Ophthalmology Research: An International Journal
4(3): 83-88, 2015, Article no.OR.2015.033
ISSN: 2321-7227

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Laser-Assisted Opening of Gold Micro Shunt's Windows in Glaucoma: Efficacy and Safety

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Authors' contributions

This work was carried out in collaboration between the two authors. Author PH designed the study and edited the manuscript. Author NC wrote the protocol and the first draft of the manuscript. Both authors read and approved the final manuscript.

Article Information

DOI: 10.9734/OR/2015/17902
Editor(s):
(1) Tatsuya Mimura, Department of Ophthalmology, Tokyo Women's Medical University Medical Center East, Japan.
Reviewers:
(1) S. K. Prabhakar, Ophthalmology, JSS University, India.
(2) Barbara Giambene, SOD Oculistica, University of Firenze, Italy.
Complete Peer review History: http://www.sciencedomain.org/review-history.php?iid=1023&id=23&aid=9579

Original Research Article

Received 30th March 2015
Accepted 26th April 2015
Published 4th June 2015

ABSTRACT

Objective: To determine the intraocular pressure-lowering effect and safety of opening the Gold Micro Shunt Plus' (GMS+) windows with a titanium-sapphire laser.
Design: Retrospective case series.
Participants: The charts of 5 patients were reviewed. Diagnoses included primary open-angle glaucoma (n=3), aphakic glaucoma (n=1) and neovascular glaucoma (n=1). There were 4 males and 1 female, aged between 56 and 81 (mean age 70±11). They had undergone a mean of 2±1.6 surgeries (range: 0-4) before GMS implantation.
Methods: IOP and number of glaucoma medications were recorded before and after the implantation of the GMS in 5 patients, as well as before and after the opening of the GMS' windows with a titanium-sapphire (Ti-Sap) laser. Patients were assessed for complications arising from implanting the GMS and opening its windows. Follow-up lasted 17 to 42 months.
Results: The GMS+ had 8 closed windows and one open flow port upon implantation. Four of these windows were opened in all five patients. Mean IOP before GMS implantation was 29.9±8.5 mmHg and it was 18.6±6.5 mmHg after implantation. Hence, implantation of the GMS was associated with an average decrease in IOP of 11.3±4.2 mmHg or 37.0% (p=0.076). The mean IOP before window-opening was 24.9±5.8 mmHg and after window opening, it was 17.6±5.7 mmHg. The IOP thus dropped 7.3±4.6 mmHg or 29.3% (p=0.055) on average after opening the

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GMS' windows. The windows were opened an average 6.4±4.5 months after GMS implantation. IOP at follow-ups remained lower than pre-GMS levels in all patients. The IOP reduction post window opening lasted throughout follow-up, i.e. from 17 to 42 months (average 30±10 months). The number of glaucoma drops for each patient did not decrease after opening the GMS' windows. One patient developed transitory cystoid macular edema after GMS implantation that resolved with a course of NSAID drops. No complications arose from the opening of the GMS' windows.
Conclusions: In our small case series, opening the GMS' windows was safe and was associated with a substantial and sustained reduction in IOP.

Keywords: Glaucoma; gold micro shunt (GMS); gold micro-shunt window opening; glaucoma shunt; suprachoroidal glaucoma shunt.

1. INTRODUCTION

Several surgical treatments exist for glaucoma. Conventional surgical approaches such as trabeculectomy and glaucoma drainage devices connect the anterior chamber (AC) to the subconjunctival space, and form a filtering bleb. These procedures have been effective in many cases but are associated with potential complications, including bleb leaks with hypotony, tube erosions and endophthalmitis [1].

A surgical technique that allows drainage of aqueous humour from the anterior chamber to the suprachoroidal space, while avoiding the complications linked to bleb formation, has been previously described [2]. The Gold Micro Shunt (GMS) (SOLX Inc, Waltham, MA) is a newer suprachoroidal shunt that also lowers IOP without bleb formation [3] and has been proven to reduce IOP from 32.6 to 45.3% [4,5].

It has been noted that both traditional shunts as well as suprachoroidal shunts, may fail due to marked encapsulation secondary to the high degree of scarring [1,2,6]. This may be due to the initial high flow through the implant, which induces fibrosis [7]. It is thus hypothesized that using a shunt in which the windows are initially closed like the GMS, and opening the windows after a few months, May lead to a slower egress of fluid and thus decrease the incidence of fibrosis and the pressure elevations associated with it.

The goal of this study was to determine the IOP-lowering effect and safety of opening the GMS' windows.

2. METHODS

2.1 Shunt Design

The Gold Micro Shunt Plus is a sterile, flat drainage device made from 24-K medical-grade (99.95%) gold. The device used in this study is approximately 6 mm long, 3 mm wide and 80 µm thick. The proximal or "head" end of the device has 8 closed ports and 1 open flow port which directs aqueous flow into the device. The 8 closed ports have a width of 100 micron and a height of 60 micron. The 1 open port is 50 micron wide by 60 micron height. The distal or "tail" end terminates in the suprachoroidal space with openings that allow aqueous to flow out through that end of the device. Larger reinforced openings aligned along the centerline of the device are designed to help in positioning the device. A protective, sterile insertion tool is supplied to aid with handling and insertion of the implant.

The GMS+ used in this study had eight closed windows. Four of these windows were opened all at once in all our patients when IOP was above target. The windows were opened with a Latina lens and Ti-Sap laser after an average of 6.4±4.5 months [range: 1-9].

2.2 Clinical Study

All cases that have undergone GMS insertion between December 2008 and March 2010 were included in this study. These five cases were retrospectively analysed from July to September 2012. The main outcomes were the complications and IOP associated with opening the GMS windows. The study was accepted by the IRB of Maisonneuve-Rosemont Hospital, and followed the tenets of the Helsinki Agreement. All patients signed an informed consent form to participate in the study.

After an initial fornix based conjunctival flap was made, a square-shaped scleral flap measuring 3.5 x 3.5 mm was dissected. Mitomycin C (500 mcg per mL) was then applied to the scleral bed for one minute, and washed with BSS. A full thickness incision into the suprachoroidal space was made posteriorly, and then the anterior

chamber was penetrated using a 2.75 keratome and enlarged. The GMS was implanted into the AC and the tail end in the suprachoroidal space. The superficial scleral flap was closed with a single 10.0 Nylon suture and the conjunctiva was closed with a 10.0 Vicryl suture using a modified Wise technique.

IOP was monitored regularly and if it was judged to be above target, the patient was scheduled for laser assisted window opening. The windows were opened after an average of 6.4±4.5 months [range: 1-9]. The Titanium-Sapphire laser procedure was performed with a 200 micron spot size, 790 nm wavelength, and 7 msec exposure time using 1-2 shots per window of 30-40 mJ. Topical Nepafenac (Nevanac, Alcon) drops were applied qid for four days after window ablation. The IOP (using a Goldmann tonometer) and number of glaucoma medications were recorded immediately after laser, as well as one, three, six and twelve months after laser. Follow-up was organized every 4-6 months thereafter.

2.3 Statistical Analysis

The paired student t-test was used to calculate differences between pre- and post-GMS implantation IOP, as well as between pre- and post-window opening IOP. The Friedman p-value was calculated to compare the pre-GMS and last follow-up's IOP (see Fig. 1), as an average of the five patients. A paired student t-test was also used to compare the number of glaucoma drops pre-GMS and at the most recent follow-up.

3. RESULTS

Among the research subjects, there were 4 males and 1 female, with a mean age of 70±11 year (range: 56-81). Three patients had primary open-angle glaucoma, one had aphakic glaucoma and one had neovascular glaucoma (Table 1). Four of the patients were Caucasian and one was Hispanic. They had undergone a mean of 2±1.6 surgeries (range: 0-4) before GMS implantation. Three patients were pseudophakic, one was phakic and one was aphakic. In terms of previous glaucoma surgeries, three had undergone a trabeculectomy, two had undergone a laser trabeculoplasty and three had other glaucoma drainage devices.

The GMS had 8 closed windows and one open port upon implantation. Four of these windows were opened in all five patients. Average follow-up post GMS implantation was 30±10 months.

Mean IOP before GMS implantation was 29.9±8.5 mmHg and it was 18.6±6.5 mmHg after implantation. Hence, implantation of the GMS was associated with an average decrease in IOP of 11.3±4.2 mmHg or 37.0% (p=0.076) (Fig. 1). The mean IOP before window-opening was 24.9±5.8 mmHg and after window opening, it was 17.6±5.7 mmHg. The IOP thus dropped 7.3±4.6 mmHg or 29.3% (p=0.055) on average after opening the GMS' windows (Fig. 1). The windows were opened an average 6.4±4.5 months after GMS implantation. IOP dropped 2.3 to 10.7% per window opened (mean 7.3%). Mean IOP at the last follow-up was 18.4±5.0 mmHg. Mean IOP reduction from pre-GMS to most recent follow-up is 38.5%.

Long-term IOP at follow-ups remained lower than pre-GMS levels in all patients. The IOP reduction post window opening lasted throughout follow-up, i.e. from 17 to 42 months (average 30 months).

The mean number of glaucoma drops was 2.6±1.1 before GMS implantation and 2.8±1.1 afterwards. The pre-operative glaucoma drops were continued as is after GMS implantation. Before opening the GMS' windows, the average number of drops was 2.4±0.9 and remained identical after opening the GMS' windows (Fig. 2). At the last follow-up, the average number of drops was 3.0±0.7 (p=0.26, student t-test). One patient developed transitory cystoid macular edema after GMS implantation that resolved with a course of Nepafenac (Nevanac, Alcon) drops four times per day during a month. No complication arose from opening of the GMS' windows.

4. DISCUSSION

Molteno et al. [7] suggested that a rapid egress of aqueous humour from the anterior chamber into the subconjuctival space after implanting a glaucoma shunt can lead to conjunctival fibrosis and subsequent elevation in IOP. In order to minimize this effect, the current study analyzed the effect of implanting a GMS with 8 closed windows and only one small open channel to limit the initial egress of fluid from the anterior chamber to the suprachoroidal space. In opening the GMS' windows a few months after implantation to decrease IOP further, it was postulated that this would limit the conjunctival fibrosis and subsequent IOP spikes described by Molteno et al. [7].

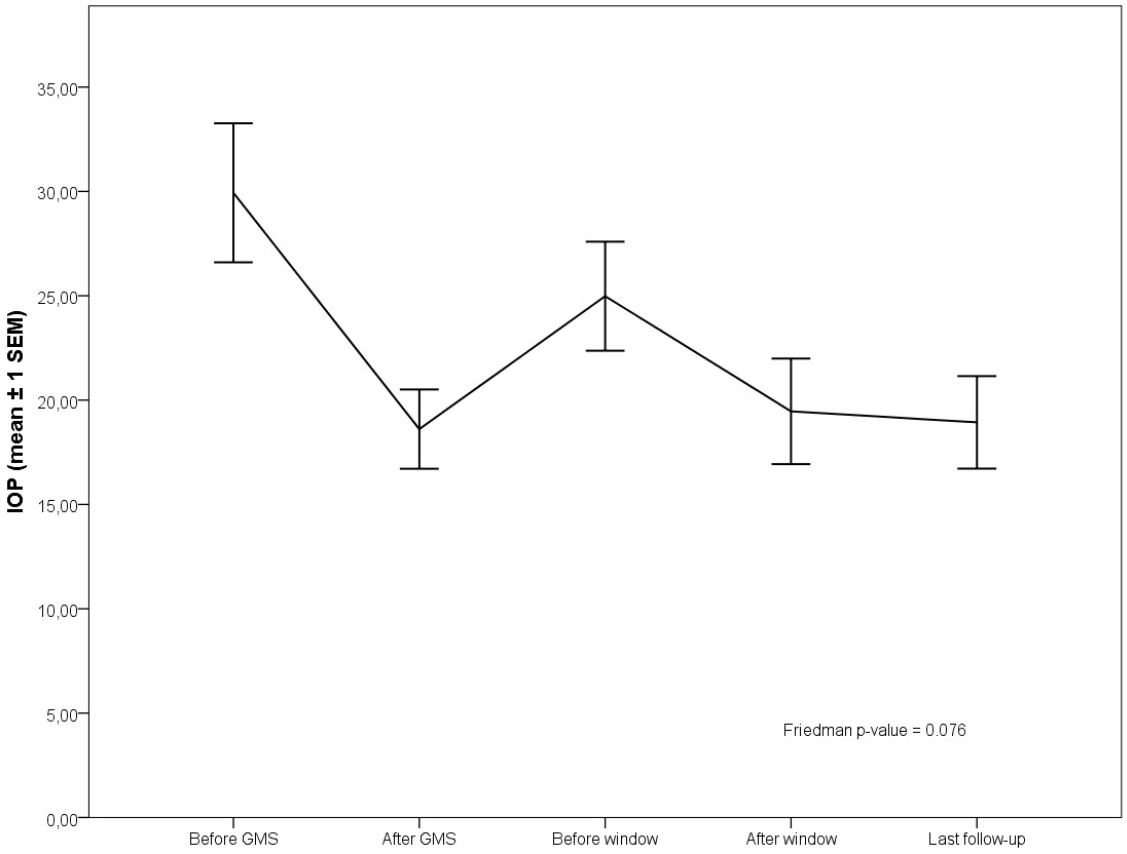

Fig. 1. IOP vs time, as an average of the five patients. IOP was measured before and after GMS implantation, before and after window opening and at the most recent follow-up

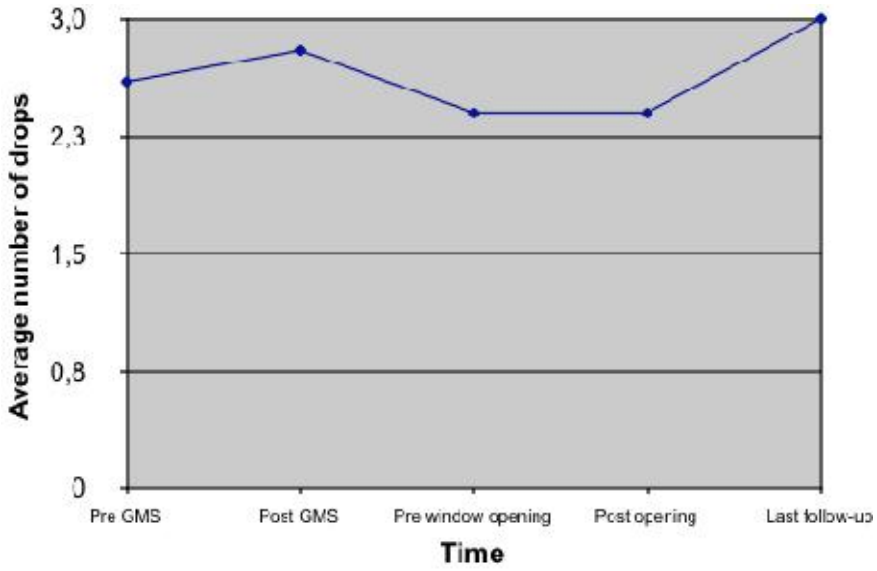

Fig. 2. Average number of drops versus time. The number of drops averaged between the 5 Patients was measured before and after GMS implantation, before and after window opening and at the most recent follow-up

Table 1. Clinical characteristics of patients enrolled in the study

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Type of glaucoma	Neovascular	Aphakic	POAG	POAG	POAG
Lens status	Pseudophakic	Aphakic	Pseudophakic	Pseudiphakic	Phakic
Pre-GMS filtration procedures	Trabeculectomy	Trabeculectomy Ahmed valve	Trabectome	none	Trabeculectomy with ex-press shunt
Maximal IOP recorded	34 OS	30 OD	34 OD	33 OD	26 OS
Central corneal thickness (in microns)	540 OS (Normal)	620 OD (High)	501 OD (Low)	535 OD (Normal)	567 OS (Slightly high)
Number of medications before GMS implantation	4	3	1	3	2

In this study, IOP decreased significantly after GMS implantation. There was still a moderate increase in IOP post-operatively, suggesting some healing response, however after opening the GMS' windows, the IOP decreased below the post-implantation level. In our small case series, this lowered IOP was sustained until the end of our patients' follow-up, without further pressure elevations. This is in contrast to a recent study that noted failure in almost all of their GMS cases [8]. This series is different not only in shunt design but in the use of MMC in our series as well. We postulate that the use of MMC diminishes fibrosis around the GMS and helps prevent late pressure spikes seen in other studies. Another recent study found that failure was associated with inflammatory cells in the suprachoroidal space [9]. In that study, a different shunt design was used and no MMC was deployed.

In this series, GMS implantation was safe, with no post-operative blebs. It has a favorable complication profile when compared to trabeculectomy and other bleb-requiring procedures. No complications linked to opening the GMS' windows were noted in this series, and no gold particles were seen within the eye at any of the post laser visits. In this small cohort of patients with high IOP on maximum medical therapy, the IOP reduction associated with GMS implantation and window opening was sustained throughout the post-operative period, but the average number of hypotensive drops remained largely constant throughout follow-up. One potential reason why the number of hypotensive drops was not decreased after laser opening of the GMS windows was that a lower target IOP was required. It has to be noted that the pre- vs post-GMS implantation ($p=0.07$) and pre- vs post-window opening ($p=0.055$) IOP reduction was not statistically significant. However, we consider that the IOP reduction was definitely significant from a clinical standpoint. The small sample size accounts for the lack of statistical significance in this study. It is also possible that had the remaining four windows also been opened, further IOP lowering may occur.

5. CONCLUSION

One of the current study's strengths is its follow-up duration (averaging 30 months and up to 42 months in one patient). However, the obvious limitation is its small sample size. Larger cohorts of patients with suprachoroidal implants that initially limit flow, used concomitantly with anti-fibrotics are needed. Future shunt designs may consider using a similar strategy that limit initial aqueous outflow, and permit future increase with office based procedures such as laser-assisted window opening, once the post-operative inflammation has subsided. Similar laser procedures have been used for suture lysis in trabeculectomies and removal of the tube ligature in Baerveldt drainage devices. In summary, in our small case series, opening the GMS' windows was safe and was associated with a substantial and sustained reduction in IOP. The GMS is thus an interesting alternative to trabeculectomy and other conventional surgical approaches in the treatment of patients with refractory glaucoma.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical

standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sciencedomain.org/review-history.php?iid=1023&id=23&aid=9579