Table 39: Effect of MIGS + Cataract Surgery Versus Comparators on Proportion of Eyes Achieving IOP Targets

Quality Assessment							Summary of Findings				Importance
							No. of Eyes		Effect	Quality	
No. of Studies	Study Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations	MIGS	Comparator			
MIGS + Cataract Surgery Vs. Cataract Surgery Alone: CyPass Micro-Stent + Phaco Vs. Phaco Alone											
1	RCT[a]	No serious risk of bias[b]	No serious inconsistency	No serious indirectness	Serious imprecision[c]	None	374	131	**CyPass Micro-Stent + Phaco > Phaco Alone:** **≥ 20% IOP reduction** from baseline (12 and 24 mo follow-up): • CyPass Micro-Stent + Phaco > Phaco alone[70]	⊕⊕⊕O MODERATE	CRITICAL
MIGS + Cataract Surgery Vs. Cataract Surgery Alone: Hydrus Microstent + Phaco Vs. Phaco Alone											
2	RCTs[d]	No serious risk of bias[e]	No serious inconsistency	No serious indirectness	Serious imprecision[f]	None	419	237	**Hydrus Microstent + Phaco > Phaco Alone:** **≥ 20% washed-out diurnal IOP reduction** from baseline: • 12 mo follow-up: Hydrus Microstent + Phaco =/> Phaco alone[71,88] • 24 mo follow-up: Hydrus Microstent + Phaco > Phaco alone[71,88] **≥ 30% washed-out diurnal IOP reduction** from baseline: • 24 mo follow-up: Hydrus Microstent + Phaco > Phaco alone[88] **≥ 40% washed-out diurnal IOP reduction** from baseline: • 24 mo follow-up: Hydrus Microstent + Phaco > Phaco alone[88]	⊕⊕⊕O MODERATE	CRITICAL
MIGS + Cataract Surgery Vs. A Different MIGS + Cataract Surgery: Goniotomy With KDB + Phaco Vs. iStent + Phaco											
1	Retrospective cohort[g]	Serious risk of bias[h]	No serious inconsistency	No serious indirectness	Serious imprecision[i]	None	KDB + Phaco, 237 iStent	NA[j]	**KDB + Phaco > iStent + Phaco:** **≥ 20% IOP reduction** from baseline (6 mo follow-up):	⊕OOO VERY LOW	CRITICAL

Quality Assessment							Summary of Findings				Importance
							No. of Eyes		Effect	Quality	
No. of Studies	Study Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations	MIGS	Comparator			
							+ Phaco, 198		• KDB + Phaco > iStent + Phaco[86]		
MIGS + Cataract Surgery Vs. A Different MIGS + Cataract Surgery: Different Numbers of iStents + Phaco											
1	Non-randomized controlled clinical trial[k]	Serious risk of bias[l]	No serious inconsistency	No serious indirectness	Serious imprecision[m]	None	2x iStent + Phaco, 28 3x iStent + Phaco, 25	NA[j]	**2 iStents + Phaco [?] 3 iStents + Phaco:** **≤15 mm Hg** (12 mo follow-up): • Only reported in the 2x iStent+Phaco group[83]	⨁OOO VERY LOW	CRITICAL

= = not significantly different between groups; > = intervention more favourable than comparator; [?] = not compared statistically or non-interpretable; 2x = two devices; IOP = intraocular pressure; KDB = Kahook Dual Blade; MIGS = minimally invasive glaucoma surgery; mo = months; NA = not applicable; no. = number; Phaco = phacoemulsification; RCT = randomized controlled trial; vs. = versus.

Note: Data were collected by RCT, non-randomized controlled clinical trial or retrospective cohort, with up to 24 months of follow-up. IOP was measured by Goldmann applanation tonometry where reported. The CyPass Micro-Stent was voluntarily withdrawn from the global market by the manufacturer in August 2018 due to five-year data from a long-term safety study;[37,38] however, at the time of report publication, this device was still active in the Medical Devices Active Licence Listing and is therefore included in this report.

[a] One RCT.[70]

[b] No serious risk of bias. Only concern was: no indication of allocation concealment.[70]

[c] Serious imprecision. Only a single study.[70]

[d] Two RCTs.[71,88]

[e] No serious risk of bias.[71,88] Only concern was: possible risk of selection bias; concealment not explicitly specified but likely, based on method of randomization (online computer algorithms).

[f] Serious imprecision. In one study, there were wide confidence intervals leading to uncertainty about the true magnitude of the effect and confidence intervals were provided only for the Phaco alone group;[71] in the other study, confidence intervals were only reported for proportion of eyes with ≥ 20% reduction in washed-out modified diurnal IOP but not for ≥ 30% or ≥ 40%.[88]

[g] One retrospective cohort study.[86]

[h] Serious risk of bias.[86] Bias due to confounding: retrospective design and rationale for assigning treatments likely to be different between groups; significant differences between groups at baseline; potential confounding variables not controlled for in analyses. Bias in selection of participants: only those with six-month complete data were included and it is possible that those with complete data were systematically different from those without complete data (i.e., different from those in routine clinical practice). Bias due to deviations from intended interventions: important co-intervention not balanced between groups (number of medications significantly different between groups). Bias due to missing data: large amount of missing data at one month and three months, reasons for missing data not reported, and amount of missing data not balanced across groups. Bias in measurement of outcomes: diurnal variation not accounted for in measurement of IOP; IOP was measured without medication washout and the number of medications was significantly different between groups. Bias in selection of the reported result: no measure of variability.

[i] Serious imprecision.[86] Only a single study and no measure of variability in the proportion of eyes achieving ≥ 20% reduction in IOP.

[j] In these studies, one MIGS performed in combination with cataract surgery was compared with another MIGS combined with cataract surgery.[83,86]

[k] One non-randomized controlled clinical trial.[83]

[l] Serious risk of bias.[83] Bias due to confounding: treatment assigned based on patient characteristics and judgment of operating surgeon (i.e., with those requiring greater IOP control receiving three versus two iStents); potential confounding variables not controlled for in analyses. Bias in selection of participants: only those with 12-month follow-up were included and it is possible that those with 12-month follow-up were systematically different from those with shorter follow-up (i.e., different from those in routine clinical practice). Bias due to deviations from intended interventions: important co-intervention not balanced between groups (number of medications significantly different between groups). Bias in measurement of outcomes: unclear whether diurnal variation was accounted for in measurement of IOP; IOP was measured without medication washout and the number of medications was significantly different between groups. Bias in selection of the reported result: complete data not reported for the three iStents + Phaco group.

[m] Serious imprecision.[83] Only a single study and no measure of variability.