Objective: To compare the effectiveness and safety of the MicroShunt versus trabeculectomy in patients with primary open-angle glaucoma (POAG).

Design: One-year results from a 2-year, prospective, randomized, multicenter, non-inferiority study (NCT01881425) conducted in the USA and Europe.

Participants: Eligible patients were aged 40-85 years with intraocular pressure (IOP) ≥15 and ≤40 mmHg and mild-to-severe POAG inadequately controlled on maximum tolerated medical therapy.

Intervention: Patients were randomized 3:1 to undergo stand-alone MicroShunt implantation or trabeculectomy, both performed with adjunctive Mitomycin C (0.2 mg/mL for 2 minutes).

Main outcome measures: The primary effectiveness endpoint was surgical success, defined as ≥20% reduction in mean diurnal IOP, IOP ≤21 mmHg at ≥2 consecutive visits, no use of antiglaucoma medications at last visit, and requirement for postoperative intervention. Additional endpoints included glaucoma medication use and adverse events.

Results: Overall, 395 (MicroShunt) and 132 (trabeculectomy) patients were randomized (mean Humphrey visual field mean deviation -12.34 dB). At year 1, probability of success was lower in the MicroShunt group compared with the trabeculectomy group (53.9% versus 72.7%, respectively).

Conclusions: Probability of success was lower with MicroShunt compared with trabeculectomy. Though reductions in IOP and glaucoma medications over 1 year were observed in both groups, the trabeculectomy group had a lower mean IOP on fewer medications.