• Clinical Research •

Clinical outcomes and safety profile of glaucoma drainage device Ahmed ClearPath® 250 mm^2: a tertiary center experience

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Abstract

● **AIM:** To present the clinical outcomes in efficacy and safety of the Ahmed ClearPath® (ACP) 250 mm^2 model as well as our surgical technique.

● **METHODS:** Single-center prospective interventional study of uncontrolled glaucoma eyes undergoing ACP implantation, as a standalone procedure or in combination with cataract phacoemulsification. Intraocular pressure (IOP) was evaluated prior to surgery and 1wk, 1, 3, 6mo and 1y postoperatively. In addition, the number of antiglaucoma drugs and intra and postoperative complications were assessed.

● **RESULTS:** A total of 30 eyes of 28 patients were included in the study. The patients were on average 72.8 (13.4) years old and 53.6% were male. Totally 40% of the eyes had primary open angle glaucoma, 16.7% had neovascular glaucoma, 16.7% had pseudoexfoliative glaucoma, 10% had glaucoma secondary to pars plana vitrectomy with silicone oil tamponade, 6.7% had aphakic glaucoma, 6.7% had primary congenital glaucoma and 3.3% had pigmentary glaucoma. Before surgery mean IOP was 26.1 (10.8) mm Hg and mean glaucoma medication use was 3.7 (0.5). At 1, 3, 6 and 12mo mean IOP was 16.1, 11.7, 11.8 and 11.5 mm Hg, respectively. Mean glaucoma medication use was 1.9, 1.5, 1.2 and 1.2, respectively. At 1y, complete surgical success was found in 46.7% patients (*n*=14) and qualified success in 53.3% (*n*=16). There were no intraoperative complications. Postoperative complications include choroidal effusion (*n*=5), transient hyphema (*n*=2), early hypotony with shallow anterior chamber (*n*=2) and late hemorrhagic choroidal detachment (*n*=1).

● **CONCLUSION:** The ACP appears to be an efficient surgical option for treating refractory glaucoma, achieving good IOP control and decreasing medication burden. The results obtained at 6mo are an important prognostic factor for long-term outcomes.

● **KEYWORDS:** glaucoma; intraocular pressure; Ahmed ClearPath® 250 mm^2 model

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INTRODUCTION

Glaucoma drainage devices (GDD) have a well-established role in glaucoma management, especially in refractory disease and in high risk cases of failure of conventional filtering surgery[1-4]. These devices are generally subdivided into valved and non-valved and allow the drainage of aqueous humor through a tube placed in the intraocular space, connected to a scleral plate[5-6].

Dr. Anthony Molteno studied and firstly introduced GDD in 1966 with the Molteno non-valved device[6-7]. As noted by the 5-year results of ABC and AVB studies, non-valved devices are able to maintain lower intraocular pressure (IOP) with the use of less IOP-lowering medication compared with valved devices, reporting lower failure rates. However, non-valved devices have higher risk of hypotony that can lead to failure and consequent loss of visual acuity. It is necessary to restrict the flow of aqueous humor through the tube in early post-operative period to allow a fibrous capsule to form around the device, creating a resistance to flow, preventing hypotony[8-10].

Since 1966, there has been a lot of research and development with new devices emerging with different characteristics and particularities. In 2019 a new non-valved GDD was introduced by New World Medical, the Ahmed ClearPath® (ACP), that consists in a medical grade silicone plate, globe-shaped,

flexible and impregnated with barium to facilitate identification in imaging tests, attached to a medical grade silicone tube. The ACP is available in 250 and 350 mm² scleral plates, with a low plate design and more anterior fixation points compared to commercially available devices, allowing for technically easier scleral adjustment and fixation. In addition, it is packaged with a 23-gauge needle to perform sclerostomy and tube's lumen is preloaded with 4-0 polypropylene ripcord suture, which can be left during surgery for later removal or alternatively be removed before implantation[11-12].

To date, there are only a few studies on the efficacy and safety of ACP. Grover *et al*[13] published a retrospective multicenter interventional case series with ACP 250 and 350 in different subtypes of glaucoma with a follow-up time of 6mo and Dorairaj *et al*[14] published a retrospective, single-surgeon, interventional case series with ACP 250 in refractory primary open angle glaucoma (POAG) with a follow-up time of 24mo.

In this study we report the outcomes of different subtypes of glaucoma that underwent ACP 250 implantation as a standalone procedure or combined with cataract phacoemulsification (PHACO), with a follow-up time of 12mo, in a Portuguese tertiary center.

PARTICIPANTS AND METHODS

Ethical Approval Patients' informed consent was obtained prior to their participation in this study and the tenets of the Declaration of Helsinki were accomplished.

Participants and Study Design The authors performed a single center prospective interventional study. It included patients with different glaucoma subtypes, refractory to medical or surgical treatment that underwent ACP 250 implantation as a standalone procedure or in combination with PHACO between November 2021 and September 2023, in Centro Hospitalar Universitário de Lisboa Central, Lisbon, Portugal.

Patients were eligible to participate in the study if they were 18y or older with the diagnosis of glaucoma of any subtype and IOP levels over 21 mm Hg or progression of glaucoma damage, despite maximal IOP-lowering medication and/or prior surgeries. Patients with less than 1wk follow-up period were excluded.

Patient demographic parameters such as age, sex and ethnicity were assessed at the baseline as well as medical history, we collected data about glaucoma type and severity (using International Classification of Diseases—10 criteria), lens status, previous surgical ophthalmological procedures and number of anti-glaucomatous drugs in use.

All patients were submitted to a complete ophthalmologic evaluation, that included best corrected visual acuity assessment with Snellen chart, biomicroscopy, dynamic gonioscopy, fundoscopy, Goldmann applanation tonometry and Octopus® standard automated perimetry.

Data about the surgery was also collected such as type of procedure (standalone or combined with PHACO) and quadrant of ACP implantation.

Patients were evaluated on the first postoperative day, and 1wk, 1, 3, 6mo and 1y postoperatively. In all visits a complete ophthalmologic assessment was performed, including visual acuity measurement, tonometry, biomicroscopy and fundoscopy. IOP was measured using Goldmann applanation tonometer (GAT), IOP lowering medication and signs of complications were recorded.

Complete surgical success was defined as IOP of ≥6 mm Hg and ≤21 mm Hg without IOP-lowering medication, qualified success was defined as IOP≥6 mm Hg and ≤21 mm Hg with IOP-lowering medication, and failure was defined as IOP<6 mm Hg or >21 mm Hg or cases requiring further surgical intervention to control IOP.

Surgical Procedure All procedures were carried out following the same protocol, by 3 glaucoma surgeons with experience in glaucoma filtering surgery, valved and non-valved drainage device implantations and minimally invasive glaucoma surgery (MIGS).

Surgery was performed under sub-Tenon's anesthesia with 2% lidocaine. A peritomy extending roughly 2 clock hours with two small relaxing incisions was made and a fornixed-based conjunctival flap was dissected using Westcott scissors. Low power cauterization was applied to the exposed scleral area. Then, tube priming was verified using balanced salt solution (BSS) and ACP plate was sutured to the sclera, with nylon 8-0 at 8 mm from the limbus in the superior quadrants or 6 mm from the limbus in the inferior quadrants.

Our team chose to remove the 4-0 intraluminal polypropylene cord, which comes with the device, and occluded the tube with a 7-0 polyglactin suture. Then, tube fenestrations were made anterior to the 7-0 polyglactin suture and the intraocular extremity was sectioned bevel-up in cases of anterior chamber (AC) implantation and bevel-down in cases of sulcus implantation.

To cover tube's subconjunctival path, a scleral tunnel was made. Subsequently, a paracentesis was performed to fill and maintain the AC with a viscosurgical device and a sclerostomy was created approximately 2-3 mm from the limbus, with a 23G needle oriented parallel to the iris plane, through which the tube was inserted in the intraocular space. Then, the conjunctiva was sutured to the limbus using 10-0 nylon suture and the relaxing incisions were sutured with 7-0 polyglactin suture. Finally, and after total viscosurgical device removal with BSS, intracameral 0.05 mL of ranibizumab 10 mg/mL and 1 mg (0.1 mL) of cefuroxime were injected in the AC and the paracentesis was hydrated. After surgery, patients followed our therapeutic protocol in the operated eye with ofloxacin

3 mg/mL 4 times a day for 2wk, dexamethasone 1 mg/mL 6 times a day tapered over 3 to 6mo and flurbiprofen 0.3 mg/mL 4 times a day for 1mo. IOP-lowering medication was adjusted as needed during follow-up, until the opening of the tube's absorbable suture. In the immediate postoperative period, we did not administer IOP-lowering medication. If necessary, this medication was initiated on the first postoperative day evaluation in order to maintain the IOP≤21 mm Hg, according to each surgeon's clinical judgment, giving preference to aqueous humor suppressors for their demonstrated anti-fibrotic effect in tube implant surgeries[15-18].

Statistical Analysis The data was analyzed with IBM® SPSS® Statistics 22.0, reporting mean IOP and IOP-lowering medication with their standard deviation (SD) and changes from the baseline considering statistically significant if $P<0.05$ after Wilcoxon signed-rank test.

RESULTS

Demographic Data and Baseline Characteristics

Tables 1 and 2 presents the clinical baseline characteristics of the patients, history of previous glaucoma procedures and surgical characteristics of ACP implantation.

Totally 30 eyes of 28 patients were submitted to ACP 250 implantation. Mean (SD) age of patients was 72.8 (13.4) years old and most of them were male (*n*=15, 53.6%) and Caucasian (*n*=22, 78.6%). The most common type of glaucoma was POAG (*n*=12, 40%) followed by neovascular glaucoma (*n*=5, 16.7%) and pseudoexfoliative glaucoma (*n*=5, 16.7%). All the patients had severe disease. Nineteen eyes (63.3%), had previous glaucoma surgery, most commonly trabeculectomy (*n*=12, 40%). All cases of POAG and pseudoexfoliative glaucoma had undergone at least one glaucoma surgery and were on maximum IOP-lowering medication. ACP 250 implantation as a standalone procedure occurred in 28 eyes (93.3%) and combined with PHACO in 2 eyes (6.7%).

Baseline and follow-up IOP measurements and IOP-lowering medication use are listed in Table 3. Before surgery mean IOP was 26.1 (10.8) mm Hg and mean glaucoma medication use was 3.7 (0.5). At 1, 3 and 6mo mean IOP was 16.1 (6.5), 11.7 (4.0) and 11.8 (3.1) mm Hg, respectively and mean glaucoma medication use was 1.9 (1.1), 1.5 (1.3) and 1.2 (1.3) respectively. In our study, at 1-year mean IOP was 11.5 (3.1) mm Hg and mean glaucoma medication use was 1.2 (1.3). There was no loss of patients during the follow-up.

Independency of IOP-lowering medication was achieved in 13 eyes at 1-year follow-up. At 6mo, complete surgical success was found in 46.7% patients (*n*=14), qualified success in 53.3% (*n*=16) and no case of failure was found. At 1-year follow-up, the same 46.7% of complete success and 53.3% of qualified surgical success were observed, also with no cases of failure.

Table 1 Clinical baseline characteristics of the patients

Parameters	*n* (%)
No. of eyes	30
Glaucoma diagnosis	
Primary open angle	12 (40)
Neovascular	5 (16.7)
Pseudoexfoliative	5 (16.7)
Secondary to pars plana vitrectomy with silicone oil tamponade	3 (10)
Aphakic	2 (6.7)
Primary congenital	2 (6.7)
Pigmentary	1 (3.3)
Glaucoma severity	
Severe	30 (100)
Octopus MD score dB	
16.0-20.0	10 (33.3)
20.0-24.0	13 (43.3)
>24.0	7 (23.3)
Lens status	
Phakic	2 (6.7)
Pseudophakic	25 (83.3)
Aphakic	3 (10)

MD: Mean deviation.

Table 2 History of previous glaucoma procedures and surgical characteristics of ACP implantation

Parameters	*n* (%)
Previous glaucoma procedures	
1 procedure	11 (36.7)
Trabeculectomy	7 (23.3)
Non-penetrating deep sclerectomy	3 (10)
Cyclodestructive procedure	1 (3.3)
2 procedures	8 (26.7)
Trabeculectomy followed by tube shunt	5 (16.7)
Non-penetrating deep sclerectomy followed by tube shunt	1 (3.3)
Minimally invasive glaucoma surgery followed by trabeculectomy	1 (3.3)
Tube shunt followed by cyclodestructive procedure	1 (3.3)
Eye laterality	
Right	17 (56.7)
Left	13 (43.3)
Procedure	
Standalone	28 (93.3)
Combined with phacoemulsification	2 (6.7)
Quadrant position	
Superior temporal	18 (60)
Inferior nasal	12 (40)

ACP: Ahmed ClearPath®.

There were no intraoperative complications. Postoperative complications included early serous choroidal detachment (*n*=5), early layered hyphema (*n*=2), early shallow AC without iridocorneal touch (*n*=2) and late hemorrhagic choroidal detachment (*n*=1). Serous choroidal detachment was successfully managed with topical and oral steroids (prednisolone

Table 3 Baseline and follow-up IOP measurements and IOP-lowering medication use

Items	Baseline	Day 1	1wk	1mo	3mo	6mo	12mo
No. of eyes	30	30	30	30	30	30	30
Mean IOP pressure (SD), mm Hg	26.1 (10.8)	21.5 (12.5)	15.6 (8.1)	16.1 (6.5)	11.7 (4.0)	11.8 (3.1)	11.5 (3.1)
P (change from baseline)		0.113	<0.001	<0.001	<0.001	<0.001	<0.001
Mean medication use (SD), *n*	3.7 (0.5)	2.1 (1.4)	1.9 (1.3)	1.9 (1.1)	1.5 (1.3)	1.2 (1.3)	1.2 (1.3)
P (change from baseline)		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
No. of eyes with IOP<12 mm Hg	0	4	7	5	14	13	13

IOP: Intraocular pressure; SD: Standard deviation.

acetate 10 mg/mL and prednisolone 1 mg/kg·d) and with longer-acting topical cycloplegic (atropine 10 mg/mL). Hyphema cases were transient and resolved spontaneously within a few days. In the case of shallow AC detected on the first postoperative day, the AC was filled with a viscosurgical device, without the need for further interventions. Late hemorrhagic choroidal detachment occurred 2mo after ACP implantation, without previous complications, this patient was referred to our Retinal Surgery Department and submitted to drainage of the hemorrhage from the suprachoroidal space and pars plana vitrectomy.

DISCUSSION

With the increasing prevalence of glaucoma worldwide it's estimated that the number of people with glaucoma will be 111.8 million (40-80 years old) in 2040, a number considerably higher compared to the 2020 estimative of 76 million of people affected with glaucoma[19-20]. This increase in prevalence will lead to an increase in the number of patients treated and inevitably to an increase in the number of patients refractory to medical and surgical therapy. There are various definitions for refractory glaucoma, but the one we use most frequently and find simplest is "glaucoma that is difficult to treat and poorly controlled on maximally tolerated medical therapy or failed surgical therapy regardless of stage of disease"[21].

In this study we present a real world experience with ACP 250 in refractory glaucoma of different etiologies, including POAG, neovascular, pseudoexfoliative, secondary to pars plana vitrectomy with silicone oil tamponade, aphakic, primary congenital and pigmentary glaucoma. This reflects the diversity of patients encountered in the daily clinical practice of a tertiary center.

Grover *et al*[13] reported mean IOP reduction of 12.6 mm Hg from 26.3 mm Hg to 13.7 mm Hg (-43.1%) and a mean reduction in IOP lowering medication of 2.1 from 3.9 to 1.8 (-52.3%) with ACP 250 in refractory glaucoma at 6mo. In our study, we were able to achieve mean IOP reduction of 14.3 mm Hg from 26.1 mm Hg to 11.8 mm Hg (-54.8%) with inferior use of IOP lowering medication that had a reduction of 2.5 from 3.7 to 1.2 (-67.6%) at month 6. These differences in outcomes can be explained by some variations in our surgical protocol[11]. The previous removal of the ripcord, tube occlusion with a 7-0 polyglactin suture and fenestrations and the creation of a scleral tunnel for the tube subconjunctival path may affect long-term outcomes, however studies with longer follow-ups are needed to establish more accurate conclusions. As recommended by the manufacturer, the use of the intraluminal ripcord is optional, but the use of the dissolvable suture around the tube is mandatory. We chose not to use the ripcord, as its use would require subsequent removal with the incision and manipulation of conjunctivas that are often thin or fibrotic. The use of ranibizumab is part of our surgical protocol, as it has been demonstrating good results in the management of neovascular glaucoma due to its anti-fibrotic and anti-angiogenic effects. In surgeries such as trabeculectomy, it appears to function as wound-healing modulators, improving outcomes[22-23]. Despite the parce evidence of its use in tube shunt surgery, it seems to maintain lower IOPs with larger bleb area, improving bleb survival[24-26].

All of our patients were in severe stages of glaucoma, which may influence the comparison with other studies. Furthermore, Grover *et al*[13] implanted ACP 250 and 350, while in our study we only implanted ACP 250, which may be a bias in the comparison of outcomes.

In POAG Dorairaj *et al*[14] reported at month 6 and 12 of follow-up a mean IOP reduction from 29 to 11.2 mm Hg (-17.8 mm Hg, -61.5%) and 10 mm Hg (-19 mm Hg, -65.5%) respectively. In terms of mean IOP lowering use of medication they reported a reduction from 3.0 to 0.7 (-2.3, -77.8%) and 0.6 (-2.4, -81.0%) in the same period mentioned above. If we analyze the results of our subgroup of POAG in Table 4 we can conclude that we achieved comparable IOP targets despite our patients having lower IOP at baseline with the use of a similar number of IOP-lowering medication. We reported at month 6 and 12 of follow-up a mean IOP reduction from 22 mm Hg to 12.3 mm Hg (-9.7 mm Hg, -44.1%) and 10.9 mm Hg (-11.1 mm Hg, -50.4%) respectively. In terms of mean IOP lowering use we reported a reduction from 3.8 to 0.8 (-3.0, -78.9%) and 0.9 (-2.9, -76.3%) in the same period mentioned above. Boopathiraj *et al*[27] reported at 36mo in POAG an IOP reduction to 10.6 (5.5) mm Hg and a mean number of

Table 4 Baseline and follow-up IOP measurements and IOP-lowering medication use in patients with primary open angle glaucoma

Items	Baseline	Day 1	1wk	1mo	3mo	6mo	12mo
No. of eyes	12	12	12	12	12	12	12
Mean IOP pressure (SD), mm Hg	22 (6.9)	23 (15.0)	13.3 (5.5)	14.3 (4.0)	9.6 (2.9)	12.3 (3.0)	10.9 (2.7)
P (change from baseline)		0.722	0.009	0.025	0.002	0.008	0.003
Mean medication use (SD), *n*	3.8 (0.4)	1.8 (1.4)	1.5 (0.9)	1.8 (0.8)	1.1 (1.0)	0.8 (1.1)	0.9 (1.2)
P (change from baseline)		0.009	0.003	0.002	0.002	0.003	0.003
No. of eyes with IOP<12 mm Hg	0	3	3	3	9	5	6

IOP: Intraocular pressure; SD: Standard deviation.

medication of 0.9 (0.9), these outcomes are very similar to ours, which suggests that the results after one year are strong indicators of long-term outcomes.

In the early post-operative period, we did not obtain the desired IOP due to the occlusion of the tube with the suture, however, as time went by, the absorbable suture gradually opened and around the sixth week it was fully open. This occurrence, combined with the tissue remodeling that takes place around the ACP's plate, allows ideal IOP to be obtained, avoiding early hypotonia[28-30]. In addition to what was described, some factors may contribute to the higher IOP values in the immediate postoperative period of our study: we dealt with patients with higher baseline IOP values which may influence the results; the viscosurgical device may not have been completely removed during surgery; patients in our study may have a more exuberant hypertonic steroid response due to the postoperative protocol than others.

Complete surgical success was achieved in 46.7%, while qualified success rate in 53.3% at 6mo, which was sustained at 1y of follow-up. This may indicate that the results obtained with ACP at 6mo are an important prognostic factor for long-term outcomes, demonstrating the stability of this device.

According to recent literature, Dixon *et al*[31] compared the outcomes of other non-valved devices, namely Molteno3 and Baerveldt GDD (250 and 350 mm^2 plate size), in various forms of glaucoma. In Molteno3 group, IOP decreased from and 22.8 (8.1) mm Hg with 3.3 (0.8) glaucoma medications to 13.3 (4.2) mm Hg with 2.0 (1.43) glaucoma medications. While in Baerveldt group, IOP decreased from 23.6 (7.2) mm Hg with 3.4 (1.0) glaucoma medications to 14.0 (4.0) mm Hg with 2.1 (1.41) glaucoma medications, after 1y of follow-up.

With regard to complications and comparing with published studies, we reported fewer early hyphema cases (6.7%) than Grover *et al*[13] (15.4%) and Dorairaj *et al*[14] (33.3%), this may be due to surgical technique differences, or differences in patient hemostasis and coagulation across the studies[13-14]. All patients undergo preoperative assessment by anesthesiology to prevent complications from systemic conditions and adjustments to anticoagulant and antiplatelet medications may be recommended. It is important to keep in mind that postoperative hyphema is not only related to the patient's systemic condition, as the trauma to the iris root during tube placement often leads to hyphema. We reported a rate of early hypotonia similar to other studies (6.7% *vs* Grover *et al*[13] 6.7%), what contributes to prevent this complication is the total occlusion of the tube with the 7-0 polyglactin suture and confirmation with BSS irrigation.

We reported higher rates of early serous choroidal detachment (16.7% *vs* Grover *et al*[13] 1.9%) mostly around 6^{th} week post-op that coincided with the time of the opening of the polyglactin suture, which possibly combined with the unformed fibrous capsule around the plate may lead to an abrupt IOP decrease. We also noted a serious complication of late hemorrhagic choroidal detachment around 2^{nd} month post-op that probably resulted from a patient's heavy lifting that induced excessive filtration, hypotony and the rupture of posterior ciliary arteries. Maintaining the preloaded intraluminal ripcord can reduce the risk of late hypotonic complications, but it implies the availability of the operating room to perform its removal in an aseptic environment or removal at slit lamp. We recommend that patients be closely monitored during the first postoperative weeks in order to promptly identify and correct possible hypotonic complications. Also, patients should be instructed about the warning signs that should make them resort to urgent ophthalmological observation, which are a sudden decrease in visual acuity, eye pain, hyperemia and conjunctival secretion, in order to detect complications early and act accordingly.

When comparing our complications rate with Molteno3 and Baerveldt 250 mm^2 published studies, even taking into account the different follow-up times, we concluded that we presented higher rates of early serous choroidal detachment (16.7% *vs* 3%-5% and 0), that were managed effectively with medical therapy, and higher rates of late hemorrhagic choroidal detachment (3.3% *vs* 3% and 0), managed with surgery[32-33]. In addition to the complications described, we did not encounter other complications that led to surgical failure or compromised visual acuity.

Välimäki[32] studied Molteno3 GDD and reported serious complications, as malignant glaucoma (in the first month post-op), retinal detachment and phthisis bulbi (after the first month

post-op), in patients with mean follow-up time of 10.3 (3.4)mo. Regarding the results with Baerveldt 250 mm², WuDunn *et al*[33] reported higher rates of hyphema, tube occlusion, corneal edema, anterior uveitis, persistent hypotonia, vitreous hemorrhage, conjunctival erosion, aqueous misdirection and light perception loss, in a mean follow-up time of 22.8 (20.3)mo. The present study is the first in Europe to report the outcomes of ACP 250 during an adequate follow-up time that contributes to a deeper comprehension of this device while supplying information to assess its efficacy and safety profile. We report the results of a multisurgeon team of our center with a singular surgical protocol that presents some variations and particularities.

Our study has some limitations. The fact that our work encompasses all the ACP 250 that were implanted in our center, without having calculated a sample size, could be a bias. The small sample size of different forms of glaucoma may not be representative of general population and can introduce some bias in our data. The lack of studies with the same methodology as ours does not allow the comparison of outcomes to be completely accurate. Comparing results from other tubes and ACP 350 implanted by the same surgeons in this study would allow for a more accurate profile to be drawn for the use of ACP 250. Although our study focuses on the efficacy in controlling IOP and the safety of the device, the information on pre- and post-operative visual acuity could provide us with additional information on the impact of this device on the patient's quality of life.

In conclusion, ACP 250 appears to be an efficient surgical option for the treatment of refractory glaucoma, achieving good IOP control and decreasing medication burden. The results obtained at 6mo are an important prognostic factor for long-term outcomes. The implantation of this GDD appears to have a relatively good safety profile, however we cannot ignore the serious complications that may arise. Further studies with longer follow-up time are needed to assess the efficacy and safety of this device.

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