Comparison of visual outcomes, spectacle independence and patient satisfaction with micro-monovision implantation of two aspheric intraocular lenses (IOLs) in the public health sector: Preliminary results of a prospective, randomized, controlled study

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Aims

To compare the visual outcomes, spectacle independence and patient satisfaction of bilateral implantation of either monofocal plus IOLs or standard aspheric monofocal IOLs, using a micro-monovision technique.

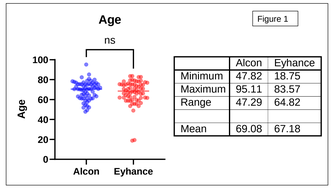
Methods

- Prospective, randomized controlled study
  - Clinicaltrials.gov no: NCT05531110
- Inclusion criteria:
  - Bilateral cataracts
  - Astigmatism <1.5D,
  - No other significant ophthalmic pathology.
- Randomization to:
  - Bilateral insertion of Alcon SN60WF

  or
  - Bilateral insertion of Tecnis Eyhance ICB00 (Johnson & Johnson)
  - Patients masked
  - Micro-monovision
    - Dominant eye 0.00 to -0.25D
    - Non-dominant eye -0.75 to -1.0D
- Follow-up 6 weeks and 6 months
- Endpoints: Visual acuity, refraction, contrast sensitivity, stereo vision, patient reported outcome measures (PROMs), need for glasses after surgery.
- Preliminary data of 130 patients who have completed 6-week reviews after bilateral CS.
  - 64 patients Alcon SN60WF IOLs
  - 66 patients Eyhance ICB00 IOLs

Results

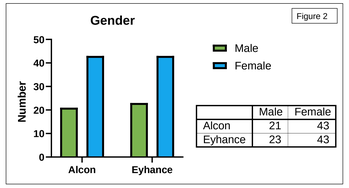
Figure 1



	Alcon	Eyhance
Minimum	47.82	18.75
Maximum	95.11	83.57
Range	47.29	64.82
Mean	69.08	67.18

Figure 1: Scatter plot of age distribution. No statistical significance found.

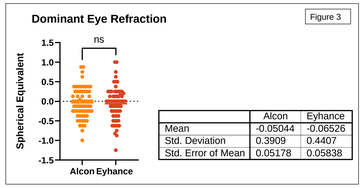
Figure 2



	Male	Female
Alcon	21	43
Eyhance	23	43

Figure 2: Bar chart demonstrating Gender distribution in two groups

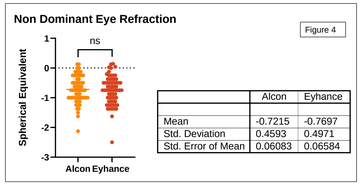
Figure 3



	Alcon	Eyhance
Mean	-0.05044	-0.06526
Std. Deviation	0.3909	0.4407
Std. Error of Mean	0.05178	0.05838

Figure 3: Scatter plot demonstrating distribution of refractive outcome in the dominant eye. No statistical significance found.

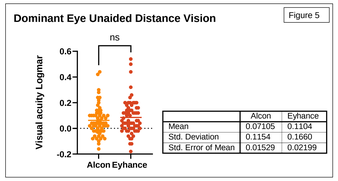
Figure 4



	Alcon	Eyhance
Mean	-0.7215	-0.7697
Std. Deviation	0.4593	0.4971
Std. Error of Mean	0.06083	0.06584

Figure 4: Scatter plot demonstrating distribution of refractive outcome in the non dominant eye. No statistical significance found.

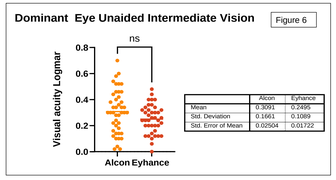
Figure 5



	Alcon	Eyhance
Mean	0.07105	0.1104
Std. Deviation	0.1154	0.1660
Std. Error of Mean	0.01529	0.02199

Figure 5: Scatter plot demonstrating distribution of unaided distance vision in the dominant eye. No statistical significance found.

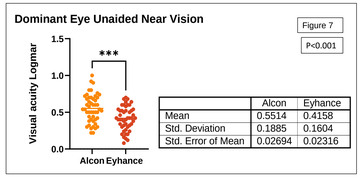
Figure 6



	Alcon	Eyhance
Mean	0.3091	0.2495
Std. Deviation	0.1661	0.1089
Std. Error of Mean	0.02504	0.01722

Figure 6: Scatter plot demonstrating distribution of unaided intermediate vision in the dominant eye. No statistical significance found.

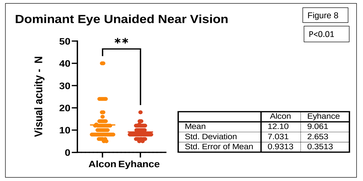
Figure 7



	Alcon	Eyhance
Mean	0.5514	0.4158
Std. Deviation	0.1885	0.1604
Std. Error of Mean	0.02694	0.02316

Figure 7: Scatter plot demonstrating distribution of unaided near vision (logMAR) in the dominant eye. (unpaired t test p<0.001)

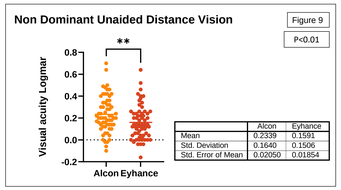
Figure 8



	Alcon	Eyhance
Mean	12.10	9.061
Std. Deviation	7.031	2.653
Std. Error of Mean	0.9313	0.3513

Figure 8: Scatter plot demonstrating distribution of unaided near vision (n chart) in the dominant eye. (Mann-Whitney p<0.01)

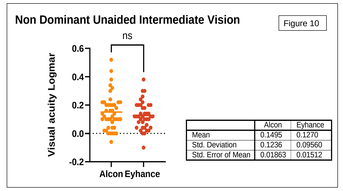
Figure 9



	Alcon	Eyhance
Mean	0.2339	0.1591
Std. Deviation	0.1640	0.1506
Std. Error of Mean	0.02050	0.01854

Figure 8: Scatter plot demonstrating distribution of unaided distance vision in the non dominant eye. (Mann Whitney, p<0.01)

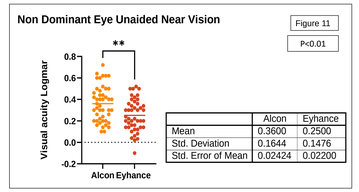
Figure 10



	Alcon	Eyhance
Mean	0.1495	0.1270
Std. Deviation	0.1236	0.09560
Std. Error of Mean	0.01863	0.01512

Figure 10: Scatter plot demonstrating distribution of unaided intermediate vision in the non dominant eye. No statistical significance found.

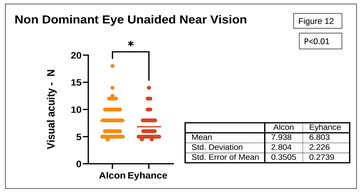
Figure 11



	Alcon	Eyhance
Mean	0.3600	0.2500
Std. Deviation	0.1644	0.1476
Std. Error of Mean	0.02424	0.02200

Figure 11: Scatter plot demonstrating distribution of unaided near vision (logMAR) in the non dominant eye. (unpaired t test p<0.01)

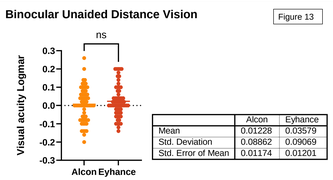
Figure 12



	Alcon	Eyhance
Mean	7.938	6.803
Std. Deviation	2.804	2.226
Std. Error of Mean	0.3505	0.2739

Figure 12: Scatter plot demonstrating distribution of unaided near visual vision (n chart) in the non dominant eye. (Mann-Whitney p<0.05)

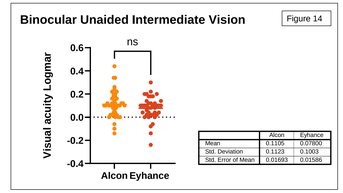
Figure 13



	Alcon	Eyhance
Mean	0.01228	0.03579
Std. Deviation	0.08862	0.09069
Std. Error of Mean	0.01174	0.01201

Figure 13: Scatter plot demonstrating distribution of binocular unaided distance vision. No statistical significance found.

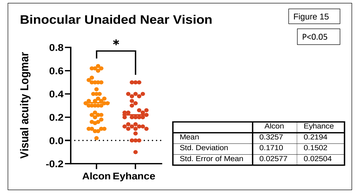
Figure 14



	Alcon	Eyhance
Mean	0.1105	0.07800
Std. Deviation	0.1123	0.1003
Std. Error of Mean	0.01693	0.01586

Figure 14: Scatter plot demonstrating distribution of unaided binocular intermediate vision. No statistical significance.

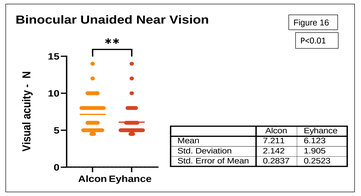
Figure 15



	Alcon	Eyhance
Mean	0.3257	0.2194
Std. Deviation	0.1710	0.1502
Std. Error of Mean	0.02577	0.02504

Figure 15: Scatter plot of distribution of unaided binocular near vision (logMAR) outcome in binocular vision. (unpaired t test, p<0.05)

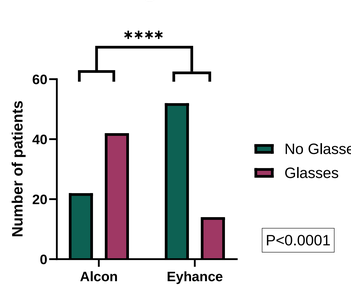
Figure 16



	Alcon	Eyhance
Mean	7.211	6.123
Std. Deviation	2.142	1.905
Std. Error of Mean	0.2837	0.2523

Figure 16: Scatter plot demonstrating distribution of unaided near vision (n chart) in binocular vision. (Mann- Whitney, p<0.01)

Figure 17



	No Glasses	Glasses
Alcon	22	42
Eyhance	52	14

Percentage of row total	No Glasses	Glasses
Alcon	34.38%	65.63%
Eyhance	78.79%	21.21%

Figure 17: Bar chart depicting glasses use in photopic conditions. (Chi Square test, Fisher's Exact Test P<0.0001)

Conclusions

Preliminary data demonstrates that the use of the Eyhance IOL with a micro-monovision approach gives patients:

Eyhance ICB00 group: Statistically significant improved unaided reading vision

78% of Eyhance patients were glasses independent in photopic conditions (needing only reading glasses in mesopic conditions)

No statistically significant differences found in: Contrast sensitivity, Stereoacuity, CatPROM & CATquest 9SF questionnaires.