Sukru Bayraktar

Studies show iStent effective in controlling IOP in many open-angle glaucoma patients

Howard Larkin
in Berlin

MEASURING just 1.0mm by 0.5mm with a lumen diameter of 0.12mm, the L-shaped titanium iStent (Glaukos, Laguna Hills CA, US) is among the smallest implant devices available for human surgery. Yet recent studies with follow-up times ranging from 11 months to 22 months suggest that this tiny trabecular micro-bypass stent is a safe and effective long-term way to lower intraocular pressure in open-angle glaucoma patients both by itself and in combination with medications and other surgical procedures. For many patients, the iStent may be a viable alternative to traditional filtration surgery and the discomfort and risks it entails.

"Filtration surgery has maintained popularity because it is very effective. But the morbidity of filtration surgery is unfortunately also very well known. We are all aware of the many complications," Prof Carlo Traverso of the University of Genova, Italy, told a symposium at the XXVI Congress of the ESCRS.

These difficulties include maintaining patency of incisions, regulating aqueous outflow to prevent hypotony, and preventing infections in the bleb and the interior of the globe.

By contrast, complications with the iStent are less common and mostly minor, Prof Traverso said. The device is essentially a miniature snorkel with one end open protruding into the anterior chamber and the other end inserted into Schlemm's canal to allow aqueous fluid to bypass blocked trabecular meshwork. In theory, the iStent bypasses 50 per cent to 75 per cent of the total resistance to aqueous outflow generated by blockage of the inner trabecular meshwork. The device is implanted through a 1.5mm corneal incision with no sutures and is held in place by three ridges on the long arm of the stent that is inserted into Schlemm's canal. "Personally, what struck me about this technique is how gentle it is and how non-traumatic it is to the eye," he added.

Prof Traverso presented 18-month follow-up data on 30 patients out of 45 enrolled in a prospective 24-month open-label study of the iStent in patients with refractory primary open-angle glaucoma at seven European centres. Enrolled patients either had failed previous medical or surgical therapy, or were considered poor prospects for filtration surgery. The primary endpoint was IOP <21 mmHG. The secondary endpoint was reduction in drugs to control ocular hypertension.

Even in this difficult population the iStent proved useful. Among the 30 patients, mean IOP dropped by more than 25 per cent, from 28.4 mmHg before implantation to 18.8 mmHg at 18 months, with 90 per cent achieving the end point of less than 21mm at month 18. Of these, only eight eyes were at or below 21 mmHg with no ocular hypotensive medications. Mean medications per patient dropped from 2.1 to 0.9 for the 30 patients at 18 months.

"The drop is substantial but the final target is not as low as you would obtain with more aggressive filtration surgery," Dr Traverso noted. Indeed, 13 of the 45 patients in the study needed further filtration surgery to obtain lower IOP to the desired range, he added.

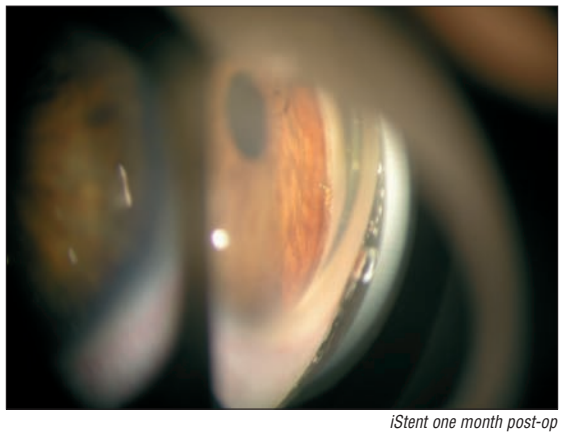
Complications were generally minor with most resulting from the learning curve for implanting the iStent, Dr Traverso said. These included four cases of the iris touched by the device and two each of malpositioned stent with subsequent reimplantation, stent lumen obstruction and anterior chamber collapse. In addition, there were one case each of malpositioned stent, shallow anterior chamber/iridotomy due to closed angle and excessive bleeding from the stent. Dr Traverso observed that complications declined as surgeons mastered the implantation technique, which he believes can be done by any ophthalmic surgeon.

"These interim results are very promising, but obviously longer-term, prospective studies and data are needed, and these studies are ongoing."

iStent vs. latanoprost vs. phaco

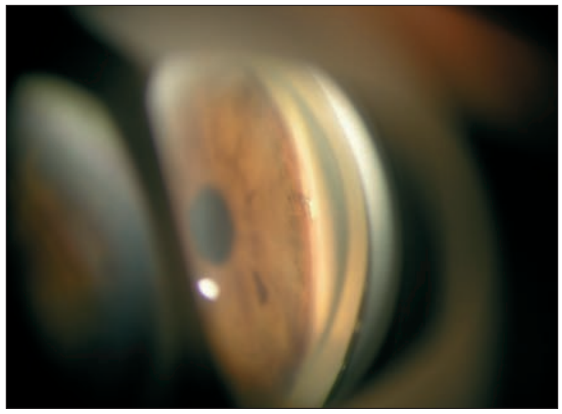
Results from one such ongoing prospective study were presented by Sukru Bayraktar MD of the Beyoglu Eye Training and Research Hospital, Istanbul, Turkey. Dr Bayraktar and Omer F Yilmaz MD are leading the three-armed study of open-angle glaucoma patients as clinical investigators for Glaukos.

In the first arm of the study, 23 eyes with medically uncontrolled open-angle glaucoma were randomly implanted with one or two stents. In the second arm, 21 newly diagnosed eyes received either two iStents or latanoprost therapy. In the third arm, 12 eyes with coexisting glaucoma and cataracts were randomly assigned to receive phacoemulsification cataract surgery only, or phaco with two iStents.

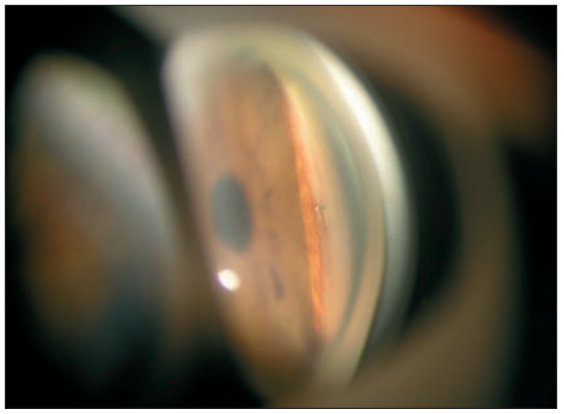


iStent one month post-op

Two months post-op



Three months post-op



Six months post-op

Courtesy of Sukru Bayraktar MD

All surgeries were performed under topical or sub-Tenon's anaesthesia through a temporal clear corneal incision allowing the stent (or stents) to be implanted in the nasal quadrant. A surgical goniolens (Swan-Jacob) was placed onto the cornea and the stents were implanted using their original single-use inserter.

The iStent performed quite well in all three arms, Dr Bayraktar reported. In the trial of one stent vs. two, mean IOP in the 13 eyes receiving one stent dropped from 20.7 mmHg to 18.7 mmHg with the mean number of medications dropping from 1.7 to 0.7 after a mean follow-up of 21.5 months. The 10 eyes receiving two stents showed a similar decline, from 21.1 mmHg to 18.7 mmHg with the mean number of meds dropping from 2.0 to 0.9 after a mean follow-up of 18.3 months. Both the declines in IOP and medications from the untreated state were found to be statistically significant ($p < 0.05$), but there was no significant difference between the amount of reduction achieved by the two subgroups.

In the iStent vs. latanoprost arm, the stent was found to be about as effective as the medication. IOP in the eight eyes in the stent group fell from a mean of 23.5 to 17.8 mmHg at a mean follow-up of 19.6 months. By contrast, the 13 latanoprost eyes fell from a mean of 22.9 to 17.6 mmHg at a mean follow-up of 16.4 months. There wasn't any statistically significant difference between latanoprost and stent patients ($p > 0.05$).

In the phaco alone vs. phaco plus stent arm of the study, the iStent recipients achieved better IOP control without medications. While the seven eyes in the phaco-only group had a mean IOP drop from 22.9 to 16.4 mmHg which was statistically significant ($p < 0.05$); the amount of medications increased slightly from 0.6 ± 0.9 to 0.8 ± 1.1 ($p > 0.05$). The phaco plus stent eyes, on the other hand, saw mean IOP drop from 23.1 ± 4.9 to 14.6 ± 2.8 mmHg along with a reduction in mean medications from 0.6 ± 0.5 to zero, a result that was strongly statistically significant ($p < 0.0001$).

Dr Bayraktar also noted that the iStent procedure is relatively easy to learn, but emphasised the need to rotate the patient's head properly in order to get a good view of the angle landmarks and to implant the device in the optimal place.

"There was no real difference between one and two stents. We got the best results with the combined phaco and stent procedure. There were also no serious complications except one IOP spike that was easily controlled with medications," Dr Bayraktar noted.

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