Stent-less Glaucoma Surgery

Expanded indications sought for minimally invasive technology.

HOWARD LARKIN REPORTS

A minimally invasive device that creates a stent-less aqueous drainage channel into the subconjunctival space for treating moderate to severe glaucoma is now under development for two new indications; rescuing failed trabeculectomies in severe glaucoma and opening passages to Schlemm's canal for mild cases.

Successfully launched at the 2023 ESCRS Congress, the Sanoculis Minimally Invasive Micro Sclerostomy® (MIMS) device is now available in several countries, including Germany and Spain.

"The market reception was great," said Nir Israeli, who is now working to set up a clinical trial for US approval by the Food and Drug Administration (FDA).

Performed through the anterior chamber, MIMS involves injecting viscoelastic into the sub-Tenon's space to expand a gap for the instrument to protrude into and create a channel for aqueous to drain into the nasal subconjunctival space, where it is absorbed by surrounding blood vessels.

The MIMS instrument is then inserted into the anterior chamber through a side port to the angle, where a trephine extends about 2.5 mm, cutting a drainage channel through to the subconjunctival space, and withdraws automatically, along with the cylinder of sclera-corneal tissue removed. The procedure takes two to three minutes.

IOP and meds reduced

Israeli presented three-year follow-up data on 120 MIMS cases, including 20 combined with cataract surgery. Mean IOP reduced from 27.9 mmHg at baseline to 17.3 and 17.4 mmHg at one and three years, respectively, for a 38% reduction. Over the same periods, the mean number of topical glaucoma medications used declined from 1.80 at baseline to 0.27 at one year for an 85% reduction and 0.53 at three years for a 71% reduction.

The percentage of MIMS patients seeing IOP reductions of at least 20% without increasing medication use, which is the FDA's success threshold, was 81.1% at one year and 57.1% at three years. By contrast, trabeculectomy achieves 72.7% success at one year and 64.4% at two years, and the PreserFlo stent (Glaukos) 54.7% and 50.6% at one and two years, respectively.

The results suggest drainage channels remain patent for at least three years without a stent, and OCT imaging bears that out. Israeli showed scans of a patient with 32 mmHg at baseline, reduced to 14.0 mm at one year and 14.5 mm at three years with no topical medications. The drainage channel and subconjunctival bleb are clearly visible on OCT scans at both follow-ups.

Expanded indications

For treating failed trabeculectomies, the sclerostomy and bleb are positioned inferonasally. When used experimentally to create channels to Schlemm's canal, a procedure dubbed "MINT™" for minimally invasive nasal trabeculostomy, the Sanoculis device trephine extends about 0.5 mm to cut five holes in the trabecular meshwork.

An interim analysis of an ongoing study involving 82 MIMS inferonasal patients showed mean IOP reduced by 23% and medication use by 34% from baseline at nine months follow up, Israeli reported. In 66 patients receiving standalone MINT, IOP was reduced by 30% and meds by 82% at nine months, which compares favourably with competing stent solutions.

"The two new indications expand our market to address all glaucoma patients who need surgery with the same stent-less technology for all indications—from mild to severe," Israeli concluded.

Nir Israeli presented at the Eyecelerator event at ASCRS 2023 in San Diego, US.

Nir Israeli MBA is co-founder and CEO of Sanoculis LTD, Kirat Ono, Israel.
nir@sanoculis.com