	12 (52.2)	5 (29.4)
2	23 (46.0)	3 (6.0)	10 (20.0)	7 (17.1)	4 (16.0)	3 (13.0)	2 (11.8)
3	8 (16.0)	0	0	0	0	0	0

There was no patient on 3 drugs from day 1 post-operatively to the end of the study period at 2 years. The mean number of drugs used post-operatively was 0.8. The median was 0.8.

The range was 0 – 2.

**Figure 7: Mean number of anti-glaucoma medication use in the post-operative period**



The peak reduction in the mean number of anti-glaucoma drugs was seen on the 1<sup>st</sup> day post – operatively where the mean number of drugs used dropped to 0.42 from 1.76.

**Table 7: Comparison of pre-operative and post-operative use of anti-glaucoma medication**

	<b>Pre-OP</b>	<b>Post-OP</b>	<b>P value</b>
1 day (n=49)	2.2 (1.0)	0.4 (0.6)	<0.001
1 month (n=49)	2.2 (1.0)	1.0 (0.6)	<0.001
3 months (n=40)	2.3 (1.0)	1.0 (0.6)	<0.001
6 months (n=25)	2.5 (1.0)	1.0 (0.9)	<0.001
1 year (n=22)	2.6 (1.0)	0.8 (0.7)	<0.001
2 years (n=17)	2.5 (1.0)	0.5 (0.7)	<0.001

There was a statistically significant reduction in the mean number of anti-glaucoma medication used post-operatively in all the follow-up periods.

**Table 8: POST OPERATIVE COMPLICATIONS**

	<b>Day 1</b>	<b>Month 1</b>	<b>Month 3</b>	<b>Month 6</b>	<b>Year 1</b>	<b>Year 2</b>
Hypotony	4	0	0	0	1	0
Tube blockage	0	1	1	0	0	0
Tube migration	0	0	0	1	1	0
Encapsulated bleb	0	0	2	0	0	0
Endophthalmitis	0	0	2	0	0	1
<b>Surgical intervention</b>						
Tube shortening	0	0	0	0	1	0
Tube repositioning	0	0	0	0	1	0

The most serious complication noted was endophthalmitis which occurred in three patients.

Hypotony occurred in 4 patients on the first post-operative day and in one patient at year one.

## **Discussion**

Glaucoma is the second leading cause of blindness worldwide. The aim of glaucoma therapy is to prevent further damage to the optic nerve by lowering the IOP hence preserving visual function.

The Ahmed valve was introduced in 1993 as a pressure sensitive unidirectional valve, which is designed to open when the IOP is 8 mm/Hg. It contains a plate, a drainage tube and a valve. When the IOP is too high the valve opens letting aqueous fluid flow out of the eye through the drainage tube then automatically closes when the pressure is normal again.

A total of 50 patient records were analysed from various institutions in Kenya where Ahmed valves are used for surgical management of glaucoma. Twenty-four of the records were obtained from Kikuyu Eye Unit, ten from KNH and sixteen from Tenwek Eye Unit. Two of the patients had bilateral AGV implantation. These records were from the year 2006 to 2012. Sixty percent of the patients were male and 40 % were female with a male to female ratio of 3:2. One patient was of Asian origin. The other 49 patients were of African descent.

All the fifty patients were compliant with their follow-up appointments at day one and month one follow-up period. At the third month of follow-up 4 of the 50 patients (8%) failed to go for their appointments. By the sixth month of follow-up only 50% of the patients were being seen in the clinic. At the end of two years only 17 patients (34%) were being followed up after AGV Implantation. It is not clear why many patients stopped coming for their appointments. Sixteen patient records were excluded from the study because they had less than three month's post-operation follow-up.

The most common indication for AGV implantation was failed trabeculectomy in 20% (10) of the patients. In the baseline data 26 % of the patients had prior surgical intervention. Out of this twelve of them (24%) had trabeculectomy whereas one paediatric patient had a combined trabeculectomy and trabeculotomy for the management of primary congenital glaucoma. In the Long term success of Ahmed glaucoma valve in refractory glaucoma study by Kaya M et al, a retrospective review of 13 patients (eyes) with refractory glaucoma who had undergone AGV



implantation was done. All of these patients had at least one incisional surgery (trabeculectomy) done before the tube shunt was inserted<sup>28</sup>.

The second most common indication was paediatric glaucoma in (16%) of the patients. Majority of the patients were in the 0 – 10 age group followed by those in the 51 – 60 year age group. Most of the patients in the 0 – 10 age group had AGV implanted mainly as a primary surgery due to congenital glaucoma. The use of Ahmed valves primarily was preferred over goniotomy or combined trabeculectomy and trabeculotomy, especially in Tenwek mission hospital where most of the patients came from low social economic backgrounds and hence compliance to regular follow-up visits and monitoring following goniotomy or combined trabeculectomy and trabeculotomy was expected to be poor.

Management of pediatric glaucoma is challenging. PCG has traditionally been controlled surgically by goniotomy, trabeculectomy and trabeculotomy with the use of antimetabolite agents such as Mitomycin C or 5-fluorouracil. A few publications have stated the preferred use of AGV with subsequent success in the management of PCG. In the outcomes of Ahmed glaucoma valve implantation in children with PCG study by Yvonne OU et al, the cumulative probability of success with a single AGV implant was 63 % at one year of follow-up. With a 2<sup>nd</sup> AGV the success was 86 % at 1 year and 69 % at five years<sup>29</sup>. Another study by Chen TC et al Ahmed valves were primarily implanted in the 41 patients who either had congenital glaucoma (38.5 %) or aphakic glaucoma (36.5%). In this study success rate in terms of IOP control and reduction in the use of anti-glaucoma medication was similar to adults<sup>30</sup>. A study conducted in East Africa by Kiage et al found that the most common indication of Ahmed glaucoma valve implantation was congenital glaucoma. This was in 11 of the 25 eyes included in the study<sup>24</sup>.

Six patients (12%) had Ahmed valves used for IOP control due to Neovascular glaucoma. Five of the patients with NVG had type two diabetes mellitus with proliferative diabetic retinopathy whereas as one had type one diabetes mellitus.

Management of Neovascular glaucoma has always been challenging due to the progression of the underlying disease. In the Ahmed Glaucoma Valve in Neovascular glaucoma study by Netland PA, 50 % of the patients enrolled had NVG. Despite the complications that were encountered following use of the shunt, it was concluded that the Ahmed valve was still safe

and effective in the control of IOP and vision preservation in patients with NVG secondary to proliferative diabetic retinopathy<sup>8</sup>.

Post penetrating keratoplasty glaucoma was the indication for valve implantation in four patients. Three of these patients had undergone penetrating keratoplasty for keratoconus while one had a PK done due to a traumatic corneal scar. Various publications have shown the successful use of AGV implants in post-penetrating keratoplasty glaucoma. A prospective clinical study by Anita Panda et al evaluated the use of the valves in twenty eyes of twenty adult patients and revealed a satisfactory outcome up to six months of follow-up in terms of decreasing the IOP from 42.95 +/-10.24 to 17.69 +/-3.64 mm/Hg. The use of anti-glaucoma medication also dropped from 2.92 to 0.39 after AGV use<sup>31</sup>.

Two of the adult patients had AGV implanted as the primary surgery for POAG. It was however not indicated in the records why the shunt was chosen as the primary surgery. It was also not indicated in the clinical records whether these two patients were poor candidates for other incisional surgery procedures such as trabeculectomy. One patient had refractory glaucoma, which was primary open angle glaucoma. This had failed to respond to Timolol, Latanoprost and oral acetazolamide. A decision was therefore made to use an Ahmed valve. A retrospective interventional case series carried out by Jitendra KS looked at the efficacy of the AGV in cases of adult refractory glaucoma in Indian eyes. Six of the fifty-two eyes included in the study underwent primary AGV implantation following failure of maximal medical therapy. Complete success as was defined in the criteria of the study was achieved in 46 eyes (88%). None of the eyes had failure to maintain IOP control hence the AGV was found to be effective in cases of adult refractory glaucoma<sup>32</sup>.

The mean pre-operation IOP was 42.50 mm/Hg(11.0), with a range of 21 – 63 mm/Hg. Yalvac et al on his study on long-term results of the AGV and Molteno implant in Neovascular glaucoma, found a pre-operative mean IOP of 39.5 +/- 4.5 mm/Hg with a range of 31 – 56 mm/Hg<sup>33</sup>.

The peak reduction in IOP was seen in the first post-operative day where there was a marked reduction to 17.50mm/Hg. The IOP then plateaued over the first to the third month after which it steadily dropped to 16.70mm/Hg at two years. The steady rise in IOP from the first to the third month of follow-up is thought to have occurred during the hypertensive phase.

Hypertensive phase is a known complication of AGV use. It is commonly seen in the first six weeks after AGV implantation. In this study none of the records clearly attributed poor IOP control between the first and the third month of follow-up to the Hypertensive phase. It is likely that some of the patients could have had hypertensive phase due to the increase in the mean IOP at month one of follow-up to 25.50mm/Hg from a mean of 17.50mm/Hg at day one post-operation. The mean IOP at month three was also elevated at 24.80mm/Hg. Chen-Wu Shiu found twelve out of the nineteen patients in his study had hypertensive phase. This hypertensive phase was found to have peaked in the first to second month after surgery with nine of the patients exhibiting it at one month and three patients at two months<sup>34</sup>.

The maximum percentage reduction in IOP from the baseline was 61.3% and this was seen at two years of follow-up. This reduction in IOP is similar to the findings of the intermediate term clinical experience with the Ahmed glaucoma valve implant where the IOP was reduced from a mean of 32.7+/-0.8mm/Hg before surgery to 15.9+/-0.6mm/Hg at the most recent follow-up after surgery<sup>35</sup>. Similarly D Kiage et al in his study in East Africa found that the mean IOP reduced from a mean of 36.4 mm/Hg pre-operatively to 16.7mm/Hg at the last review date. The mean percentage IOP lowering was 53.2%. A slight IOP spike was noted on day 30 followed by a subsequent reduction<sup>24</sup>.

Majority of the patients (46%) were on two drugs pre-operatively. These were mainly beta blockers especially Timolol and oral calcium anhydrase inhibitors (acetazolamide). Timolol was commonly used in most of the health institutions because it is cheaper and readily available. Acetazolamide was given to those patients who had poorly controlled IOP despite the use of other anti-glaucoma drugs. Acetazolamide was mainly given orally a few days prior to surgery. Six percent of the patients were on three drugs this comprised of a beta-blocker, an oral calcium anhydrase inhibitor and a prostaglandin analogue mainly Latanoprost. The range of the number of drugs used was 0 to 3.

In the Ahmed glaucoma Valve in patients with NVG study by Peter A Netland et al the number of anti-glaucoma drugs used preoperatively was 3.3+/- 1.3 with a range of 3 to 5<sup>15</sup>. Eksioğlu U similarly found the number of drugs used to be 3.4+/-0.5 with a range of 2 to 4<sup>36</sup>.

The mean number of drugs used pre-operatively was 1.76. The range was 0 to 3 with all the patients on 3 drugs having been started on oral acetazolamide a few days prior to surgery. One patient was noted to have been on no drug pre-operatively. It was not indicated in the file why the patient was not on any drug despite having high IOP ranges of 22 to 43mm/Hg. The mean number of drugs used post-operatively was 0.8 with a range of 0 to 3. At the first post-operative day the mean number of drug use had significantly reduced from 1.76 in the pre-operative period to 0.42.

Majority of the patients (64%) were not started on any drug after the first post-operative review. However fifteen patients (30%) were started on one drug (Timolol) since the IOP was still high, whereas three patients were started on 2 drugs (Timolol and Latanoprost) due to poorly controlled IOPs despite AGV implantation the previous day. None of the patients was on three drugs post-operatively. The mean number of drugs increased to 0.98 in the first post-operative month. This may have been due to the hypertensive phase which is most commonly seen with the use of AGV and which occurs between the fourth and the sixth week post-operatively.

The mean number of drugs used then significantly dropped to 0.93 at the third month and this may be as a result of the end of the hypertensive phase. However at the sixth month follow-up period the mean increased to 0.96. At the last follow-up period of two years out of the seventeen patients who were still consistent with their clinic attendance, ten were on no drug, five were on one drug and two were on two drugs. Kiage D et al study on AGV use in East Africa found that the mean number of drugs reduced from 1.32 pre-operatively to 0.20. The low usage of drugs post-operatively was not only attributed to the surgery itself but it was thought that the drug unavailability and high costs considering the low socio-economic status of the patients may have hindered most of them from buying and using IOP lowering drugs post-operatively. Secondly most of the patients in this study were children (72%) and since the management of PCG is usually surgical most of them were not started on drugs post-operatively<sup>24</sup>. A similar study in Ethiopia by Giorgis A, found a mean reduction in post-operative anti-glaucoma drug use to 1.08 +/-0.44, from a pre-operative mean of 2.23 +/-0.44<sup>37</sup>.

Hypotony was the most common complication in the first post-operative day. The lowest IOP recorded was 2mm/Hg. This complication may have occurred as a result of aqueous leaking around the tube as a result of a loose occlusion suture therefore resulting into excessive drainage. Hypotony as a complication of AGV use occurred in four of the patients on day one and in one patient at year one of follow-up. The hypotony was however transient in the four patients in whom it was noted in the first post-operative day. The cause of hypotony in the patient at the first year post-operation could not be identified from the records. The IOP in this patient was however noted to be normal in the subsequent visits. Huang MC found hypotony in 13 eyes (8%)<sup>36</sup>.

Tube blockage was also noted as a complication in two adults, at the first and the third month of follow-up. In one of the patients tube blockage was reported to have been due to iris incarceration into the open end of the tube. There was however no mention of the cause of the blockage in the other patient. An iris plug on the tube occurred in one patient in the study by Shiu Chen on the clinical experience with the AGV in complicated glaucoma<sup>38</sup>.

Tube migration was a complication of AGV use in two adult patients. One of the patients had anterior migration of the tube resulting into lenticular touch. It was however not clearly indicated in the records the mechanism of the tube migration in the second patient. One of the patients with a migrated tube underwent tube repositioning and shortening.

No surgical intervention for the other patient with a migrated tube was mentioned in the records. Shefali K found 3 cases of dynamic tube migration into the anterior chamber. This was thought to be due to loosening of the non-absorbable suture used or the extrusion of the suture from the sclera<sup>39</sup>.

Endophthalmitis which is a dreaded complication in AGV use as well as all other intra-ocular surgeries was seen in two patients at month three of follow-up and in one patient at the two year follow-up period. This was the most serious complication recorded. One of these patients was a child aged three years where the AGV had been used as primary surgery for Primary congenital glaucoma. Out of the three patients, two had evisceration done whereas no mention on the management of this complication for the third patient was mentioned in the file.

A study by Al-Torbak on endophthalmitis associated with the Ahmed Glaucoma Valve use, found that 9 of the 542 eyes included in the study developed endophthalmitis. This was higher in children than in adults and it was thought to arise from dehiscence of the conjunctiva covering the tube<sup>40</sup>. The cause of endophthalmitis in the three patients in this study was not clear. Conjunctival dehiscence over the tube could have been the most likely source especially in the child.

Bleb encapsulation was seen in two of the patients. This was at month 3 of follow-up. One of the patients had an elevated IOP of 32 mm/Hg as a result of the bleb encapsulation. The second patient had normal IOP of 18 mm/Hg despite the encapsulated bleb. No surgical intervention was mentioned for the blebs of the two patients. In a study on the incidence and management of encapsulated cysts following AGV insertion, 13 of the 57 patients included in the study developed encapsulated cysts. On needling with 5-Fluorouracil only two of the patients developed normal pressures. The rest required surgical excision of the cysts to achieve adequate IOP control<sup>41</sup>.

## **STUDY LIMITATIONS**

1. Two of the five institutions where Ahmed glaucoma valves are used declined to participate in this study. Thus, the previous calculated sample size of 79 eyes had to be revised. The margin of error therefore had to be increased and the sample size recalculated to fit the sample obtained from the three that consented.
2. Missing data in some of the records was also a limitation. Some of the records had no IOP records. This made it difficult to collect reliable data on the pre-operative and post-operative outcome measures.
3. Missing records for some of the patients who had undergone AGV surgery was also a limiting factor, which made it difficult to achieve the desired large sample size.
4. Loss to follow-up was high. Some of the patients failed to comply with their post-operation appointments schedule. Patients who had less than three months of post-operative follow-up were excluded. Sixteen patients' records were excluded because they were lost to follow-up after the 1<sup>st</sup> post-operative month.

## **CONCLUSION**

1. The most common indication for AGV use in Kenya was failed trabeculectomy. Other common indications were primary congenital glaucoma and neovascular glaucoma.
2. Good IOP control was achieved with the AGV In patients who had uncontrolled glaucoma with the use of conventional medical therapy.
3. There was a statistically significant reduction in the number of anti-glaucoma medications used after AGV surgery compared to the pre-operative period.
4. Hypotony was the most common complication noted with the use of the AGV. It however resolved without further complications. The most serious complication was endophthalmitis which occurred in three patients.



## **RECOMMENDATIONS**

1. The Ministry of Medical services should collaborate with the manufacturers of Ahmed valves to provide cheaper valves in our set-up where issues of compliance to anti-glaucoma drugs and follow-up are poor. This will ensure that patients from poor economic backgrounds have early surgery to prevent further disease progression.
2. More ophthalmologists should be trained on the use of the Ahmed valve. This will ensure that more patients benefit from this form of surgical therapy for glaucoma, without having to travel to institutions with glaucoma specialists to undergo this surgery.
3. There is available evidence to show that counseling and creating special glaucoma clinics improves follow-ups. This could be tried to improve the poor follow-up observed in this study.
4. Co-operation between health care providers and teaching institutions should be encouraged since the future of better health care provision is based on research.
5. In future another study with a larger sample size can be carried out to further assess the indications, outcomes and complications of Ahmed glaucoma valve use.

## Appendix 1: Approval letter from Ethics and Research committee



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4<sup>th</sup> April 2013

Dr. Loise Kwamboka Moguche  
Dept. of Ophthalmology  
School of Medicine  
University of Nairobi

Dear Dr. Moguche

### Research proposal: Indications and outcomes of Ahmed Glaucoma valve implants in Kenya (P660/12/2012)

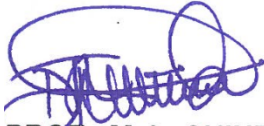
This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above revised proposal. The approval periods are 4<sup>th</sup> April 2013 to 3<sup>rd</sup> April 2014.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- Submission of an *executive summary* report within 90 days upon completion of the study  
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN)

Yours sincerely



**PROF. M. L. CHINDIA**  
**SECRETARY, KNH/UON-ERC**

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC  
The Deputy Director CS, KNH  
The Principal, College of Health Sciences, UoN  
The Dean, School of Medicine, UoN  
The Chairman, Dept.of Ophthalmology, UoN  
Supervisors: Dr. S. Marco, Dr. Millicent Kariuki-Wanyoike

**Appendix 2: Questionnaire**

**INDICATIONS & OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA**

**VISIT 1 (DAY1)**

File / card number .....

Serial number .....

Age ..... Gender; M ..... F .....

African ..... Non- African .....

Study Eye OD ..... OS .....

**PRE-OPERATION DATA**

BCVA .....

IOP .....

Examination findings

Vertical CDR .....

Visual field

30 – 2 HVF MSD ..... PSD ..... Not Done .....

Antiglaucoma medication

Beta-blocker .....

PGA .....

Alpha 2 agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total drugs .....

Prior surgical intervention for IOP control

TET .....

Goniotomy .....

Combined TET and trabeculotomy .....

LTP .....

Other (specify) .....

**INDICATION FOR AGV IMPLANTATION**

Primary surgery .....

Failed TET .....

Refractory glaucoma .....

Paediatric glaucoma .....

NVG .....

Uveitic glaucoma .....

Post- PK glaucoma .....

Aphakic glaucoma .....

Other (specify) .....

**POST-OPERATION DATA FOR VISIT 1 (DAY 1)**

Surgery Date ..... / ..... / .....

Visit Date ..... / ..... / .....

IOP .....

BCVA .....

Post- operative use of glaucoma medication

Beta blocker .....

PGA .....

Alpha 2 Agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total meds .....

**POST-OPERATIVE COMPLICATIONS**

- Hypotony .....
- Flat AC .....
- Suprachoroidal haemorrhage .....
- Tube blockage / obstruction .....
- Tube migration .....
- Extruded tube .....
- Corneal decompensation .....
- Encapsulated bleb .....
- Endophthalmitis .....
- Other (specify) .....

**SURGICAL INTERVENTION**

- Second Valve .....
- Needling .....
- Tube shortening .....
- Tube repositioning .....
- Other .....

**INDICATIONS & OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA**

**VISIT 2 (MONTH 1)**

File / card number .....

Serial number .....

Age ..... Gender; M ..... F .....

African ..... Non- African .....

Study Eye      OD .....      OS .....

**PRE-OPERATION DATA**

BCVA .....

IOP .....

Examination findings

Vertical CDR .....

Visual field

30 – 2 HVF      MSD .....      PSD .....      Not Done .....

Antiglaucoma medication

Beta-blocker .....

PGA .....

Alpha 2 agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total drugs .....



Prior surgical intervention for IOP control  
TET .....  
Goniotomy .....  
Combined TET and trabeculotomy .....  
LTP .....  
Other (specify) .....

**INDICATION FOR AGV IMPLANTATION**

Primary surgery .....  
Failed TET .....  
Refractory glaucoma .....  
Paediatric glaucoma .....  
NVG .....  
Uveitic glaucoma .....  
Post- PK glaucoma .....  
Aphakic glaucoma .....  
Other (specify) .....

**POST-OPERATION DATA FOR VISIT 2(MONTH 1)**

Surgery Date ..... / ..... / .....

Visit Date ..... / ..... / .....

IOP .....

BCVA .....

Post- operative use of glaucoma medication

Beta blocker .....

PGA .....

Alpha 2 Agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total meds .....

**POST-OPERATIVE COMPLICATIONS**

- Hypotony .....
- Flat AC .....
- Suprachoroidal haemorrhage .....
- Tube blockage / obstruction .....
- Tube migration .....
- Extruded tube .....
- Corneal decompensation .....
- Encapsulated bleb .....
- Endophthalmitis .....
- Other (specify) .....

**SURGICAL INTERVENTION**

- Second Valve .....
- Needling .....
- Tube shortening .....
- Tube repositioning .....
- Other .....

**INDICATIONS & OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA**

**VISIT 3(MONTH 3)**

File / card number .....

Serial number .....

Age ..... Gender; M ..... F .....

African ..... Non- African .....

Study Eye OD ..... OS .....

**PRE-OPERATION DATA**

BCVA .....

IOP .....

Examination findings

Vertical CDR .....

Visual field

30 – 2 HVF MSD ..... PSD ..... Not Done .....

Antiglaucoma medication

Beta-blocker .....

PGA .....

Alpha 2 agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total drugs .....

Prior surgical intervention for IOP control  
TET .....  
Goniotomy .....  
Combined TET and trabeculotomy .....  
LTP .....  
Other (specify) .....

**INDICATION FOR AGV IMPLANTATION**

Primary surgery .....  
Failed TET .....  
Refractory glaucoma .....  
Paediatric glaucoma .....  
NVG .....  
Uveitic glaucoma .....  
Post- PK glaucoma .....  
Aphakic glaucoma .....  
Other (specify) .....

**POST-OPERATION DATA FOR VISIT 3(MONTH 3)**

Surgery Date ..... / ..... / .....

Visit Date ..... / ..... / .....

IOP .....

BCVA .....

Post- operative use of glaucoma medication

Beta blocker .....

PGA .....

Alpha 2 Agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total meds .....

**POST-OPERATIVE COMPLICATIONS**

- Hypotony .....
- Flat AC .....
- Suprachoroidal haemorrhage .....
- Tube blockage / obstruction .....
- Tube migration .....
- Extruded tube .....
- Corneal decompensation .....
- Encapsulated bleb .....
- Endophthalmitis .....
- Other (specify) .....

## **SURGICAL INTERVENTION**

- Second Valve .....
- Needling .....
- Tube shortening .....
- Tube repositioning .....
- Other .....

**INDICATIONS & OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA**

**VISIT 4(MONTH 6)**

File / card number .....

Serial number .....

Age ..... Gender; M ..... F .....

African ..... Non- African .....

Study Eye OD ..... OS .....

**PRE-OPERATION DATA**

BCVA .....

IOP .....

Examination findings

Vertical CDR .....

Visual field

30 – 2 HVF MSD ..... PSD ..... Not Done .....

Antiglaucoma medication

Beta-blocker .....

PGA .....

Alpha 2 agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total drugs .....



Prior surgical intervention for IOP control  
TET .....  
Goniotomy .....  
Combined TET and trabeculotomy .....  
LTP .....  
Other (specify) .....

**INDICATION FOR AGV IMPLANTATION**

Primary surgery .....  
Failed TET .....  
Refractory glaucoma .....  
Paediatric glaucoma .....  
NVG .....  
Uveitic glaucoma .....  
Post- PK glaucoma .....  
Aphakic glaucoma .....  
Other (specify) .....

**POST-OPERATION DATA FOR VISIT 4(MONTH 6)**

Surgery Date ..... / ..... / .....

Visit Date ..... / ..... / .....

IOP .....

BCVA .....

Post- operative use of glaucoma medication

Beta blocker .....

PGA .....

Alpha 2 Agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total meds .....

**POST-OPERATIVE COMPLICATIONS**

- Hypotony .....
- Flat AC .....
- Suprachoroidal haemorrhage .....
- Tube blockage / obstruction .....
- Tube migration .....
- Extruded tube .....
- Corneal decompensation .....
- Encapsulated bleb .....
- Endophthalmitis .....
- Other (specify) .....

**SURGICAL INTERVENTION**

- Second Valve .....
- Needling .....
- Tube shortening .....
- Tube repositioning .....
- Other .....

**INDICATIONS & OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA**

**VISIT 5(YEAR 1)**

File / card number .....

Serial number .....

Age ..... Gender; M ..... F .....

African ..... Non- African .....

Study Eye OD ..... OS .....

**PRE-OPERATION DATA**

BCVA .....

IOP .....

Examination findings

Vertical CDR .....

Visual field

30 – 2 HVF MSD ..... PSD ..... Not Done .....

Antiglaucoma medication

Beta-blocker .....

PGA .....

Alpha 2 agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total drugs .....

Prior surgical intervention for IOP control  
TET .....  
Goniotomy .....  
Combined TET and trabeculotomy .....  
LTP .....  
Other (specify) .....

**INDICATION FOR AGV IMPLANTATION**

Primary surgery .....  
Failed TET .....  
Refractory glaucoma .....  
Paediatric glaucoma .....  
NVG .....  
Uveitic glaucoma .....  
Post- PK glaucoma .....  
Aphakic glaucoma .....  
Other (specify) .....

**POST-OPERATION DATA FOR VISIT 5 (YEAR 1)**

Surgery Date ..... / ..... / .....

Visit Date ..... / ..... / .....

IOP .....

BCVA .....

Post- operative use of glaucoma medication

Beta blocker .....

PGA .....

Alpha 2 Agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total meds .....

**POST-OPERATIVE COMPLICATIONS**

- Hypotony .....
- Flat AC .....
- Suprachoroidal haemorrhage .....
- Tube blockage / obstruction .....
- Tube migration .....
- Extruded tube .....
- Corneal decompensation .....
- Encapsulated bleb .....
- Endophthalmitis .....
- Other (specify) .....

**SURGICAL INTERVENTION**

- Second Valve .....
- Needling .....
- Tube shortening .....
- Tube repositioning .....
- Other .....

**INDICATIONS & OUTCOMES OF AHMED GLAUCOMA VALVE IMPLANTS IN KENYA**

**VISIT 6 (YEAR 2)**

File / card number .....

Serial number .....

Age ..... Gender; M ..... F .....

African ..... Non- African .....

Study Eye OD ..... OS .....

**PRE-OPERATION DATA**

BCVA .....

IOP .....

Examination findings

Vertical CDR .....

Visual field

30 – 2 HVF MSD ..... PSD ..... Not Done .....

Antiglaucoma medication

Beta-blocker .....

PGA .....

Alpha 2 agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total drugs .....



Prior surgical intervention for IOP control

TET .....

Goniotomy .....

Combined TET and trabeculotomy .....

LTP .....

Other (specify) .....

### **INDICATION FOR AGV IMPLANTATION**

Primary surgery .....

Failed TET .....

Refractory glaucoma .....

Paediatric glaucoma .....

NVG .....

Uveitic glaucoma .....

Post- PK glaucoma .....

Aphakic glaucoma .....

Other (specify) .....

**POST-OPERATION DATA FOR VISIT 6 (YEAR 2)**

Surgery Date ..... / ..... / .....

Visit Date ..... / ..... / .....

IOP .....

BCVA .....

Post- operative use of glaucoma medication

Beta blocker .....

PGA .....

Alpha 2 Agonist .....

Pilocarpine .....

CAI (oral) .....

CAI (Topical) .....

Other .....

Total meds .....

**POST-OPERATIVE COMPLICATIONS**

- Hypotony .....
- Flat AC .....
- Suprachoroidal haemorrhage .....
- Tube blockage / obstruction .....
- Tube migration .....
- Extruded tube .....
- Corneal decompensation .....
- Encapsulated bleb .....
- Endophthalmitis .....
- Other (specify) .....

## SURGICAL INTERVENTION

- Second Valve .....
- Needling .....
- Tube shortening .....
- Tube repositioning .....
- Other .....

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