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The Outcomes of a Low-cost, Non-valved Glaucoma Drainage Device Using Mitomycin-C: One-year Results

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GLAUCOMA

The outcomes of a low-cost, non-valved glaucoma drainage device using mitomycin-C: 1-year results

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Abstract
Purpose To evaluate the indications, outcomes, and complications of the usage of Aurolab Aqueous Drainage Implant

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Introduction

- Glaucoma drainage devices (GDD) are currently the main players in the management of glaucoma, either as a primary or secondary surgical intervention.

- In 2013, a low-cost none valved GDD was introduced to the market in India; The Aurolab aqueous drainage implant (AADI) [Aurolab, Madurai, India]. The design of this device is based on the BGI 350-mm^2 but with a much lower cost (about 70 dollars per device).

- In this study we report the 1-year safety and efficacy of the AADI using Mitomycin-C and insertion of a ripcord in the tube as modifications of the originally described technique among Egyptian glaucoma patients.

Methods

- The study was a real-world retrospective non-comparative interventional case series.

- All patients who underwent AADI placement between April 2018 and June 2020 at the Department of Ophthalmology, Ain Shams University Hospitals, Cairo, Egypt and completed at least 1-year follow-up period were included.

- Demographic data, type and duration of glaucoma, number of anti-glaucoma medications (AGM), history of previous eye surgery, and baseline ophthalmological assessment (BCVA, anterior segment assessment, pre-operative IOP) were extracted.

Methods (Cont.)

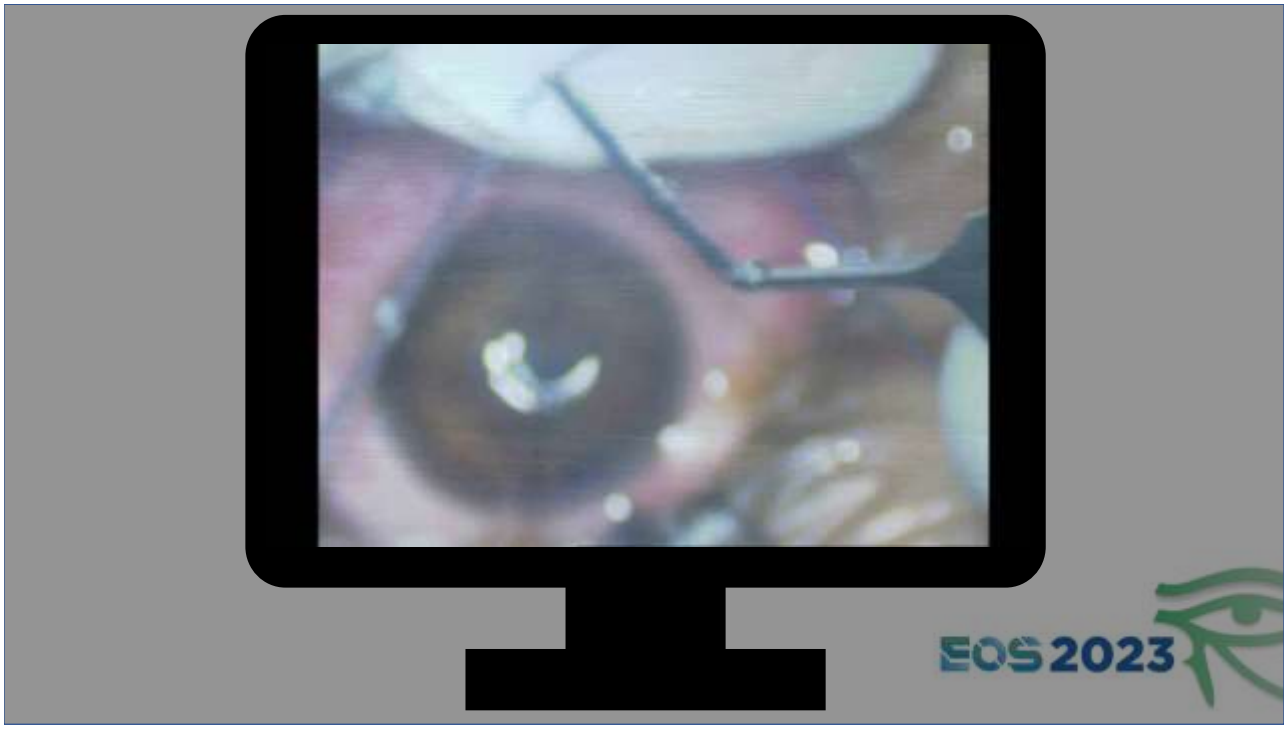
- The follow-up records for all visits up to 1 year or more were revised. Data regarding BCVA, IOP, the number of glaucoma medications, the need to remove the proline suture, and any post-operative complications were extracted.

- Incomplete medical records were excluded from the study.

- Surgical technique:

The surgical technique described by Pathak Ray and Rao was used with very few differences, mainly, the use of Mitomycin-C and ripcord.

Pathak Ray V, Rao DP (2018) Surgical outcomes of a new low-cost nonvalved glaucoma drainage device in refractory glaucoma: Results at 1 year. J Glaucoma 27(5):433-439.



Outcomes

- The primary outcome was **IOP reduction**.
- Complete success was defined as IOP ≥ 5 mmHg and ≤ 21 mmHg or reduction of IOP by ≥ 20% from baseline without any antiglaucoma medications.
- Qualified success was defined as reaching the same IOP range with the aid of antiglaucoma medications.
- Failure of the surgery was defined as loss of vision (no light perception), the need for a second glaucoma surgery or tube explantation during the follow-up period.

Outcomes (Cont.)

- Hypertensive phase (HTP) was defined as a rise of IOP>21 mm Hg, with a high tense cystic bleb around the plate. This may start after 10 days of surgery and persist up to 6 months requiring AGM for control of IOP.
- Resolving or resolved HTP was defined as: subsequent reduction in bleb height, with step-down of AGM, or discontinuation.
- Data from the post-operative visits at 1 week, 2 months, 6 months, and 1 year were extracted and analyzed.

Results

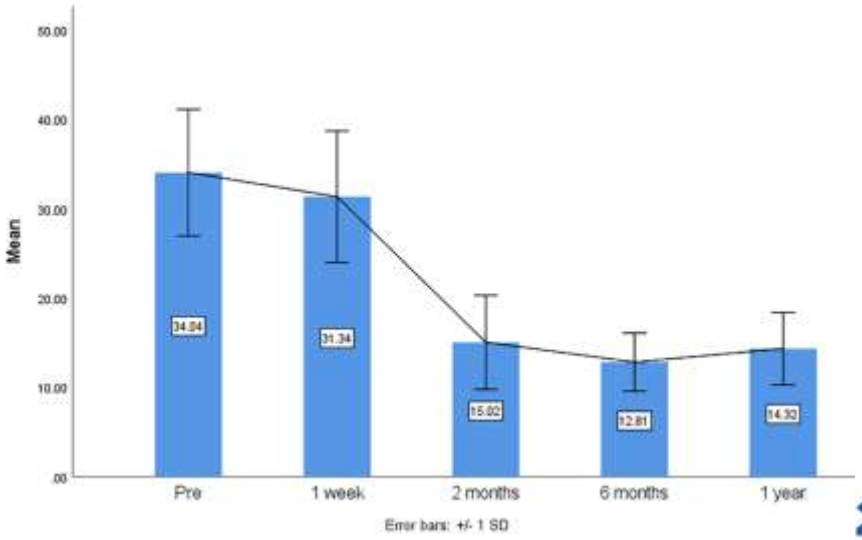
- 50 eyes of 48 patients (29 males and 19 females) were included. The mean age was 42.1± 20.2 years, with a range from 1.5 to 66 years.

- The mean glaucoma duration since the first diagnosis was 4.9± 6.2 years, with a range from 3 months up to 28 years.

Etiologies of glaucoma in the included sample

Etiologies of glaucoma	Frequency	Percent
Congenital	10	20%
Silicon induced	12	24%
Neovascular	13	26%
Secondary to a complicated keratoplasty	6	12%
POAG	3	6%
Others: angle recession, 2ry to microspherophakia in a case of Weil Marchesani, uveitic, unidentified cause in a case of Steven Johnson Syndrome	6	12%
Total	50	100%

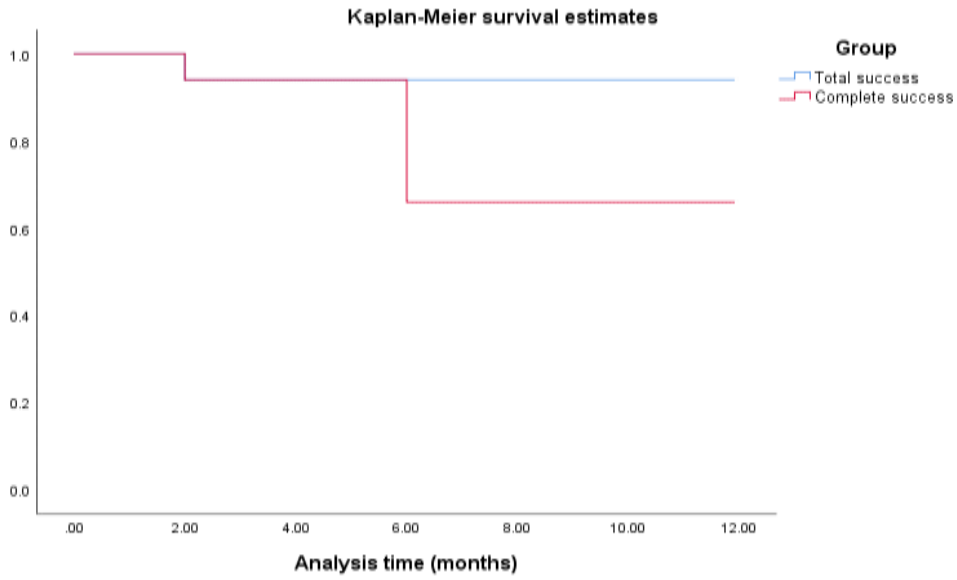
The mean IOP (intraocular pressure) pre-operative and at 1 week, 2months, 6 months and 1 year



Results (Cont.)

- The preoperative median number of AGM was 3 (mean ± SD = 2.84 ± 1), and after 12 months was 1 (mean ± SD = 0.52 ± 0.89).
- No significant changes in the BCVA were observed.
- Complete success, as previously defined, was achieved in 33 patients (66%). Qualified success was achieved in 14 patients (28%). The total success rate was 94% (95% confidence interval (CI) at 1 year of 84.8%-98.3%).
- Failure was encountered in 3 eyes.

Kaplan-Meier survival graph showing the survival of the AADI over one year in terms of total success (complete and qualitative) and complete success



Results (Cont.)

- A transient hypertensive phase, as defined before, occurred in 7 patients (14%) between the sixth and the twelfth week. All of them were medically controlled and resolved within one to three weeks.

- The removal of the prolene suture ripcord from the tube was done in only 15 eyes (30%) during the follow-up period. The earliest removal was done three months after surgery.

Recorded postoperative complications (early and late) with the timing of occurrence:

Complications	Frequency	Percent	Timing of occurrence
Early complication (within 1 month):			
Conjunctival opening without tube exposure	1	2.0	2nd week
Early opening of the device (without hypotony)	2	4.0	1st week and 2nd week
Early hypotony and cataract progression	1	2.0	2nd week
Uncontrolled uveitis with uncontrolled IOP (extensive anterior synechea)	1	2.0	1st week
Late complications:			
Cataract progression	1	2.0	9th month
Uncontrolled IOP	2	4.0	4th month
Severe encapsulation	1	2.0	4th month
Silicon egression	1	2.0	2nd month
Tube exposure	3	6.0	3rd, 6th, and 9th month
No complications	37	74.0	

Discussion

- This is the largest report of the outcome of this device among the Egyptian population.
- Neovascular glaucoma was the commonest indication (26%), followed by silicone-induced glaucoma (24%), and congenital glaucoma (20%). This might be related to the pattern of referral in Ain Shams Glaucoma clinic.
- Our results regarding IOP and number of AGM reduction was comparable, or even slightly better than previous studies.

Discussion (Cont.)

- We had a lower rate of complications than the previous studies.
- The transient hypertensive phase occurred in only 14% of patients. This lower incidence might be attributed to the difference in the surgical technique used in our study as Mitomycin-C was applied to all patients.
- We also had a lower incidence of postoperative hypotony which is attributed to the use of rip cord.

Conclusion

- The results of this study show that use of Mitomycin-C during implantation of AADI is a highly effective and relatively safe method of control of IOP in refractory and advanced cases of glaucoma.
- We had a similar success rate to the previous studies on this device with a much lower complication rate which might highlight the importance of the simultaneous use of Mitomycin-C and ripcord.
- The availability and the low cost of the device might give it the edge over other drainage devices in the markets of developing countries with more restricted resources.

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