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A trabecular micro-bypass stent combined with phacoemulsification efficiently reduces intraocular pressure in open angle glaucoma in Mexican population

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Abstract

Background: Glaucoma is the second most common cause of irreversible blindness worldwide. First choice treatment is the use of topical hypotensives, and surgery is the gold standard. However, there are several associated complications. Minimally invasive glaucoma surgeries require less surgical manipulation and are generally safer. Trabecular microbypass stent devices allow a decreased resistance to the the aqueous humor outflow and a subsequent reduction in intraocular pressure. **Purpose**: The aim of this trial was to evaluate the efficacy and safety of a trabecular micro-bypass stent (*iStent*) combined with cataract surgery (phacoemulsification) in subjects with mild to moderate open angle glaucoma. **Methods:** A clinical trial was performed at Mexico's Hospital Central Militar. The intervention was the implantation of a trabecular micro-bypass stent combined with phacoemulsification. 23 patients who met the inclusion criteria were recruited into the trial. Intraocular pressure, best corrected visual acuity, visual field functional study, and the use of hypotensive drugs were documented, and the patients were divided into two random groups, one underwent cataract surgery and the other underwent cataract surgery plus a trabecular mycrobypass stent implantation. **Results:** iStent implantation was well tolerated and resulted in a significant reduction in intraocular pressure and the use of topical hypotensive drugs after one year of surgery. **Conclusion:** The use of the iStent combined with phacoemulsification results in a sustained hypotensive effect in Mexican patients diagnosed with open angle glaucoma.

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Introduction

Glaucoma is the second most common cause of blindness worldwide (Quigley 2006), but the first for irreversible blindness. According to the World Health Organization, the prevalence of blindness in Latin America is 1-4%, and 1.5% in Mexico (IAPB 2020; LIAPB 2020), but there are no information about glaucoma-related blindness.

Open-angle glaucoma (OAG) is a chronic and progressive eye disease that causes loss of the optic nerve rim and the retinal nerve fiber layer with associated field defects (Gedde et al. 2021). OAG represents 80-85% of all glaucoma cases worldwide, and 53.7% of glaucoma cases in Mexico (Galvez-Rosas et al. 2018).

Risk factors include older age, Latino/Hispanic ethnicity, family history of glaucoma, and lower ocular perfusion pressure (Gedde et al. 2021). The main risk factor for its development and progression is ocular hypertension, and the major therapeutic option to prevent glaucomatous damage is to reduce the intraocular pressure (IOP) (EGSTGG 2021). In Mexico, OAG IOP in adults has been reported as 17.1 (Galvez-Rosas et al. 2018). First choice treatment for glaucoma is the use of topical hypotensives, often more than once a day, and usually in combination with double or triple therapy, and has been associated with poor compliance (Newman-Casey et al. 2015) and low tolerability (Schuman 2000; Dreer, Girkin, and Mansberger 2012; Gatwood et al. 2021), which can lead to treatment failure.

The *ab externo* surgery is still considered the gold standard, as it has good efficacy; however, it has a high rate of complications, such as endophthalmitis, hypotonia, blister infections, blister leaks or fibrosis (Shah 2019; Birnbaum, Neeson, and Solá-Del Valle 2021; Garudadri, Rao, and Senthil 2010; Nassiri et al. 2020; Watanabe et al. 2019). Further, surgery alone results in only a modest reduction in IOP (Tennen and Masket 1996; Shingleton et al. 1999, 2006; Hudovernik and Paho 2003; Qassim et al. 2020; Hayashi et al. 2001; Poley, Lindstrom, and Samuelson 2008).

Minimally invasive glaucoma surgeries (MIGS) require less surgical manipulation and are generally safer, with more benefits to IOP reduction and lower rates of serious complications (Ferguson et al. 2017). First and second generation trabecular microbypass stent devices acts at the level of the trabecular meshwork, allowing to create a direct pathway from the anterior chamber to the drainage canal. This results in a decreased resistance to the the aqueous humor outflow of up to 30% and a subsequent reduction in IOP of up to 6 mmHg (Zhou and Smedley 2005; Samuelson et al. 2011).

Here we evaluated the effectiveness and safety of a trabecular micro-bypass stent implant combined with phacoemulsification in Mexican population with OAG.

Methods

Study design: A clinical trial was carried out in patients diagnosed with open angle glaucoma with mild to moderate damage according to Hodapp criteria, and with a diagnosis of cataract at Mexico's Hospital Central Militar. Patients older than 18 years that completed one year of follow-up were included. Exclusion criteria were follow-up of less than 12 months, neovascular, closed angle, or traumatic glaucoma, any previous glaucoma surgery (except laser trabeculoplasty), previous ocular trauma, patients with increased episceral venous pressure (active thyroid orbitopathy, carotid-cavernous fistula, Sturge-Weber syndrome), corneal opacity that makes gonioscopy and cataract difficult.

Clinical evaluation: A clinical evaluation of the patients was carried out, with a complete medical history and ophthalmological examination, including visual acuity and best corrected visual acuity, intraocular pressure measurement with Goldmann tonometry, slit lamp examination, gonioscopy with a 4-mirror Sussman lens, and dilated fundus examination. Prior to the surgery, preoperative studies included axial length measurement, anterior chamber width, anterior chamber volume, specular microscopy, 24-2 visual fields, and optic nerve & ganglion cells optical coherence tomography.

Surgery: All subjects underwent regular phacoemulsification cataract extraction with intraocular lenses (IOL) implant. Preoperative peribulbar anesthesia was used, after cataract extraction acetylcholine was used in the anterior chamber after implanting the IOL to induce pupil contraction. A first generation heparin-coated, medical-grade titanium, 1mm in length, 0.3mm diameter, 120 μ m lumen trabecular micro-bypass stent (iStent; Glaukos Corporation, Laguna Hills, CA) was also implanted. For the implantation of one iStent it was necessary to fill the anterior chamber with viscoelastic. This was found pre-loaded in a single-use inserter that will be advanced internally to the globe towards the inferior nasal sector of the iridiocorneal flexure, towards the pigmented portion of the trabecular meshwork towards Schlemm's canal guided by gonioscopy ab interno using a Swan-Jacobs. gonioscope. After verifying the proper implantation of the iStent, the applicator was removed, the viscoelastic was washed and the cataract surgery ports were hydrated. At the end of the surgical procedure, simple moxifloxacin topical antibiotic drops were placed. Postoperative care was performed with moxifloxacin 0.5% ophthalmic solution, which was continued for one week, in addition to the use of 1% prednisolone acetate, with a reduced dose for 4 weeks.

Follow-up: Follow-up was carried out by the same doctor after surgery the following day, and after one week, one, three, six and twelve months. At each visit, visual acuity, best-corrected visual acuity, IOP by Goldmann tonometry, need to continue with antihypertensive drugs (it was documented how many drugs the patient continued with or the need to withdraw or add them), associated complications were documented, such as infection, eye pain, low vision, increased or low intraocular pressure. Visual fields, OCT and specular microscopy were performed at 6 and 12 months after surgery.

Ethical approval declarations This protocol was approved by the Hospital Central Militar Ethic's Committee and was carried out in accordance with the relevant guidelines and regulations. All participants received and signed an informed consent.

Data analysis All records were collected in a database. Descriptive statistics, t-SNE dimensional analysis, and t-student

were performed in R 4.2.3 and GraphPad Prism 10.0.2 (171) for all our analyses.

Results

A total of 26 patients with a diagnosis of glaucoma were studied. Females 71 years old in average were the predominant patients. Primary open angle glaucoma (POAG) was the main diagnosis (Table 1), while secondary open angle glaucoma (SOAG), including pseudoexfoliative (PXG) and pigmentary (PG) glaucoma, accounted for the remaining diagnosis.

Table 1. Descriptive statistics. POAG, primary open angle glaucoma; SOAG, secondary open angle glaucoma; PXG, pseudoexfoliative glaucoma; PG, pigmentary glaucoma; CED, corneal endothelial cell density

Descriptive statistics	
Variable	n=23
Age, mean (SD)	71.2 (9.4)
Sex, n (%)	
Female	16 (69.6)
Male	7 (30.4)
Diagnosis, n (%)	
POAG	20 (87.0)
SOAG	3 (13.0)
PXG	2 (8.7)
PG	1 (4.3)
Right eye	13 (56.5)
Left eye	10 (43.5)
CED, mean (SD)	
Pre-surgery	2181.39 (362.14)
Post-surgery	1660.69 (341.84)

The mean corneal endothelial cell density (CED) pre-operatively was 2181.39 ± 362.14 $cells/mm^2$ while post-operatively at 1 month it was 1660.69 ± 341.84 $cells/mm^2$.

A dimensional reduction analysis by tSNE performed on all 26 variables from the 23 patients to identify the effect of the iStent implant showed that samples separated based on CED and IOP, with 3 distinct groups identified (Figure 1).

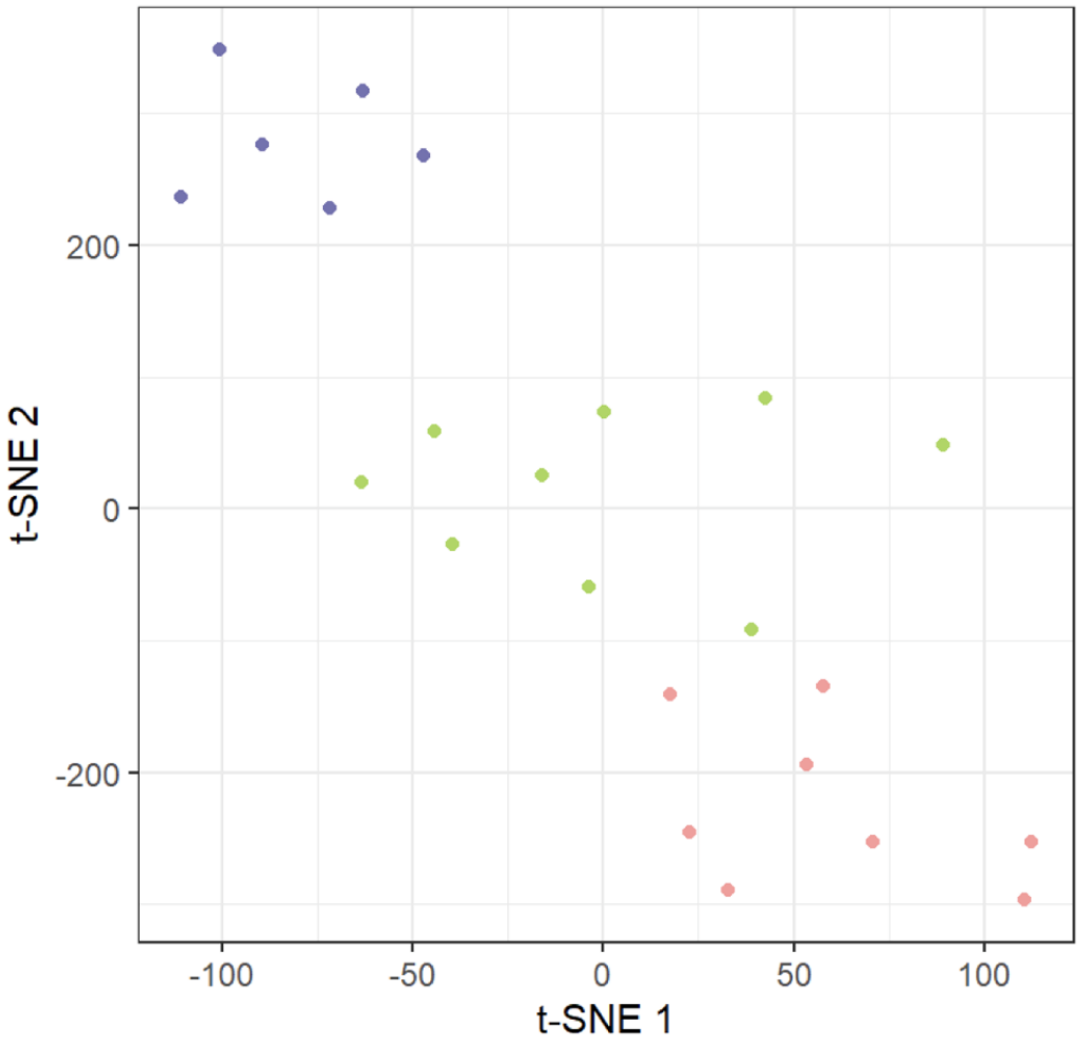

Figure 1. Multidimensional analysis. A t-sne analysis segregates the patients in 3 distinct groups accordingly to CED and IOP, and indicates these are the main variables that can predict an improvement after the iStent procedure.

Consistent with this observation, the iStent implantation produced a strong and sustained hypotensive effect. The intraocular pressure showed a rapid and constant decrease (Figure 2). A 12% reduction was achieved just 1 day after surgery, and reached a 19% reduction at 1 week, to stabilize at an average of 14.5% reduction, from 1 month up to 1 year. Importantly, the corneal endothelial cell count showed only a 23.8% decrease 1 month after surgery compared with the mean pre-surgery count (Figure 3).

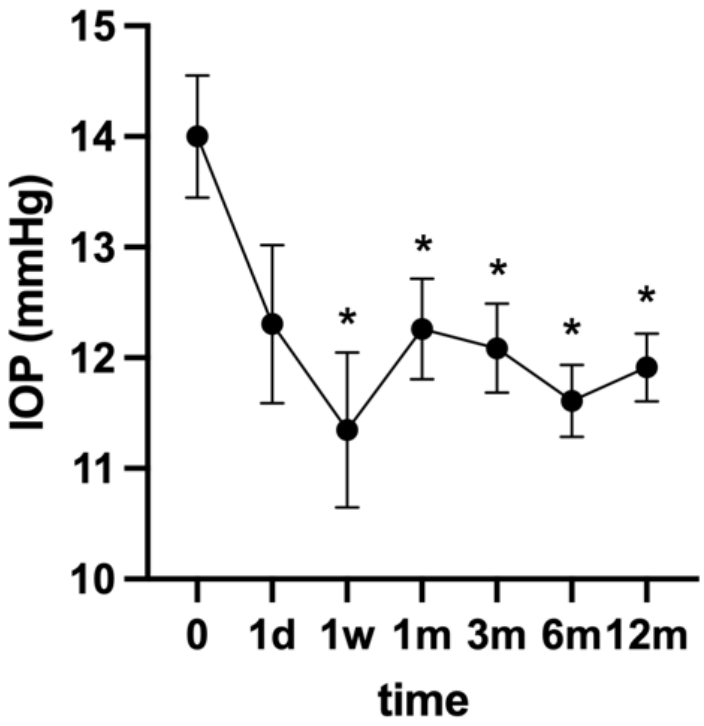

Figure 2. Intraocular pressure. iStent implants reduce intraocular pressure. *p*=0.05

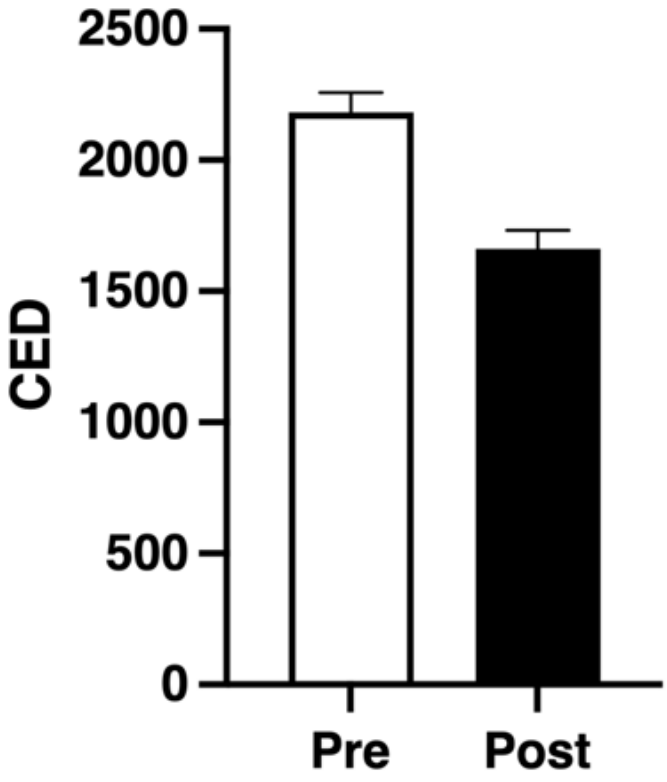

Figure 3. Endothelial cells. iStent implant modestly reduces corneal endothelial cell density. *p*=0.00005

These clinical improvements resulted in a dramatic decrease in the number of different conventional treatments received after surgery (Figure 4). All subject required no treatment in the first month following the iStent implantation, and reached an average 78% reduction in treatment for the remaining of the follow up. Further, during the whole 12 month follow up the iStent implant the patients reported no adverse effects.

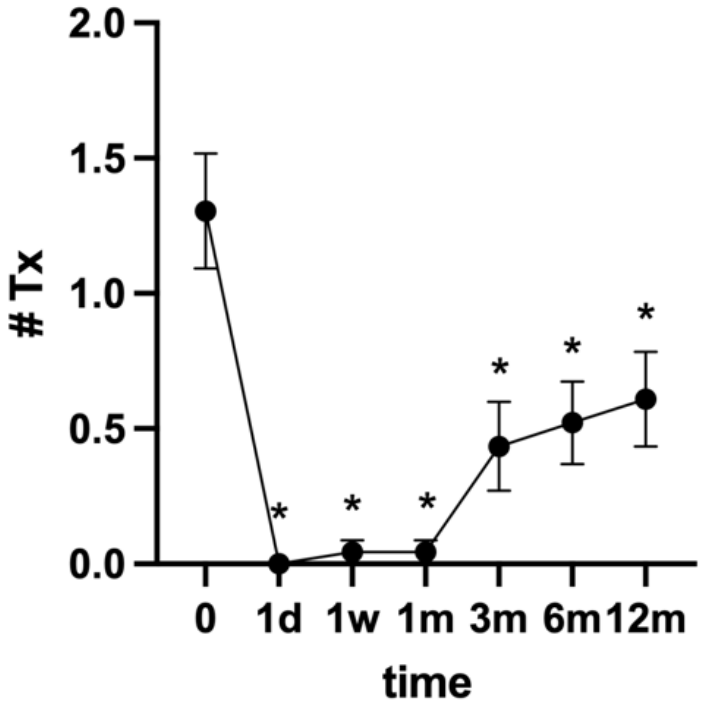

Figure 4. Treatment. Number of different conventional treatments after iStent implant. p=0.05

Discussion

From all variables studied, our multidimensional analysis suggests IOP and CED, both pre- and post-surgery, are crucial for an effective OAG surgery using a trabecular micro-bypass stent, and are factor to be considered during the recovery. These highlights the importance of a good procedure to minimize the loss of corneal endothelial cells, and the intraocular pressure as the main benefit from these kind of implants.

The strong hypotensive effect induced by the iStent implant was in line to the 13% reduction in IOP reported elsewhere (Chen et al. 2015). Typical glaucoma hypotensive treatment includes a combined therapy of at least 2 drugs, and several studies have reported that phacoemulsification reduces glaucoma medications by 12% in POAG (Chen et al. 2015).

Here we show that iStent implantation achieves an average reduction of 78% in the use of topical hypotensive drugs during the first year after surgery. This results in less damage to the ocular surface caused by the constant use of the hypotensive eye drops, and promote better adherence to treatment. Thus, this represents a significant decrease in expenses for both the institution and the patient. Further, it has been reported that the annual cost of hypotensive eye

drops in Mexico was $360 in 2013 (Lazcano-Gomez et al. 2013). The current annual cost adjusted by inflation is approximately $696 dollars, this is comparable to the $864 cost of the iStent implant in Mexico. Together, the benefits of the iStent become economically more evident after the first year.

Corneal endothelial cells are crucial in maintaining clarity of vision and a proper IOP (Islam, Saeed, and Mehboob 2017). Normal adults have between 2000-3000 $cells/mm^2$, in line with our patients average of 2181 $cells/mm^2$ despite being 71 years old. Severe corneal endothelial cell loss can occur after phacoemulsification (Bourne 2004), up to 42.6% (Soro-Martinez et al. 2021). We observed only a modest 23% decrease in these cells after surgery, suggesting the iStent has not a great impact. Our results in endothelial cells decrease after surgery are slightly above what has been reported elsewhere for a similar microbypass (Ahmed et al. 2023). This may be related to the surgery being performed by ophthalmology residents rather than fully-trained glaucoma ophthalmologists, and shows a potential area of improvement that can translate to further positive effects of the iStent implant.

Interestingly, although secondary OAG represents only 13% of our sample, this procedure works similarly for patients with primary OAG or secondary OAG, suggesting it can be used in a broad range of glaucoma surgeries.

The strong hypotensive effect induced by the iStent implant, together with the small corneal endothelial cell loss, was constant and showed little variability during the follow-up period. Similar to other studies (Ahmed et al. 2023), we did not observe any signs of corneal edema or any other complications and/or need for keratoplasty associated to the iStent implant. Compared with the typical permanent (8%) or transient (56%) vision loss after glaucoma surgery (Francis 2011), the iStent implant resulted in no vision loss in our patients.

These observations suggest the iStent implant has long-term reproducible positive effects, with great efficacy, safety, and benefits for the eye after surgery, but also promotes greater adherence to treatment in the long term.

Conclusion

iStent implant represents a cost effective alternative to traditional open angle glaucoma surgery plus conventional hypotensive drugs. The use of the iStent implant has no long-term adverse effects, and promotes greater adherence to treatment in the long term.

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