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‘Off the Shelf’ Toric Intraocular Lenses for NHS Patients: Preliminary Data of a Randomised Control Trial

Khayam Naderi , Sancy Low, Vijay Wagh, Mani Bhogal, Ailsa Ritchie, Scott Robbie, Chris Hammond, Moin Mohamed, Nick Stanojcic, Elodie Azan, Lily Lai, Chris Hull, David O’Brart

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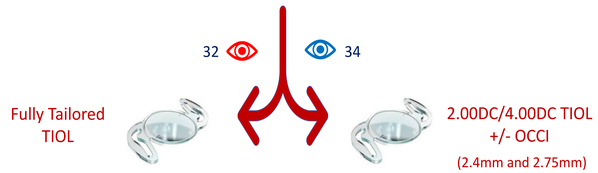
Background

- >20% of patients undergoing cataract surgery in the NHS have a pre-operative astigmatism of >1.50DC.
- Toric intraocular lens (TIOL) implantation associated with ↑ rates of spectacle independence, ↑ QOL scores, and a ↓ lifetime patient economic burden.
- TIOLs available in only a small proportion of NHS hospitals due to increased associated costs.
- A ‘reduced’ in-house bank of TIOLs can reduce additional costs/storage, allowing NHS patients routine access to them.

Purpose: Compare visual performance and refractive outcomes of “Off the Shelf” TIOLs, with a set cylindrical correction of 2.00D or 4.00D +/- OCCIs versus fully targeted correction.

Methodology

Inclusion Criteria: All adult patients with regular astigmatism of >1.50D on biometry



4-week and 6-month follow-up

Primary Outcomes:

- Subjective Refractive Error (D)
- Uncorrected Distance Visual Acuity (logMAR)
- Best-Corrected Distance Visual Acuity (logMAR)

Results

Post-operative Results: Fully Tailored vs ‘Off the Shelf’

Four Weeks Post-Op

FT (n=32) Mean (+/- SD)		OTS (n=34) Mean (+/- SD)
0.17 (0.15)	UCVA (logMAR) p=0.22	0.13 (0.12)
0.0022 (0.091)	BCVA (logMAR) p=0.52	0.018 (0.11)
0.87 (0.53)	Residual Refractive Cylinder (D) p=0.044*	0.64 (0.35)
-4.20 (2.55)	CATPROM5 p=0.98	-4.23 (2.89)
0.92 (0.13)	EQ-5D-3L Score p=0.33	0.95 (0.11)

Six Months Post-Op

FT (n=16) Mean (+/- SD)		OTS (n=19) Mean (+/- SD)
0.14 (0.16)	UCVA (logMAR) p=0.96	0.14 (0.15)
0.024 (0.11)	BCVA (logMAR) p=0.57	0.0032 (0.10)
0.69 (0.31)	Residual Refractive Cylinder (D) p=0.19	0.87 (0.46)
-4.59 (2.19)	CATPROM5 p=0.0024*	-7.13 (2.36)
0.84 (0.16)	EQ-5D-3L SCORE p=0.13	0.92 (0.13)

Vector Analysis (6-month Follow-up)

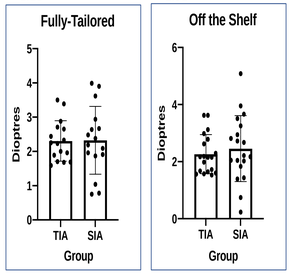
Variable	Fully Tailored (n=16) Mean (+/- SD)	Off the Shelf (n=19) Mean (+/- SD)	p-value (95% Confidence Interval)
Target-induced Astigmatism (D)	2.31 (0.59)	2.26 (0.68)	p=0.84 (-0.49 to 0.40)
Surgically-induced Astigmatism (D)	2.33 (0.99)	2.46 (1.15)	p=0.72 (-0.61 to 0.88)
Difference Vector (D)	0.69 (0.31)	0.87 (0.46)	p=0.19 (-0.094 to 0.46)
Correction Index	0.99 (0.29)	1.08 (0.39)	p=0.45 (-0.15 to 0.33)
Index of Success	0.33 (0.20)	0.40 (0.23)	p=0.30 (-0.072 to 0.23)
Angle of Error	2.75 (9.23)	3.26 (7.97)	p=0.86 (-5.40 to 6.43)
Magnitude of Error (D)	0.02 (0.58)	0.20 (0.77)	p=0.45 (-0.30 to 0.65)

Target Induced Astigmatism vs Surgically Induced Astigmatism Agreement at 6/12 Post Op

(Bland-Altman Comparison)

Bias: -0.020
SD: 0.578
95% CI: -1.15 to 1.11

Bias: -0.197
SD: 0.771
95% CI: -1.71 to 1.31



Discussion

- ‘Off the Shelf” (OTS) model does not appear to be inferior to a fully tailored approach for up to 5.0 DC.
- There were no cases needing further surgery to reposition a TIOL.
- 91.2% and 100% of patients in the OTS group achieved an UCVA of at least 0.30 logMAR (6/12) at 4 weeks and at 6 months, respectively.
- Having a bank of 2.00DC and 4.00DC TIOLs in-house may allow the majority of NHS patients with regular astigmatism to achieve good UCVA to meet driving standards
- Bulk production of 2.00DC and 4.00DC TIOLS could allow manufacturers to supply such TIOLS at reduced costs/same costs as monofocals.

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