Safety Profile of a Superciliary MIGS Implant: Reviewing Clinical Data

This device is implanted in the ciliary cleft to provide outflow to the superciliary space.

Although safety concerns associated with incisional glaucoma surgeries have historically restricted their use to more severe glaucoma manifestations, the availability of MIGS devices and techniques offers an alternative approach. By definition, MIGS procedures are "minimally invasive," and are associated with a safety profile at least on parr with cataract surgery.[1] Thus, they are appropriate for use earlier in the disease course, particularly in eyes with mild to moderate glaucoma.

Newer entrants serve to expand the options by targeting different physiologic outflow mechanisms. One of the recent devices to market, the CyPass Micro-Stent (Alcon), is implanted in the ciliary cleft to provide outflow to the supraciliary space, thereby taking advantage of the uveoscleral outflow pathway.

CyCLE DATA

In clinical trials, this implant demonstrated a safety profile that justifies its definition as a MIGS device insofar as it is performed via an ab interno approach, is minimally invasive, effective, and associated with a rapid recovery.[2] In the prospective, open-label, interventional, multicenter CyCLE (CyPass Clinical Experience) study, 460 patients were randomized to CyPass implantation alone (n = 222) or implantation in conjunction with cataract extraction (n = 238). Overall, the safety profile was relatively benign compared to incisional techniques, and at 2 years of follow up, there were no reports of endophthalmitis, suprachoroidal hemorrhage, or hypotony maculopathy.[3] The most commonly reported adverse events were transient hypotony (15.4%), stent obstruction (8.8%), and postoperative IOP spike (4.4%).[3]

Although the rate of transient hypotony in CyCLE is notable (for purposes of the study, the investigators defined hypotony as any instance of IOP lower than 6 mm Hg), it is important to differentiate numerical hypotony from more troubling clinical manifestations.

In the multicenter, interventional COMPASS study in eyes with mild to moderate glaucoma, 131 patients were randomized to cataract surgery alone and 374 were randomized to receive the microstent at the time of cataract surgery.[4] In this study, transient hypotony occurred in 11 individuals in the active arm (2.9%) compared with zero in the control group. Of these, three were considered clinically significant, described as not associated with visual acuity loss, although exhibiting signs of early maculopathy. "In reviewing data from these three patients, it is plausible that mitigating factors played a role and it is not entirely clear if patient-specific factors contributed to their hypotony," says Richard Lewis, MD, who is in private practice in Sacramento, Calif.

Hoeh and colleagues have suggested that cases of transient hypotony noted after implantation of this device may be due to a novel mechanism, in which "excessive flow into the suprachoroidal space through the surrounding cyclodialysis cleft in the immediate postoperative period" may lead to excessive aqueous drainage, but that "this cleft often contracts around the stent 4 to 6 weeks following surgery. Such gradual closure may explain why IOP does not rise suddenly, but rather slowly to a level consistent with suprachoroidal access being limited to that occurring via the microstent."[5]

COMPASS STUDY

In the COMPASS study, hyphema occurred in 2.7% in the study group—a rate that is favorable compared with reported rates in trabeculectomy as high as 25% in some series.[6,7] In addition, more than 98% of the overall study subjects had 20/40 BCVA or better at 24 months, and there were no vision-threatening microstent-related adverse events reported.

"Clinical trial data should always be viewed with a grain of salt. Generalizing findings from well-controlled study conditions with well-trained and experienced operators is inherently risky," Lewis says. "It is reasonable to assume that any surgeon who starts using CyPass in the clinic will experience a learning curve. That said, clinical trial data with CyPass reaffirm the safety of this device and give us a basis for understanding how it will perform in larger populations." ■

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Dr. Lewis serves as a consultant for Alcon.