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REVIEW

A review of the iStent® trabecular micro-bypass stent: safety and efficacy

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Abstract: There is a significant demand for procedures that can effectively treat glaucoma with low risk and good visual outcomes. To fill this void, procedures termed "minimally invasive glaucoma surgery", are gaining in popularity. This review will focus on the safety and efficacy of one such minimally invasive glaucoma surgery procedure, the trabecular micro-bypass stent. This stent is intended to lower intraocular pressure by directly cannulating Schlemm's canal and thereby enhancing aqueous outflow. Recent randomized controlled trials and case series have demonstrated the micro-bypass stent to be a relatively safe procedure, with limited complications and no serious adverse sequelae. The most common complication across all studies was stent obstruction or malposition, which generally did not result in any adverse outcome in vision or pressure control. In addition, increased rates of hypotony, choroidal hemorrhage, or infection were not seen with the micro-bypass stent in comparison to cataract surgery alone.

Keywords: glaucoma, minimally invasive glaucoma surgery, MIGS, Schlemm's canal

Introduction

Glaucoma is a progressive optic neuropathy that affects over 60 million individuals, and causes visual impairment and blindness in a large percentage.[1] The prevalence of glaucoma worldwide is projected to increase to almost 80 million by 2020.[2] To date, the only proven treatments for glaucoma are aimed at lowering intraocular pressure (IOP) and initial treatment most commonly involves the use of topical ocular hypotensive medications. Unfortunately up to 40% of the glaucoma population in the USA requires more than one agent to effectively lower IOP.[3] Among the multiple disadvantages of topical therapy are difficulties with compliance and adherence to medications. When topical and systemic medications are not effective, laser trabeculoplasty or incisional glaucoma surgery is often indicated. Although incisional surgeries including trabeculectomy (with or without adjuvant antimetabolite) and glaucoma drainage devices (GDDs), are effective in lowering IOP, several large randomized clinical trials have shown uncommon, but significant complications.[4]

There is a demand for interventions with less morbidity that can effectively treat glaucoma and lessen the burden of disease. To this end, procedures termed "minimally invasive glaucoma surgery" (MIGS) may decrease IOP and have a better safety profile than traditional glaucoma surgery. This review focuses on one MIGS procedure: the trabecular micro-bypass stent, or iStent (Glaukos Corporation, Laguna Hills, CA, USA). This procedure is intended to lower IOP via direct cannulation of Schlemm's canal in order to enhance aqueous outflow. Although trabecular micro-bypass surgery has been recently reviewed,[5–9] this paper provides an update on published data with a focus on safety and efficacy.

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In general, the disadvantage of MIGS procedures is their inability to reduce IOP as effectively as trabeculectomy and GDD placement. When determining which MIGS procedures are best suited for patients requiring moderate IOP reduction, one must consider the iStent in relation to other MIGSs, including canaloplasty, trabectome, endocyclophotocoagulation, and ab interno gonioscopy-assisted transluminal trabeculotomy. Unfortunately, no head-to-head data exist comparing these techniques to each other. This review summarizes the current state of the iStent in order to determine where this procedure fits into the spectrum of glaucoma treatment.

Specifications and design

The trabecular micro-bypass stent (iStent®) is an ab interno, surgical-grade, heparin-coated, non-ferromagnetic titanium device (magnetic resonance imaging-safe up to 3 Tesla). The first-generation iStent was initially approved for use in Europe (August 2004) and later approved as an investigational device by the US Food and Drug Administration (FDA) in June 2012. There are two models available: GTS100R and GTS100L ("R" and "L" indicate right- and left-pointed tips, respectively). Although this designation was initially developed to indicate insertion into right and left eyes, it is currently recommended that right-handed surgeons insert "left"-facing stents for the most natural hand position. The iStent Inject® is the second-generation device. Unlike the first-generation device, which requires sideways slanting for cannulation of Schlemm's canal, the iStent Inject enables perpendicular injection into Schlemm's canal. The iStent Inject was approved for use in Europe in 2006. Studies are ongoing in the USA but FDA approval is not expected for several years. A third-generation device, the iStent suprachoroidal micro-bypass system, has not yet been commercialized. The mechanism for this device will involve the shunting of fluid to the suprachoroidal space.

The surgical technique for implanting the iStent has been thoroughly reviewed elsewhere;[5,10] we emphasize that there is a significant learning curve to obtaining an adequate gonioscopic view of the angle and proper placement of the device. Some of the difficulties with placement of the first-generation device have been alleviated in the design of the second-generation device.

Indications

The indication for the first-generation stent in the USA is:

> In conjunction with cataract surgery for the reduction of … IOP … in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.[11]

Prior to iStent placement, gonioscopic evaluation is essential to confirm that there is adequate view and there is no obstruction of the angle structures (corneal edema or opacity, congenital angle abnormality, or peripheral anterior synechia). The iStent has not been investigated for use in the setting of complicated cataract surgery (including corneal burns, capsular violation, anterior or posterior vitrectomy, and placement of intraocular lens in the sulcus or anterior chamber). Moreover, the iStent is currently contraindicated in all forms of angle-closure glaucoma, neovascular glaucoma, and elevated episcleral venous pressure (including Sturge–Weber syndrome).[11]

The pivotal trial was not powered to evaluate the specific outcomes in pseudoexfoliative or pigmentary glaucomas.[10] In fact, exclusion criteria for clinical trials include children, history of trauma, history of chronic inflammation or uveitic glaucoma, pseudophakia, and prior laser trabeculoplasty.[11]

Randomized controlled trials

Randomized controlled trials reviewed are summarized in Table 1.

iStent versus phacoemulsification

In 2012, the Ocular Hypertension Treatment Study Group demonstrated that cataract surgery achieved significant IOP reduction in ocular hypertensive patients.[12] This retrospective analysis of Ocular Hypertension Treatment Study patients demonstrated an IOP 16.5% (mean) lower in those that had cataract surgery (63 eyes) versus those who did not (743 eyes) ($P<0.001$). Recent studies have sought to determine if this IOP reduction can be augmented with the use of the iStent device.

Thus far, the iStent Study Group has produced the largest prospective, randomized, controlled, multicenter study of the iStent versus phacoemulsification.[10,13] Subjects with cataracts and open-angle glaucoma were randomized to either a treatment group that underwent phacoemulsification with a single iStent (n=117) or a control group that underwent phacoemulsification alone (n=123). After 12 months, Samuelson et al reported that 72% of subjects who received the iStent achieved the primary efficacy outcome of an IOP of ≤21 mmHg without ocular hypotensive medications.[10] In contrast, only 50% of controls achieved this outcome ($P<0.001$). The iStent group also faired significantly better when considering the secondary outcome measure of IOP reduction ≥20%

Table 1 iStent randomized controlled trials: summary of results

Study	Treatment group (n= number of eyes)	Control group (n= number of eyes)	Follow-up (months)	Attrition rate, treatment group/control group (%)	Treatment group mean IOP reduction (%)	Control group mean IOP change (% reduction)	Treatment group mean medications (% reduction)	Control group mean medications (% reduction)
Fea[14]	Phaco + 1 iStent (n=12)	Phaco (n=24)	15	0.0/12.5	17.3*	9.2	80*	31.6
Fernández-Barrientos et al[15]	Phaco +2 iStents (n=17)	Phaco (n=16)	12	0.0/0.0	27.3**	16.5	100*	41.7
Samuelson et al[10]	Phaco + 1 iStent (n=117)	Phaco (n=123)	12	9.4/8.9	8.2	5.4	86.7*	73.3
Craven et al[13]	Phaco + 1 iStent (n=117)	Phaco (n=123)	24	16.2/17.9	8.1	4.3	80.0	66.7

Notes: The values listed under the columns "mean IOP change" and "mean medications" indicate the reduction from baseline. *P*-values where available from original publication: *$P<0.05$, **$P<0.005$.
Abbreviations: IOP, intraocular pressure; phaco, phacoemulsification.

without ocular hypotensive medications (66% vs 48% of control subjects, $P=0.003$). Although both groups had achieved similar IOP lowering at 1 year, medication reliance was less in the iStent group (0.2±0.6 [mean ± standard deviation] medications versus 0.4±0.7 in the control group). Craven et al reported on the 24-month follow-up of these subjects.[13] From 12 to 24 months, the mean IOP remained stable in the iStent group but increased in the control group. The proportion of subjects achieving the primary efficacy outcome at 24 months remained significantly higher in the iStent group ($P=0.036$). At this time point, there was no longer a significant difference in the number of ocular hypotensive medications ($P=0.09$). Overall, this study demonstrated a more substantial and prolonged reduction of IOP with iStent treatment compared to phacoemulsification alone.

A 2010, prospective, double-masked clinical trial compared subjects with primary open-angle glaucoma and cataracts who were randomized to either phacoemulsification alone or phacoemulsification with a single iStent.[14] After 15 months, the mean IOP in the iStent group (n=12) improved from 17.9±2.6 to 14.8±1.2 mmHg (17.3% reduction, $P<0.05$). This reduction was greater than that of the control group (n=24), which improved from 17.3±3.0 to 15.7±1.1 mmHg (9.2% reduction, $P<0.05$). At this same time point, the mean number of ocular hypotensive medications was 0.4±0.7 and 1.3±1.0 in the iStent and control groups, respectively ($P=0.007$). Moreover, 67% of iStent subjects and 24% of control subjects no longer required ocular hypotensive medications.

Another 2010 report utilized fluorophotometric studies to evaluate the efficacy of the iStent based upon aqueous humor dynamics.[15] Subjects (n=33) with cataracts and glaucoma (either primary open-angle glaucoma or ocular hypertension) were randomized to either phacoemulsification with two iStents or phacoemulsification alone. After 12 months, IOP reduction was evident in both groups but was more pronounced in the iStent group (6.6±4.0 mmHg or a 27.3% reduction in the iStent group, 3.9±2.7 mmHg or a 16.5% reduction in the control group, $P=0.002$). These findings corresponded with increased trabecular outflow facility, which increased by 275% and 46% in the iStent and control groups, respectively. In addition, five control subjects required resumption of ocular hypotensive medications, while none of the iStent subjects required medication ($P=0.007$).

Case series

Case series reviewed are summarized in Table 2.

Table 2 iStent prospective case series: summary of results

Study	Treatment (n= number of eyes)	Follow-up (months)	Attrition rate (%)	Mean IOP change (% reduction)	Mean medications (% reduction)
	iStent				
Spiegel et al[17]	1 iStent (n=6)	12	0.0	23.90	18.5
Buchacra et al[18]	1 iStent (n=10)	12	20.0	27.30*	62.0*
Ahmed et al[16]	2 iStents (n=39) + travoprost	18	0.0	46.90	50
	Phacoemulsification + iStent				
Spiegel et al[20]	Phaco +1 iStent (n=47)	6	0.0	25.40***	66.7***
Spiegel et al[22]	Phaco +1 iStent (n=47)	12	10.6	21.40***	75.0***
Arriola-Villalobos et al[21]	Phaco +1 iStent (n=19)	60	31.6	16.33*	63.6*
Patel et al[19]	Phaco +1 iStent (n=44)	6	0.0	20.90**	74.3**
	Phacoemulsification + multiple iStents				
Belovay et al[23]	Phaco +2 iStents (n=28)	12	0.0	20.2% reduction***	64.3% reduction***
	Phaco +3 iStents (n=25)	12	0.0	20.4% reduction***	84.6% reduction***

Notes: Values listed under the columns "mean IOP change" and "mean medications" indicate the reduction from baseline. *P*-values where available from original publication: *$P<0.05$, **$P<0.01$, ***$P<0.001$.
Abbreviations: IOP, intraocular pressure; phaco, phacoemulsification.

iStent alone

In the most recent prospective, nonrandomized study of the iStent, Ahmed et al recruited phakic open-angle glaucoma subjects on two ocular hypotensive medications.[16] These subjects underwent washout of all glaucoma medications followed by implantation of two iStents with concurrent initiation of travoprost ophthalmic solution. After 1 month, mean IOP was reduced from the baseline of 22.2±2.0 to 14.0± 2.2 mmHg. After 12 months, all subjects had achieved an IOP reduction of 20% or more from the baseline IOP as well as the reduction of one medication (all patients continued on travoprost alone). A total of 29 patients achieved an IOP reduction of 40% or more from the baseline. All (100%) of patients had an IOP of ≤18 mmHg. Ahmed et al suggest that the iStent has the potential to be an alternative to multiple medications. They plan to present 5-year follow-up data in the future.[16]

Earlier studies include the initial pilot study of the iStent, published in 2007, by Spiegel et al.[17] This was a prospective, non-comparative, interventional case series of six patients with open-angle glaucoma who underwent insertion of a single iStent with observation over a 12-month follow-up period.[17] In this group, mean IOP was reduced from a baseline of 20.2±6.31 to 15.3±3.72 mmHg. This represents a mean reduction of 23.9% from the baseline but, in fact, four of the six patients achieved an IOP reduction of 25% or more. In 2011, Buchacra et al presented another case series of ten patients with secondary open-angle glaucoma (traumatic, steroid induced, pigmentary, and pseudoexfoliative).[18] After 12 months, IOP was reduced by 6.6±5.4 mmHg from a baseline IOP of 26.5±7.9 (27.3%, $P<0.05$). In both of these small case series of iStent insertion as the sole procedure, the authors observed ≥20% reduction of IOP and a reduction in the mean number of ocular hypotensive medications.

iStent with phacoemulsification

In a 2013 prospective, uncontrolled, interventional case series by Patel et al, 40 subjects underwent phacoemulsification with implantation of a single iStent.[19] After 6 months, mean IOP was reduced from a baseline IOP of 21.1 to 16.7 mmHg (20.9%, $P<0.01$). Mean ocular hypotensive medications were reduced from 2.30 to 0.59 (74.3% reduction, $P<0.0001$). Almost two-thirds (65.9%) of subjects required no medications 6 months after device implantation, while 100% of patients (n=6) who were on oral acetazolamide were able to discontinue use. This level of reduction in IOP is consistent with that of Spiegel et al[20] which is discussed following.

A case series published by Arriola-Villalobos et al provides the longest-duration follow-up period of iStent combined with phacoemulsification.[21] Of 19 patients with mild or moderate open-angle glaucoma who underwent phacoemulsification with a single iStent, 16 subjects completed 4 years and 13 patients completed 5 years of follow-up. In this group, IOP was reduced by 16.33% and ocular hypotensive medications were reduced by 63.6% after 5 years. In fact, at the end of the follow-up period, 62% (eight patients) maintained an IOP ≤21 mmHg without medications. These results imply that the efficacy of the iStent did not decline significantly over the 5-year postoperative period.

In 2008, Spiegel et al reported the interim results of a 24-month, multicenter, prospective, non-comparative study of phacoemulsification with iStent in 47 patients with open-angle glaucoma.[20] This interim report presented 6-month follow-up data in which mean IOP was reduced by 25.4% from a baseline of 21.5±3.7 to 15.8±3.0 mmHg ($P<0.001$). The mean number of ocular hypotensive medications was reduced from 1.5±0.7 to 0.5±0.8 (66.7% reduction, $P<0.001$). A second report of this study group presented the 12-month data analysis for 42 patients from the aforementioned group.[22] At this time point, the mean IOP reached 16.9 mmHg, representing a 21.4% reduction from the baseline. The mean number of ocular hypotensive medications required to reach this lower IOP was reduced by 1.2±0.7 ($P<0.0001$).

Placement of three iStents

To date, as far as we are aware, there is only one published study attempting to evaluate the utility of implanting more than two iStents in a single eye. Belovay et al provided evidence that the implantation of multiple devices could allow titration to achieve target pressure.[23] In 2012, they reported on a comparative case series in which 53 subjects with open-angle glaucoma underwent phacoemulsification with concurrent placement of two or three iStents (in 28 and 25 subjects, respectively). Their study revealed a significant IOP reduction in both the two- and three-iStent groups (20.2% and 20.4% reduction, respectively; not statistically significant). Although there was no significant difference in the degree of reduction of IOP between the two groups, the mean number of topical hypotensive medications was reduced by 64% in the two-iStent group and 85% in the three-iStent group. At 12 months, IOP reduction was adequate to discontinue medications in 46% of the two-iStent subjects and 72% of the three-iStent subjects ($P<0.05$).

Published studies: iStent Inject

The second-generation iStent, the GTS-400 iStent Inject, has been studied in both a randomized controlled trial and a case series. Fea et al have presented the most recent randomized, prospective, multicenter evaluation of the iStent Inject GTS400.[24] This study intended to demonstrate whether the iStent Inject was at least as effective as medical therapy. A total of 192 subjects with open-angle glaucoma underwent washout of their current ocular hypotensive medication. Those subjects meeting the post-washout IOP inclusion criteria (IOP ≥22 mmHg and <38 mmHg) were randomized to either surgery with two iStent Inject devices or medical therapy. After stent implantation or initiation of fixed-regimen medical therapy (latanoprost/timolol or travoprost/timolol), subjects were followed with a standard examination schedule over 12 months. After 12 months, reduction in IOP from screening was 38.4% and 36.2% for the iStent Inject and control groups, respectively (25.2±1.4 to 12.0±2.3 mmHg in the iStent Inject group and 24.8±1.7 to 13.2±2.0 mmHg in the control group). The primary efficacy outcome of an IOP reduction of ≥20% below the non-medicated baseline was achieved in 94.7% of treatment subjects and 91.8% of control subjects. Of note, significantly more subjects in the iStent Inject group achieved an IOP reduction of ≥50%. Overall, this study suggests that treatment with two iStent Inject devices is comparable to medical therapy and may be beneficial in reducing medication burden.

Voskanyan et al recently investigated the efficacy of the GTS-400 iStent Inject in the absence of phacoemulsification, in a multicenter, prospective, unmasked case series.[25] After 12 months, iStent Inject subjects achieved a 39.7% reduction in mean IOP (n=99). Medication burden was significantly improved in 86.9% of subjects and, of those, 66% of subjects did not require any ocular hypotensive agents to achieve an IOP of ≤18 mmHg. Finally, Arriola-Villalobos et al enrolled 20 subjects who were followed for 1 year after undergoing phacoemulsification with implantation of two iStent Inject devices.[26] After 12 months, IOP was reduced by 35.68% (from a baseline of 19.95±3.71 to 16.75±2.24 mmHg [$P<0.001$]). Reliance upon medication was reduced by 76.9%, from a baseline of 1.3±0.66 to 0.3±0.57 ocular hypotensive medications. While the reduction in medications is comparable to that reported by other studies, the reduction in IOP is augmented in this group. A summary of the iStent Inject device publications is presented in Table 3. As far as we are aware, no studies to date have compared the first- and second-generation devices to each other.

Safety

In the published data regarding the iStent, the nature and frequency of adverse events were similar across studies.[10,13–15] In addition, the rates of adverse events and secondary interventions were similar between iStent and control groups.[10,13–15]

In the 24-month randomized controlled trial of the iStent Study Group, Samuelson et al and Craven et al reported similar incidence of corneal edema, anterior chamber inflammation, discomfort, epithelial defect, paracentesis for elevated IOP, macular edema, and posterior capsular opacification in the iStent and control groups.[10,13] Overall, there were no reports of significant postoperative complications such as

Table 3 iStent Inject clinical studies: summary of results

Study	Design	Treatment (n= number of eyes)	Follow-up (months)	Attrition rate (%)	Mean IOP change (% reduction)	Mean medications (% reduction)
Fea et al[24]	RCT	Treatment (2 iStent Inject) (n=94) vs control (medication) (n=98)	12	Treatment 0.0 vs control 7.1	Treatment 38.40 vs control 36.20*	NA
Arriola-Villalobos et al[26]	Case series	Phaco +1 iStent Inject (n=3) Phaco +2 iStent Inject (n=17)	12	0.0	35.68**	76.9**
Voskanyan et al[25]	Case series	2 iStent Inject (n=99)	12	7.1	39.70	Data not provided

Notes: The values listed under the columns "mean IOP change" and "mean medications" indicate the reduction from baseline. *P*-values where available from original publication: *$P<0.05$, **$P<0.001$.
Abbreviations: IOP, intraocular pressure; NA, not applicable; phaco, phacoemulsification; RCT, randomized controlled trial; vs, versus.

choroidal detachment, flattening of the anterior chamber, or endophthalmitis.[18–21]

The most common complication across studies was early postoperative stent occlusion and malposition, which was observed in 2.6%–18.0% of study subjects.[10,13–15,17,18,20–24]

The iStent Study Group reported stent obstruction (by iris, vitreous, fibrous overgrowth, fibrin, blood) in 4.3% and stent malposition in 2.6% of iStent subjects.[10,13] In total, 4.5% of patients required secondary surgical intervention for stent malposition or obstruction (three stent repositionings, one stent replacement, one laser iridoplasty).[10,13] Although Fea found two of 12 (16.7%) iStents to be malpositioned, neither iStent required surgical revision nor did it cause ocular sequelae.[14] Finally, in the fluorophotometric study, Fernández-Barrientos et al reported that, during the first postoperative month, 18% of iStents were found to be malpositioned.[15] There were no significant sequelae of malposition.[15] Overall, studies do not provide specific information about the qualifications for malposition nor do they provide a specific protocol for determining whether intervention was necessary. Across all studies, malposition and occlusion necessitated surgical intervention (neodymium-doped yttrium aluminum garnet laser, recombinant tissue plasminogen activator, or stent revision) in a range of 4.5%–11.3% of study subjects.[10,13–15,18,20–23]

Occurrence of hyphema ranged from 2.3% to 70.0%,[18,19] however, specific definitions of what constituted normal bleeding versus complicated bleeding were not given. Other adverse events were rare. Ahmed et al reported one subject (2.6% of subjects) with transient postoperative hypotony, which resolved without intervention.[16]

Less common events reported by other studies included: anterior chamber collapse during phacoemulsification (2.1%), vitreous wick incarceration (2.1%), posterior capsular opacity (4.3%),[21,22] and presumed steroid-related increase in IOP (3.8%).[23] Reports of complications with the iStent Inject are similar to those reported with the first-generation iStent. Importantly, there were no significant reports of hypotony, choroidal effusion, or postsurgical flat chamber with the use of the iStent Inject.[24–26]

Visual outcomes were discussed in varying detail across the studies. The iStent Study Group reported that, after 1 year, best corrected visual acuity (BCVA) was similar across iStent and control groups (≥95% of both treatment and control subjects experienced improvement in BCVA from the preoperative baseline).[10,13] At the 24-month follow-up, visual-field mean deviation was stable in both groups.[10,13] In contrast, Ahmed et al reported that four subjects (10.2%) experienced progression of cataract and there was a decline in the proportion of eyes with BCVA better than 20/40 (from 89.7% preoperatively to 84.6% postoperatively).[16]

Cost-effectiveness

In determining the role of MIGS, cost-effectiveness will be essential. Most iStent studies have shown the IOP-lowering effect to be significant though modest compared to trabeculectomy and GDD surgery. The data indicate that patients may achieve a reduction in medication burden after iStent implantation. Therefore, one must compare the cost of the procedure with that of long-term glaucoma medication use. At this time, a single Canada-based study has addressed the cost of treating patients with two iStent devices compared with topical medical therapy.[27] According to this report, the cost savings over a 6-year period were CA$1272 when compared with two-drug therapy, and CA$2124 when compared with three-drug therapy. Although similar literature is not available for the USA, one could estimate the cost of drug therapy over 5 to 10 years for an individual patient and compare this with the cost of iStent implantation. It is possible that the iStent could be cost-effective over the long-term, especially considering the substantial reduction of medication burden.

Conclusion

The emergence of new glaucoma surgical procedures introduces an exciting new era of treatment for this devastating disease. Progressive glaucoma produces visual impairment in our rapidly expanding elderly population in whom mobility and independent living must be extended into later in life. The data pertaining to iStent efficacy imply that it is indicated for moderate glaucoma that is controlled on one or two medications. Pressure-lowering effects of this device are not comparable to traditional incisional glaucoma surgery. Furthermore, patients who receive the iStent can expect 3%–10% of additional pressure lowering over cataract surgery alone, and some reduction in their medication burden.

In evaluating the utility of the trabecular micro-bypass stent, the limiting factors are the paucity of randomized controlled trials and the limited duration of follow-up. Additional shortcomings include the lack of powerful data on subtypes of open-angle glaucoma, secondary open-angle glaucoma, and inflammatory glaucoma. Future directions in glaucoma treatment are moving toward earlier and more patient-friendly options. Trabecular micro-bypass stent certainly fits these criteria and may be a good option for early, minimally invasive intervention.

Disclosure

The authors declare no conflicts of interest in this work.

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