

Supporting information

Efficacy of the PRESERFLO MicroShunt and a Meta-Analysis of the Literature

Contents:

Table S1: Summary of the retrieved studies from the systematic review.

Table S2: Quality assessment of the included studies according to the Newcastle–Ottawa Scale.

Figure S1: Scatterplot showing preoperative and postoperative IOP for PRESERFLO MicroShunt as a standalone procedure and as a cataract-combined procedure.

Figure S2: Flowchart showing the selection process for inclusion of studies from our searches according to the PRISMA guidelines.

Figure S3: Meta-analysis of the effect of the PRESERFLO MicroShunt on IOP for all specified time intervals.

Figure S4: Meta-analysis of the effect of the PRESERFLO MicroShunt on IOP-lowering medication for all specified time intervals.

Table S1. Summary of the retrieved studies from the systematic review

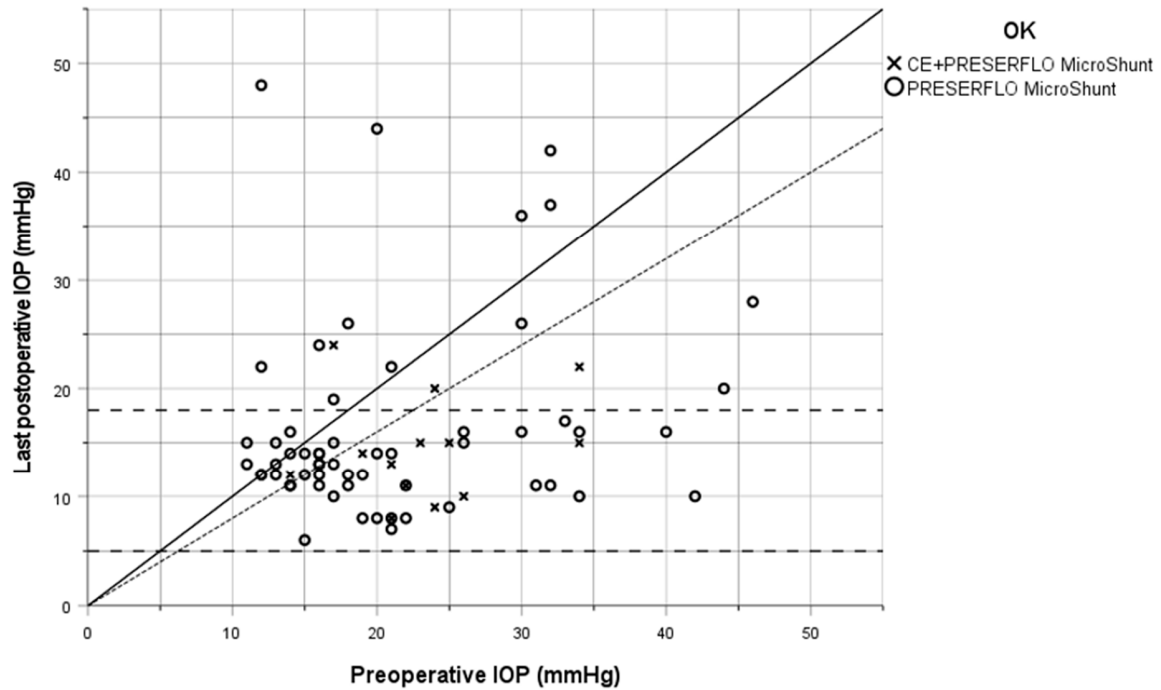
	STUDY		DESIGN	EYES PER GROUP (N)	DIAGNOSIS	INTERVENTION*	FOLLOW-UP (MONTHS)	IOP REDUCTION MMHG MEAN±SD (%)	NEEDLING (%)	SECONDARY SURGERIES (%)	HYPOTONY (%)	CHOROIDAL DETACHMENT/ EFFUSION (%)
1	Ahmed et al. 2022 [17]	R	Case series	8	POAG	PRESERFLO+ MMC	72	(30.7)	63	NA	NA	NA
2	Batlle et al. 2016 [18]	P	Observational study	23	POAG	PRESERFLO+MMC (+CE n=9)	36	(55)	NA	4.3	13	8.7
3	Beckers et al. 2021 [19]	P	Single arm Multicenter study	81	POAG	PRESERFLO+MMC	24	7.8±4.1	6.2	6.4	11.1	NA
4	Durr et al. 2022 [20]	R	Case series	85	Glaucoma	PRESERFLO+MMC	12	(43.3)	11.8	14.1	5.9	12.9
5	Baker et al. 2021 [28]	P	Randomized, Multicenter study	395	POAG	PRESERFLO+MMC	24	(29.1)	NA	NA	7.1	4.6
6	Barberá et al. 2022 [30]	R	Single-center, non-randomized	64	POAG	PRESERFLO+MMC (+CE=13)	9	(43.05)	1.6	15.6	7.8	7.8
7	Saletta et al. 2022 [29]	R	Chart review	30	Glaucoma	PRESERFLO+MMC	12	(34.7)	0.1	0.1	NA	NA
8	Tanner et al. 2022 [27]	R	Multicenter, Cohort study	104	Glaucoma	PRESERFLO+MMC	12	(37.2)	12.5	11.5	20.2	10.6
9	Fea et al. 2021 [21]	R	Open label, Multicenter study	104	Glaucoma	PRESERFLO+MMC	12	(43.8)	18.3	13.5	NA	4.8
10	Martinez -de la casa et. Al. 2021 [9]	R	Open label, Multicenter	58	Glaucoma	PRESERFLO+MMC (+CE n=23)	12	(32.1)	NA	NA	1.7	3.5
11	Quaranta et al. 2021 [22]	R	Chart review	31	POAG	PRESERFLO+MMC	12	(47.9)	19.3	3.3	19.3	9.6
12	Schlenker et al. 2020 [23]	R	Single center, Interventional, Case series	164	Glaucoma	PRESERFLO+MMC	12	(37.9)	8.5	1.8	1.2	9.2
13	Scheres et al. 2021 [24]	R	Comparative case series	41	POAG	PRESERFLO+MMC	24	(39)	5	22	39	2
14	Vastardis et al. 2021 [26]	R	Case series	25	POAG	PRESERFLO+MMC	6	(49.1)	NA	4	NA	NA

*= between brackets the number of eyes from the total study population that underwent a combined procedure, P=prospective, R=retrospective, CE=cataract extraction, MMC=mitomycin C, POAG=primary open angle glaucoma, SD= standard deviation, glaucoma= mixture of different types of glaucoma, NA=not applicable

Table S2. Quality assessment of the included non-randomized studies according to the Newcastle–Ottawa Scale.

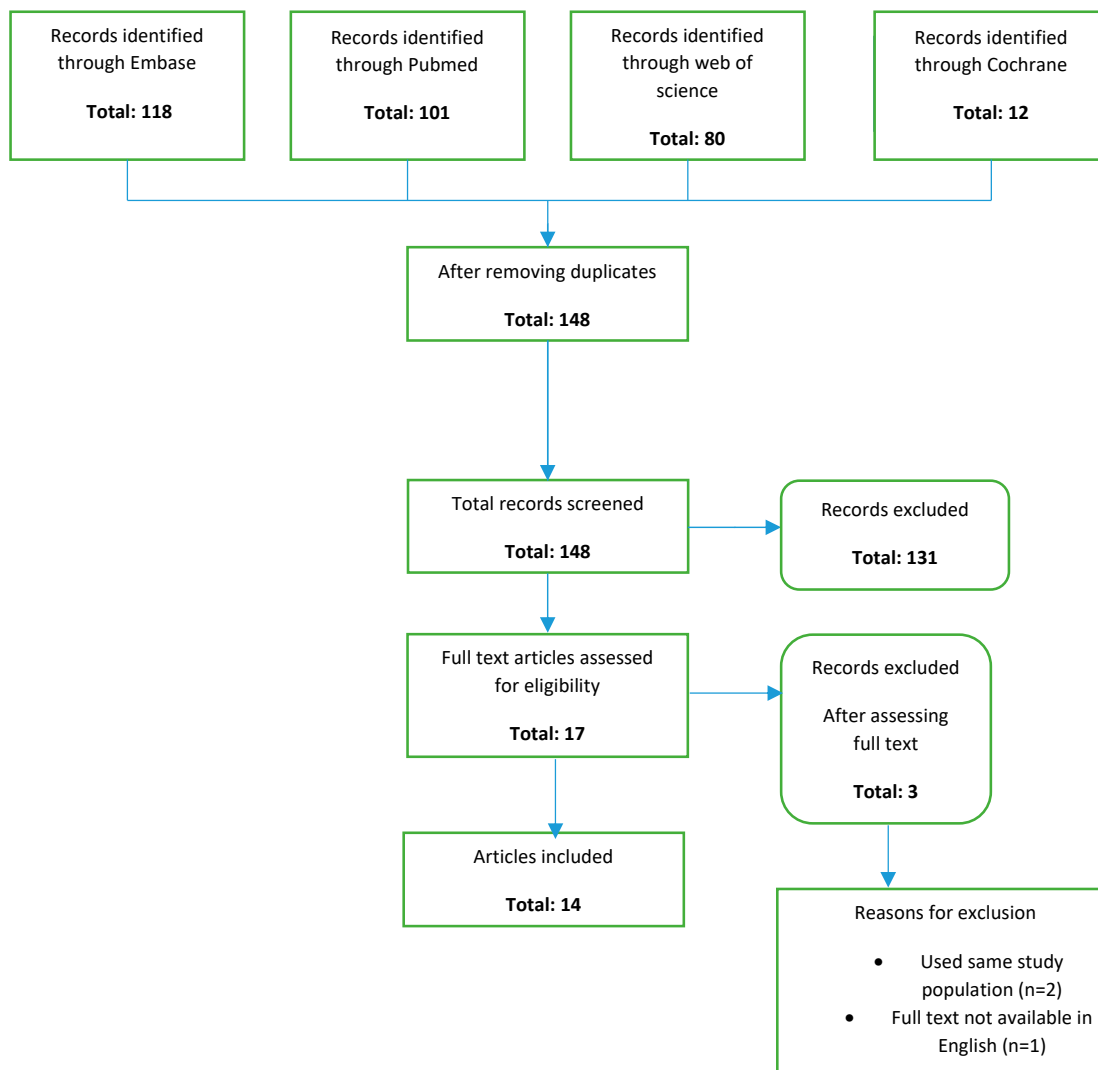
	<i>Author</i>	<i>Selection</i>	<i>Comparability</i>	<i>Outcome (Cohort)/ Exposure Case control</i>	<i>Total score (max. 9)</i>
1	Ahmed et al. 2022 [17]	3	2	2	7
2	Batlle et al. 2016 [18]	3	2	3	8
3	Beckers et al. 2021 [19]	3	2	3	8
4	Durr et al. 2022 [20]	3	2	2	7
5	Baker et. al 2021 [28]	3	2	3	8
6	Barberá et al 2022 [30]	3	2	3	8
7	Saletta et al. 2022 [29]	3	2	3	8
8	Tanner et al. 2022 [27]	3	2	3	8
9	Fea et al. 2021 [21]	3	2	2	7
10	Martinez-de la casa et. al. 2021 [9]	3	2	3	8
11	Quaranta et al. 2021 [22]	3	2	2	7
12	Schlenker et al. 2020 [23]	3	2	3	8
13	Scheres et al. 2021 [24]	3	2	3	8
14	Vastardis et al. 2021 [26]	3	2	3	8

Figure S1. Scatterplot showing preoperative and postoperative IOP for PRESERFLO MicroShunt as a standalone and as a cataract-combined procedure.



The dotted horizontal lines represent the 5mmHg and 18mmHg IOP-levels and the diagonal dotted line represents the 20% reduction level. IOP=intraocular pressure, CE= cataract extraction, PRESERFLO MicroShunt=standalone procedure, CE+PRESERFLO MicroShunt=combined procedure.

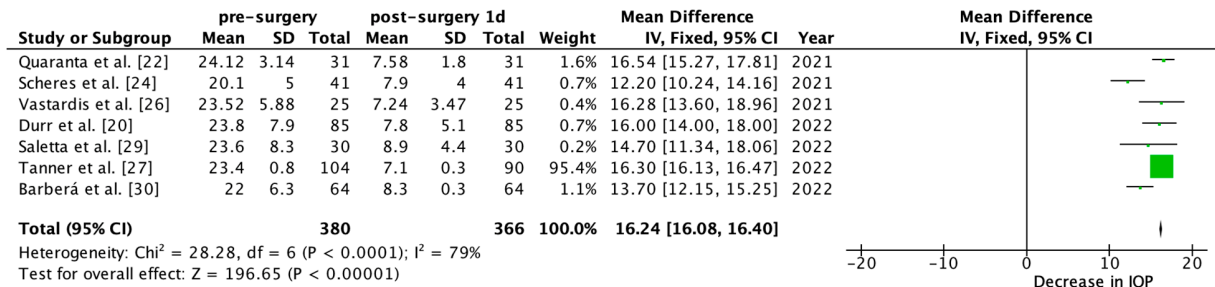
Figure S2. Flowchart showing the selection process for the inclusion and exclusion of the searched articles (according to PRISMA). PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



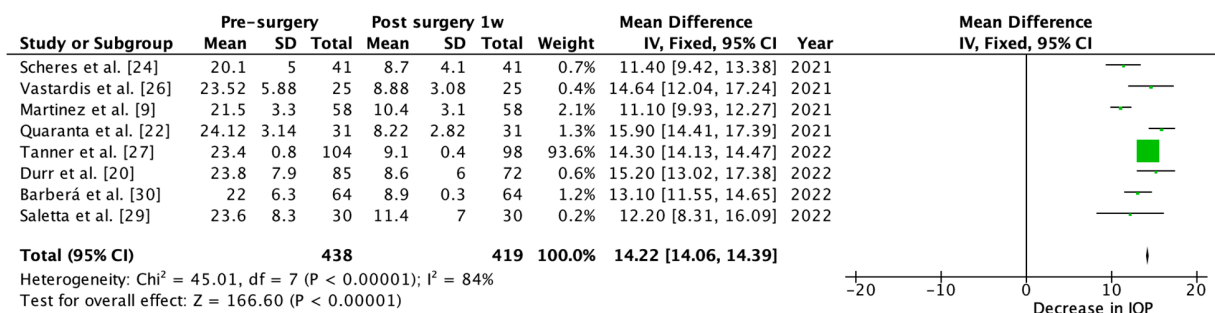
Search strings: **Embase.com** ('innfocus microshunt'/de OR ((styrene/de OR isobutylene/de OR 'poly(styrene block isobutylene block styrene)'/de) AND (glaucoma/exp OR 'glaucoma surgery'/exp OR 'intraocular pressure'/de OR 'glaucoma drainage implant'/de)) OR (Innfocus OR Preserflo OR (Aqueous-Humor NEAR/3 Shunt*) OR ((SIBS* OR Styrene-block-IsoButylene* OR polyIsoButylene* OR poly-IsoButylene* OR Styrene-IsoButylene*) NEAR/10 (glaucoma* OR subconjunctiv*-drain* OR intraocul* OR intra-ocul* OR microshunt* OR micro-shunt* OR ophthalmol*)) OR ((subconjunctiv* OR sub-conjunctiv*) NEAR/3 ab-externo NEAR/3 glaucoma) OR ((microshunt* OR micro-shunt*) NEAR/3 (ab-externo*)):ab,ti). **Medline All Ovid (Pubmed)** (((Styrene/ OR Styrenes/) AND (exp Glaucoma/ OR Intraocular Pressure/ OR Glaucoma Drainage Implants/)) OR (Innfocus OR Preserflo OR (Aqueous-Humor ADJ3 Shunt*) OR ((SIBS* OR Styrene-block-IsoButylene* OR polyIsoButylene* OR poly-IsoButylene* OR Styrene-IsoButylene*) ADJ10 (glaucoma* OR subconjunctiv*-drain* OR intraocul* OR intra-ocul* OR microshunt* OR micro-shunt* OR ophthalmol*)) OR ((subconjunctiv* OR sub-conjunctiv*) ADJ3 ab-externo ADJ3 glaucoma) OR ((microshunt* OR micro-shunt*) ADJ3 (ab-externo*)):ab,ti.) **Web of science (SCI-EXPANDED & SSCI, 1975-)** TS=(Innfocus OR Preserflo OR (Aqueous-Humor NEAR/2 Shunt*) OR ((SIBS* OR Styrene-block-IsoButylene* OR polyIsoButylene* OR poly-IsoButylene* OR Styrene-IsoButylene*) NEAR/10 (glaucoma* OR subconjunctiv*-drain* OR intraocul* OR intra-ocul* OR microshunt* OR micro-shunt* OR ophthalmol*)) OR ((subconjunctiv* OR sub-conjunctiv*) NEAR/2 ab-externo NEAR/2 glaucoma) OR ((microshunt* OR micro-shunt*) NEAR/2 (ab-externo*))) **Cochrane Central Register of Controlled Trials** ((Innfocus OR Preserflo OR (Aqueous NEXT Humor NEAR/3 Shunt*) OR ((SIBS* OR Styrene NEXT block NEXT IsoButylene* OR polyIsoButylene* OR poly NEXT IsoButylene* OR Styrene NEXT IsoButylene*) NEAR/10 (glaucoma* OR subconjunctiv* NEXT drain* OR intraocul* OR intra NEXT ocul* OR microshunt* OR micro NEXT shunt* OR ophthalmol*)) OR ((subconjunctiv* OR sub NEXT conjunctiv*) NEAR/3 ab NEXT externo NEAR/3 glaucoma) OR ((microshunt* OR micro NEXT shunt*) NEAR/3 (ab NEXT externo*)):ab,ti)

Figure S3. Meta-analyses for the effect of the PRESERFLO MicroShunt on IOP for all specified time intervals.*

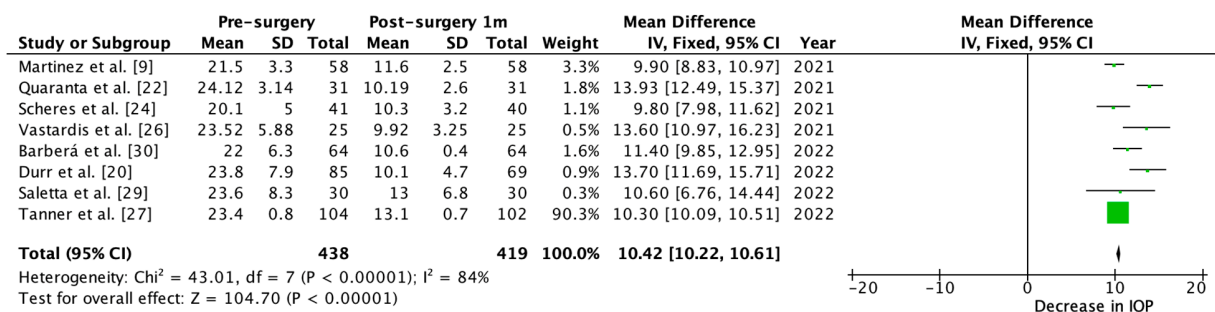
(A)



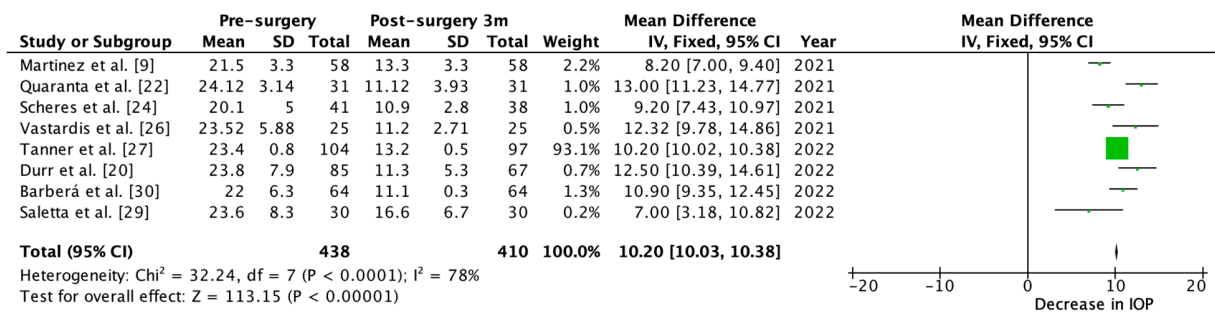
(B)



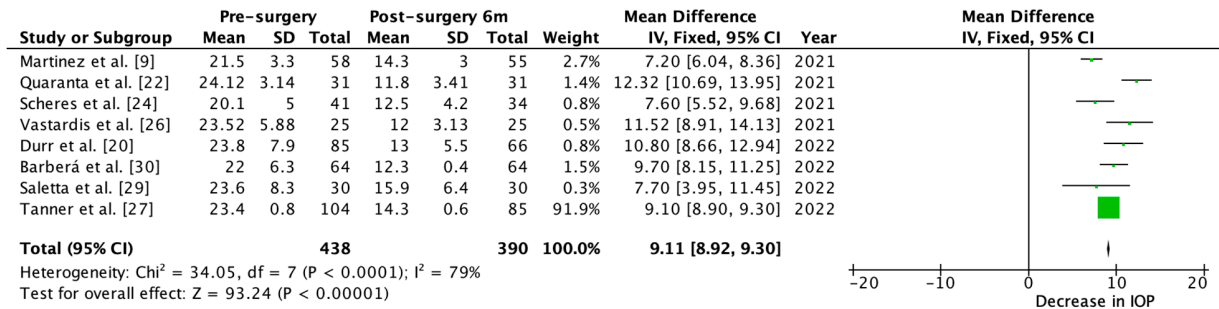
(C)



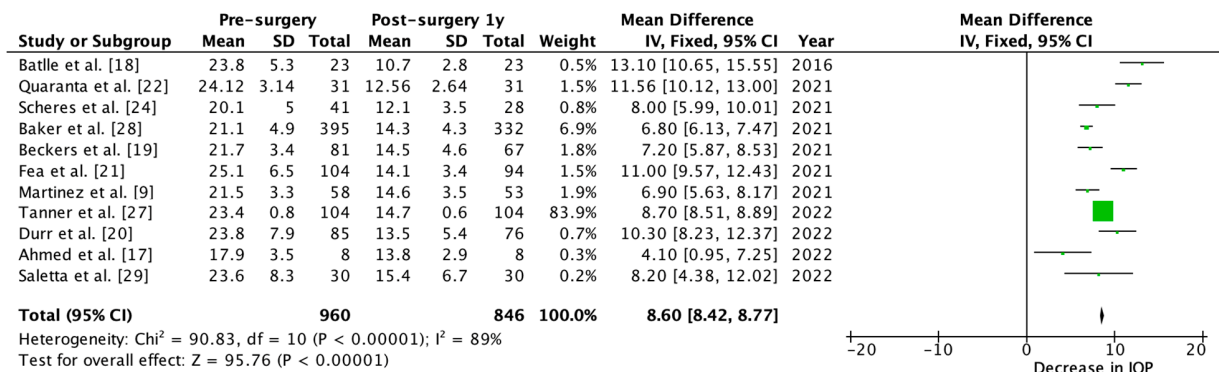
(D)



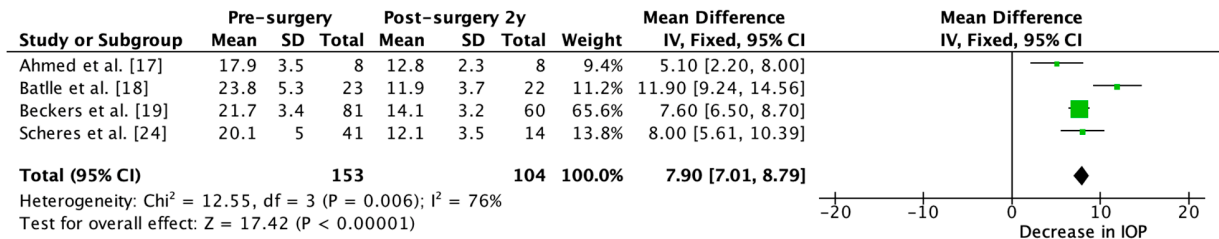
(E)



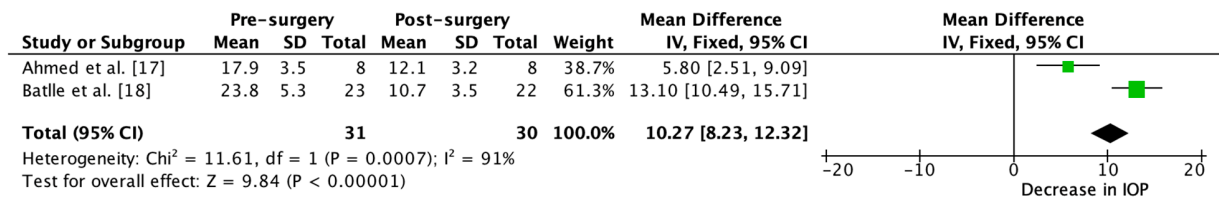
(F)



(H)



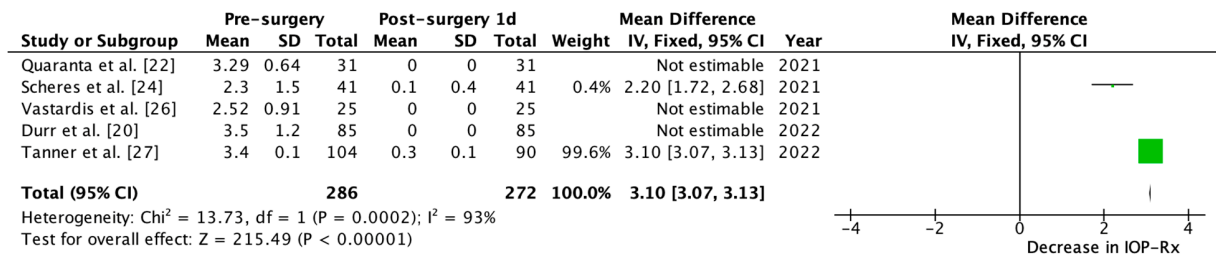
(I)



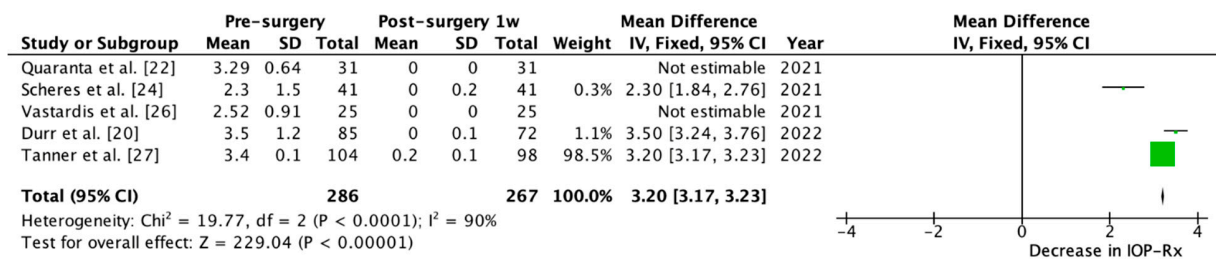
* = Presented as the mean decrease in IOP at 1 day (A), 1 week (B), 1month (C), 3 months (D), 6 months (E), 1 year (F), 2 years (G) and 3 years (H) follow-up. Black diamonds indicate the overall weighted mean difference (WMD). The size of the green box is inversely proportional to the variance. Horizontal lines indicate the 95% confidence interval (CI). The dashed vertical line in each panel shows the value for no effect (WMD = 0) compared to pre-surgery IOP. IOP = intraocular pressure; CI = confidence interval; SD = standard deviation; IV = inverse variance, WMD = weighted mean difference.

Figure S4. Meta-analysis for the effect of the PRESERFLO MicroShunt on IOP-lowering medication for all specified time-intervals.*

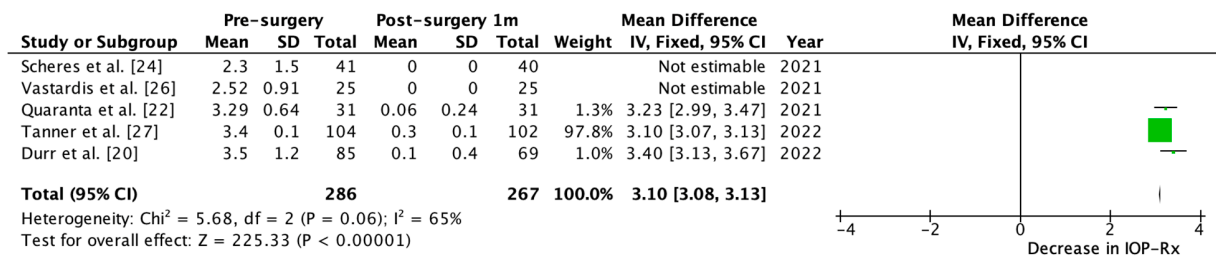
(A)



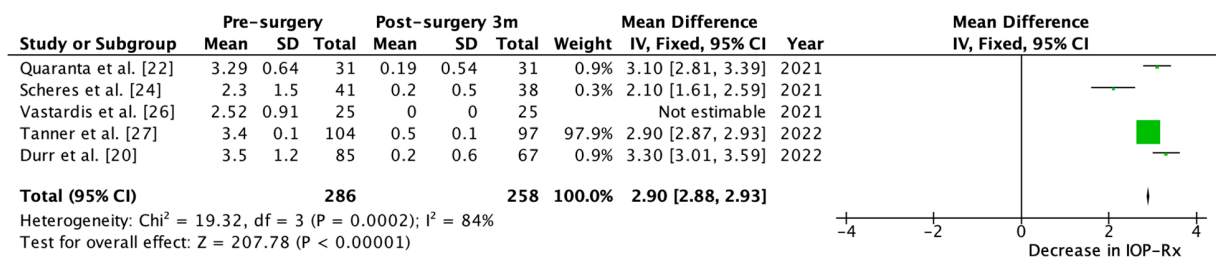
(B)



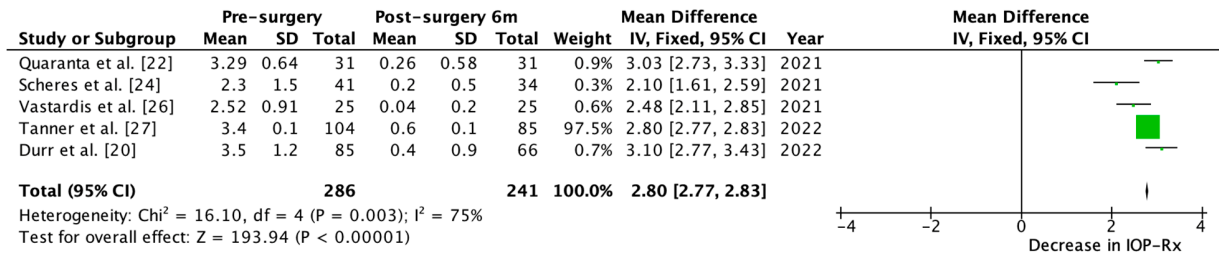
(C)



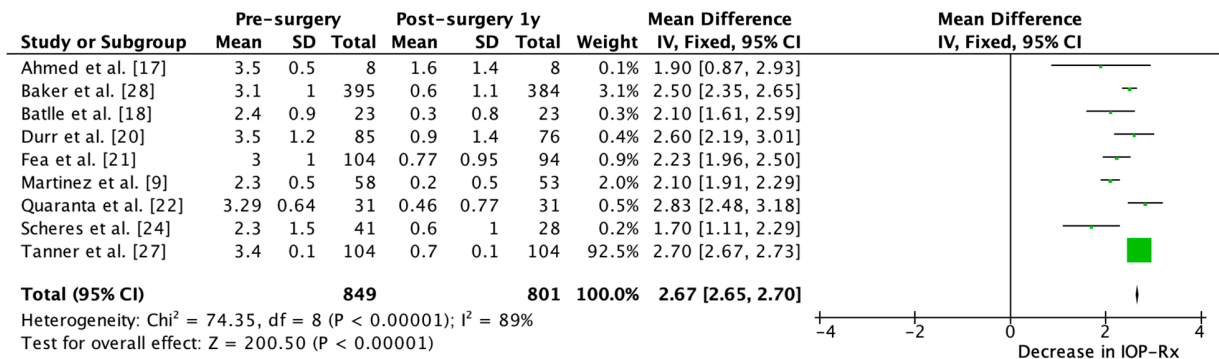
(D)



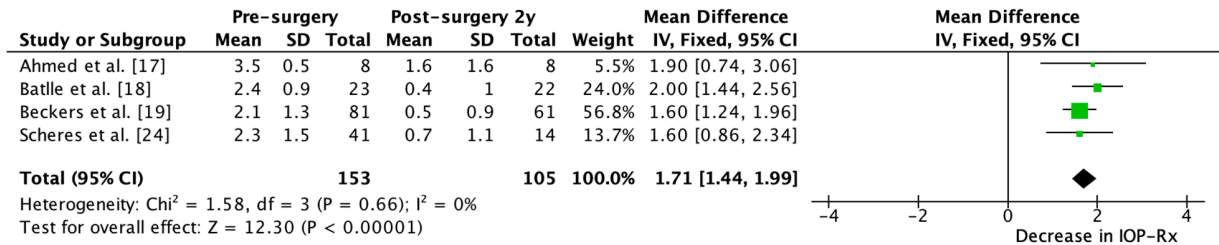
(E)



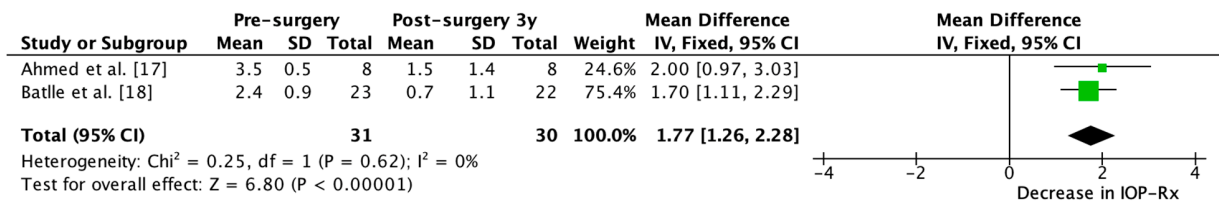
(F)



(G)



(H)



* = Presented as the mean decrease in IOP-lowering medication at 1 day (A), 1 week (B), 1 month (C), 3 months (D), 6 months (E), 1 year (F), 2 years (G), 3 years (H) of follow-up. Black diamonds indicate the overall weighted mean difference (WMD). The size of the green box is inversely proportional to the variance. Horizontal lines indicate 95% confidence interval (CI). The dashed vertical line in each panel shows the value for no effect (WMD = 0) compared to pre-surgery IOP-lowering medications. IOP = intraocular pressure; CI = confidence interval; SD = standard deviation; IV = inverse variance, WMD = weighted mean difference