ORIGINAL ARTICLE

Canaloplasty and Trabeculotomy Using the OMNI Surgical System in Three Patients with Angle Closure: A Case Series

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Received on: 15 March 2024; *Accepted on:* 01 September 2024; *Published on:* 29 October 2024

Abstract

Aim and background: The OMNI surgical system allows for 360° canaloplasty and trabeculotomy for patients with glaucoma, either as a standalone procedure or in combination with cataract surgery. There is currently limited evidence on its use in forms of angle-closure glaucoma, though other microinvasive glaucoma surgeries have been used. We present three patients with angle closure who underwent the procedure.

Methods: Retrospective review of three patients who underwent canaloplasty and trabeculotomy with the OMNI surgical system with forms of angle closure. Data on demographics, intraocular pressure (IOP), glaucoma medication use, best corrected visual acuity (BCVA), visual fields (VFs), and complications were collected for a 6-month period.

Results: Three eyes of three patients underwent the procedure: one with primary angle closure glaucoma (PACG), one acute angle closure, and one primary angle closure (PAC). All had surgery combined with phacoemulsification and intraocular lens (IOL) implantation. The mean age was 56 years. Preoperative IOP was 25.33 ± 2.49 mm Hg, improving to 11.67 ± 2.87 mm Hg at 6 months. Mean glaucoma medication use was reduced by 3.00, from 3.67 ± 1.21 to 0.67 ± 0.94. Preoperative mean BCVA was 0.10 ± 0.08 and 0.20 ± 0.08 LogMAR at 6 months. Mean deviation (MD) on VFs was –9.67 preoperatively and –6.72 at 6 months. Two patients had mild, self-limiting hyphema postoperatively which resolved without further intervention; no other complications were reported.

Conclusion: We have found the OMNI surgical system to be a safe, effective tool in the management of angle-closure glaucomas in a small cohort of patients.

Clinical significance: The OMNI surgical system has the potential to add a less invasive surgical solution in the management of angle closure glaucoma, prior to the use of filtering surgery such as trabeculectomy or glaucoma drainage device. Larger trials assessing the use of microinvasive glaucoma surgery (MIGS) in these patients will be eagerly received.

Keywords: Angle closure, Glaucoma, Microinvasive glaucoma surgery, Trabeculectomy.

Journal of Current Glaucoma Practice (2024): 10.5005/jp-journals-10078-1449

Introduction

Primary angle closure glaucoma (PACG) places a significant burden on patients and their health systems, with around half of glaucoma-related blindness worldwide being due to the condition.[1] Treatment options for the condition are varied, including medical therapy, laser iridotomy, and surgery. Cataract surgery alone has relatively good success rates of 62–72%,[2–4] and in recent years the EAGLE trial has cemented its role in early treatment of primary angle closure (PAC) and PACG. Despite this, there is ample scope for enhancements of the procedure; the rise of microinvasive glaucoma surgery (MIGS) has led to a plethora of such options, which can help bridge the gap between standard phacoemulsification and intraocular lens (IOL) insertion, and penetrating surgery such as trabeculectomy. The MIGS techniques that target the angle itself are particularly attractive, targeting as they do the underlying pathological region.

The OMNI surgical system (Sight Sciences, California, USA) is one such device, allowing for up to 360° canaloplasty and trabeculotomy either alone or with phacoemulsification. While there is good evidence for the procedure in patients with primary open-angle glaucoma (POAG),[5,6] no studies to date have assessed its efficacy in PACG. We present three patients who had good outcomes following the procedure, and hope to contribute to what is likely to be a growing base of evidence.

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How to cite this article: Richardson-May J, Ibrahim SA, Law K, *et al.* Canaloplasty and Trabeculotomy Using the OMNI Surgical System in Three Patients with Angle Closure: A Case Series. J Curr Glaucoma Pract 2024;18(3):117–120.

Source of support: Nil

Conflict of interest: None

Methods

We undertook a retrospective review of the notes of three known patients who underwent OMNI insertion with a diagnosis of PAC or PACG. We collected data on demographic information, diagnosis, previous ocular diagnoses or surgery, and lens status, along with pre- and postoperative intraocular pressure (IOP), best corrected visual acuity (BCVA), visual field (VF) mean deviation (MD), operative procedure, and postoperative course

including complications. We assessed a follow-up period of 6 months.

Intraocular pressure, medication, BCVA, and VF data are given as mean ± SD. BCVA is reported as LogMAR. Data were analyzed in Microsoft Excel.

Surgical Technique

All patients underwent surgery under topical and intracameral anesthesia without sedation. Standard phacoemulsification and IOL insertion were performed initially, with good fill of the anterior chamber (AC) with ophthalmic viscoelastic device (OVD; Healon, Johnson and Johnson). In the event that the angle had not opened sufficiently during phacoemulsification, one could consider mechanical or visco-goniosynechialysis to aid visualization and device insertion, though this was not required in our patients. Following this, the patient's head was turned away from the surgeon and operating microscope also inclined. A Swan Jacob direct gonioscopy prism (Glaukos, California, USA) provided the view of the angle. Once we had confirmed adequate visualization of the angle following phacoemulsification, the OMNI surgical system was inserted through the main incision and subsequently the trabecular meshwork. 360° of viscocanaloplasty followed by 180° of trabeculotomy (90° superonasal and 90° inferonasal) were performed, the device was removed, and the remaining OVD was removed after returning the patient and microscope to the central position. Wounds were sealed by hydration and intracameral cefuroxime was injected.

Postoperatively, patients received topical dexamethasone 0.1% four times a day for 4 weeks and chloramphenicol 0.5% four times daily for 2 weeks. Their usual glaucoma drops were stopped. Patients were reviewed on day 1, week 1, month 2, and month 6.

Results

Three eyes of three patients underwent OMNI insertion for angle closure; two males and one female, with a mean age of 56 years. All had left eye surgery. All procedures were undertaken in phakic patients and were combined with phacoemulsification and IOL insertion. Table 1 offers an overview of our three patients. All patients had 6 months of follow-up data. One patient had a glaucoma diagnosis of PACG, one acute angle closure glaucoma, and the third PAC. The third patient had a previous failed OMNI in the same eye and had required contralateral trabeculectomy with mitomycin C for PACG. All patients had peripheral anterior synechiae (PAS), which the OMNI procedure helped to release.

Intraocular pressure over time is demonstrated in Figure 1. The mean preoperative IOP was 25.33 ± 2.49 mm Hg. This improved

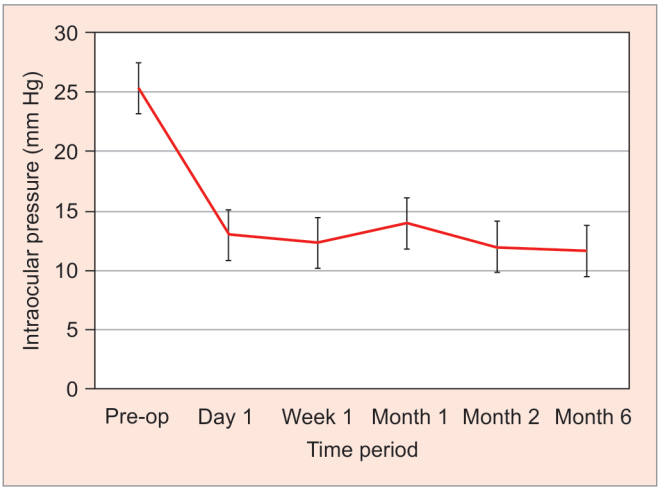

Fig. 1: Mean IOP (mm Hg) over time

Table 1: Overview of each patient

Patient	1	2	3
Sex	Male	Male	Male
Age	51	55	62
Glaucoma diagnosis	PACG	Acute angle closure glaucoma	PAC
Other ophthalmic diagnoses	Nil	Amblyopia	Nil
Previous ocular procedures	LPI	LPI Squint surgery	Nil
Lens status	Phakic	Phakic	Phakic
Past medical history	Asthma	Hypertension Osteoarthritis	Nil
Preoperative BCVA (LogMAR)	0.10	0.20	0.10
6-month BCVA (LogMAR)	0.10	0.30	0.20
Preoperative IOP (mm Hg)	26	28	22
6-month IOP (mm Hg)	15	12	8
Preoperative VF MD	–7.69	–19.82	–1.51
6-month VF MD	–1.51	–15.68	–2.96
Preoperative glaucoma medications	5	4	2
6-month glaucoma medications	2	0	0
Operative complications	Nil	Mild hyphema	Mild hyphema

BCVA, best corrected visual acuity; IOP, intraocular pressure; LPI, laser peripheral iridotomy; MD, mean deviation; VF, visual field

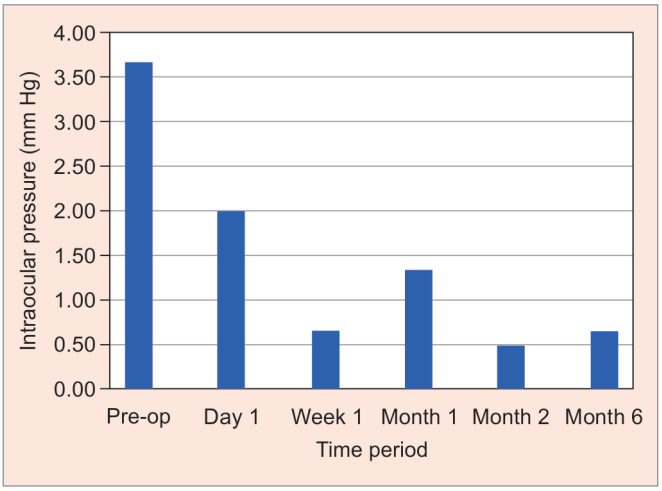

Fig. 2: Mean glaucoma medication use over time

to 11.67 ± 2.87 mm Hg at 6 months, giving a mean reduction of 13.67 mm Hg. Patients were on a mean of 3.67 ± 1.21 glaucoma medications preoperatively, improving to 0.67 ± 0.94 at 6 months; a mean reduction of 3.00 (Fig. 2).

Preoperative mean BCVA was 0.10 ± 0.08 and 0.20 ± 0.08 LogMAR at 6 months. MD from a Humphrey 24-2 automated VF was –9.67 preoperatively, and –6.72 at 6 months.

Complications in this small cohort were rare and mild when they occurred. Two patients had mild hyphema in the immediate postoperative period, which resolved without further intervention. At 6 months, no patients required further surgery. There were no incidents of IOP spike or hypotony in this group.

Discussion

Primary angle closure glaucoma accounts for around half of glaucoma-related blindness worldwide.[1] Its management has seen some significant changes over recent years following the results of studies such as EAGLE, with lens extraction being utilized earlier in the treatment pathway.[7] Despite this, there is still scope for the augmentation of standard cataract surgery and medical treatment with further surgical options. Traditionally, this has been in the form of incisional surgery such as trabeculectomy and glaucoma drainage devices (GDD). With the rise of MIGS, however, there is the potential to intervene earlier in the treatment pathway and offer angle-based procedures which may delay the need for penetrating surgery such as these. Surgical procedures aimed at the angle itself, once it has been mechanically opened following lens surgery, are particularly alluring; allowing the clinician to directly target the area underlying the pathophysiology of the angle closure disease.

The OMNI surgical system (Sight Sciences, California, USA) is a form of MIGS consisting of a single-use disposable instrument. It delivers a microcatheter into Schlemm's canal through the cannula tip; through this, viscoelastic can be injected to undertake a canaloplasty, dilating the Schlemm's canal and collector channels. This can then be followed by the removal of the microcatheter, which creates up to 360° of trabeculotomy.[8]

The OMNI device is well established in the treatment of POAG and has typically been used in mild-to-moderate glaucoma which is uncontrolled by medical management. The ROMEO and ROMEO2 studies found mean IOP reduction to 15.6 mm Hg and 15.9 mm Hg respectively, with mean glaucoma medication use of 1.4 and 1.3. They found high primary success rates as well as low rates of adverse events, which were mild when they occurred and were common to most forms of angle surgery (drop in BCVA, mild inflammation, IOP elevation, and hyphema).[5,6] Similar findings were identified in the GEMINI study in patients with concurrent phacoemulsification surgery,[9] and by multiple authors who have confirmed the safety and efficacy of the device both alone and with phacoemulsification. This includes long-term studies by Ondrejka et al. who again found similar IOP reductions, which persisted up to 42 months.[10–13]

In addition, the OMNI surgical system is beginning to find its use in other forms of glaucoma. Porsia and Nicoletti utilized OMNI in a 4-month-old full-term infant with congenital glaucoma associated with Sturge–Weber syndrome, with an improvement in IOP from >30 mm Hg bilaterally at presentation to 18 and 17 mm Hg at 10 months.[14] Terveen et al. have also reported good success in a retrospective review of 27 patients with previous trabecular micro-bypass stenting with the iStent or iStent inject MIGS devices (Glaukos, California, USA), suggesting OMNI as a viable option to avoid formal penetrating surgery such as trabeculectomy or GDD insertion in such patients.[15] To date, however, there is very limited data on the use of the OMNI device in eyes with PAC or PACG.

Cataract surgery alone has traditionally been an early part of the surgical care for angle closure patients, with success rates of 62–72% in PACG.[2–4] Forms of MIGS have been trialed in the surgical treatment of angle closure disease though as yet none are officially licensed for such an indication; Song et al. present a review of the practice so far, including the iStent, Kahook dual blade, gonioscopy-assisted transluminal trabeculotomy (GATT), Xen, and Hydrus. To date, evidence has suggested that MIGS can be both safe and effective in the management of PACG.[16] GATT, for example, has been found to offer 78% success rates at 24 months with a mean IOP of 12.1 mm Hg on 0.8 medications, with low rates of adverse events. This procedure is in some ways similar to the OMNI, comprising a form of ab interno trabeculotomy with a 5-0 polypropylene suture or illuminated microcatheter.[17] There is, however, a lack of robust, randomized trials allowing direct comparison between techniques. Two ongoing studies, the "PVP" study (phacotrabeculectomy vs phacogoniotomy) and the "TVG" study (trabeculectomy vs peripheral iridectomy plus goniotomy) aim to address some areas of PACG management.[18,19]

To date, we are unaware of published data on the use of the OMNI device in PACG. It is important to note that Sight Sciences do not recommend the use of the OMNI device in eyes where the iridocorneal angle is compromised or damaged due to issues with visualization of the angle as well as difficulty when passing the microcatheter.[20] We utilized the OMNI device only following phacoemulsification in these eyes and ensured an adequate view of the iridocorneal angle and trabecular meshwork prior to deploying the device to reduce the potential risks associated with a poor view. We would not recommend the procedure in phakic eyes with angle closure.

Our results demonstrate good IOP reduction in a small cohort of patients following combined phacoemulsification, IOL, and OMNI surgery. We have found improvement in BCVA as expected with cataract surgery and a reduction in glaucoma medications. Additionally, we had no cases of either IOP spike or hypotony and associated complications were mild—consisting of only mild, self-limiting hyphema. No patients required further surgery in the 6-month period.

Our study is limited in that it is a very small case series with a 6-month follow-up period. A larger study with a longer follow-up

period would be very beneficial, particularly one comparing standard phacoemulsification to combined surgery. However, we hope that this small study will demonstrate the possibility of the use of OMNI in these patients and contribute to a growing evidence base.

Conclusion

We have found OMNI combined with phacoemulsification and IOL surgery to be a safe, effective treatment in the surgical management of PAC and PACG in a small series of eyes. We found a mean IOP of 11.67 mm Hg at 6 months, a reduction of 13.67 mm Hg, with a corresponding reduction in glaucoma medications of 3.00. While a small series, we hope this will contribute to a growing bank of evidence demonstrating the use of MIGS in angle closure disease, allowing patients to delay the need for penetrating surgery such as trabeculectomy or GDD.

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