# ‘Off the Shelf’ Toric Intraocular Lenses to allow better access in Public Healthcare: A Randomised Control Study

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Despite benefits (1), toric intraocular lenses (TIOLs) comprise only 0.4% of IOLs implanted in the NHS (2). Reasons include typically higher IOL prices, delivery logistics/costs as on-site storage of TIOLs is impractical due to large numbers of TIOL spherical and cylindrical combinations, and increased consultation/operative and administration times (3). By using TIOLs with only two-cylinder powers, on-site TIOL banks might be feasible due to lower numbers of lens combinations and TIOL unit price possibly reduced by bulk manufacture (3).

This was an ethics approved (19/WA/0272), single-centre, prospective, single-masked, randomised case-control study, which adhered to the tenets of the Declaration of Helsinki and UK Data Protection Act (2018). Inclusion criteria were age over 18 with full capacity and symptomatic cataract(s), without other significant ocular pathologies and regular corneal astigmatism (1.50-5.00D).

Forty-seven patients were randomised to a fully tailored' (FT) and 44 to an 'off the shelf' group (OTS). The refractive target was emmetropia, with the aspheric RayOne single-piece, hydrophilic acrylic TIOL (Rayner, Worthing, West Sussex, UK) being implanted. FT patients received a TIOL with full correction of corneal astigmatism. OTS patients received either a 2.00D or 4.00D cylinder TIOL, with residual calculated astigmatism corrected by opposite clear corneal incisions (OCCI), the degree of astigmatism correction being estimated at 0.25D and 0.50D with 2.4-millimetre (mm) and 2.75mm incision sizes respectively (4-5). Patients were reviewed at 4 weeks (4W) and 6 months (6M). Primary outcome measures were monocular uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (BDVA), and residual subjective refractive cylinder (D). Secondary outcomes were patient-reported outcome measures (PROMs), TIOL rotational stability, and adverse events. Statistical analysis was performed using GraphPad Prism (GraphPad Software, San Diego, California USA). Alpins vector analysis was performed using the online VekTrAK software (http://www.assort.com). Data-set normality was assessed using the Shapiro-Wilk test. Parametric data were analysed with student unpaired t-test with statistical significance set at $p<0.05$.

There were no differences in baseline demographics (table 1). At 4W, mean UDVA (+/- standard deviation) was 0.14 (0.11) in the OTS and 0.15 (0.14) in the FT group ($p$=0.65); mean BDVA was 0.02 (0.1) in OTS and 0.00 (0.085) in FT ($p$=0.27); mean RC was 0.73D (0.39) in OTS, and 0.85D (0.49) in FT ($p$=0.23). At 6M, mean UDVA was 0.16 (0.15) in OTS and 0.10 (0.13) in FT (p=0.075); mean BDVA was 0.01 (0.10) in OTS and -0.01 (0.09) in FT (p=0.34); mean RC was 0.89D (0.50) in OTS and 0.84D (0.42) in FT (p=0.59). There were no differences in PROMs between the groups (table 2). No cases required further surgery to reposition the TIOL.

In this study our OTS approach was not significantly inferior to a FT method. Using TIOLs with only 2.0DC and 4.0DC cylinder powers could facilitate increased access to TIOLs in the NHS/public health sector and the developing world by allowing 'on-site' TIOL banks, reducing costs in administrative time, lens transport/delivery, inventory wastage and giving manufacturers the opportunity to produce 2.00D and 4.00DC TIOLs in high volume, allowing possible reductions in production costs.


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| Parameter | Off The Shelf (n=47) Mean (SD) | Fully Tailored (n=44) Mean (SD) | *p*-value (95% Confidence Interval) |
|---|---|---|---|
| Age (Years) | 69.13 (11.86) | 69.45 (11.97) | 0.90 (-4.64 to 5.29) |
| Gender (Male:Female) | 25:22 | 12:32 | 0.018 |
| Pre-operative UDVA (logMAR) | 0.92 (0.52) | 0.83 (0.43) | 0.37 (-0.29 to 0.11) |
| Pre-operative BDVA (logMAR) | 0.55 (0.45) | 0.46 (0.37) | 0.32 (-0.26 to 0.86) |
| Axial Length (mm) | 24.21 (1.47) | 24.64 (1.55) | 0.18 (-2.00 to 1.06) |
| Pre-operative Biometric K1-K2 (D) | 2.31 (0.62) | 2.33 (0.64) | 0.89 (-0.24 to 0.28) |
| Pre-operative Pentacam K1-K2 (D) | 2.25 (0.67) | 2.23 (0.73) | 0.92 (-0.31 to 0.28) |
| Endothelial Cell Count | 2498 (263.7) | 2515 (280.9) | 0.76 (-96.25 to 130.6) |
| IOP (mmHg) | 15.43 (3.11) | 14.43 (3.47) | 0.15 (-3.27 to 0.38) |
| CATPROM-5 Rasch-calibrated Score | 0.809 (2.57) | 0.301 (2.63) | 0.35 (-1.59 to 0.57) |
| EQ-5D-3L Value Score | 0.888 (0.15) | 0.808 (0.24) | 0.06 (-0.16 to 0.0033) |
| EQ-5D-3L VAS | 83.77 (18.18) | 79.52 (18.77) | 0.28 (-11.94 to 3.45) |

Table 1: Baseline Demographics of the two study groups.

SD=Standard deviation; UDVA=Uncorrected distance visual acuity; BDVA= Best-corrected distance visual acuity; K=Keratometry; D=Dioptres; IOP=Intraocular Pressure (measured using icare); VAS=Visual Analogue Scale.

Fisher's exact test to compare proportions of each gender between the two groups,

Unpaired t-test used to compare means between two groups. Mean (+/-Standard deviation)

| | 4 weeks Follow-up (mean, SD) | | | 6 months Follow-up (mean, SD) | | |
|---|---|---|---|---|---|---|
| | OTS (n=47) | FT (n=44) | *p*-value (95% CI) | OTS (n=43) | FT (n=41) | *p*-value (95% CI) |
| UDVA (logMAR) | 0.14 (0.11) | 0.15 (0.14) | 0.65 (-0.41 to 0.066) | 0.16 (0.15) | 0.10 (0.13) | 0.075 (-0.12 to 0.0057) |
| BDVA (logMAR) | 0.023 (0.098) | 0.0011 (0.085) | 0.27 (-0.060 to 0.017) | 0.01 (0.10) | -0.01 (0.09) | 0.34 (-0.063 to 0.022) |
| Residual Subjective Refractive Cylinder (D) | 0.73 (0.39) | 0.85 (0.49) | 0.23 (-0.073 to 0.30) | 0.89 (0.50) | 0.84 (0.42) | 0.59 (-0.25 to 0.15) |
| SE (D) | -0.45 (0.52) | -0.60 (0.47) | 0.17 (-0.35 to 0.062) | -0.30 (0.58) | -0.37 (0.39) | 0.53 (-0.28 to 0.15) |
| Pentacam K1-K2 (D) | 1.93 (0.74) | 2.06 (0.70) | 0.40 (-0.17 to 0.43) | 1.98 (0.62) | 2.12 (0.75) | 0.35 (-0.16 to 0.44) |
| Endothelial Cell Count | 2191 (416) | 2002 (580) | 0.08 (-399.7 to 20.49) | 2259 (399.4) | 2163 (372.1) | 0.26 (-265.3 to 72.50) |
| IOP (mmHg) | 13.04 (3.83) | 12.73 (3.82) | 0.70 (-1.91 to 1.28) | 11.81 (2.68) | 12.05 (3.18) | 0.72 (-1.04 to 1.51) |
| CATPROM-5 Score | -4.30 (2.63) | -4.23 (2.81) | 0.90 (-1.07 to 1.01) | -6.15 (3.03) | -5.19 (2.91) | 0.14 (-0.33 to 2.25) |
| EQ-5D-3L Value Score | 0.93 (0.12) | 0.91 (0.13) | 0.49 (-0.071 to 0.034) | 0.88 (0.18) | 0.84 (0.20) | 0.31 (-0.12 to 0.041) |
| EQ-5D-3L VAS | 88.23 (11.15) | 85.74 (12.94) | 0.33 (-7.54 to 2.56) | 87.12 (15.38) | 87.73 (11.49) | 0.84 (-5.36 to 6.57) |
| TIA (D) | 2.31 (0.62) | 2.33 (0.64) | 0.89 (-0.24 to 0.28) | 2.28 (0.59) | 2.29 (0.63) | 0.28 (-0.25 to 0.28) |
| SIA (D) | 2.46 (0.82) | 2.54 (1.05) | 0.68 (-0.31 to 0.47) | 2.35 (0.98) | 2.46 (0.93) | 0.60 (-0.31 to 0.52) |
| DV (D) | 0.73 (0.39) | 0.84 (0.37) | 0.27 (-0.079 to 0.28) | 0.89 (0.50) | 0.84 (0.52) | 0.59 (-0.25 to 0.15) |
| AOE (Degrees) | 2.02 (7.59) | 2.84 (9.52) | 0.65 (-2.76 to 4.40) | 4.65 (9.96) | 2.90 (9.28) | 0.41 (-5.93 to 2.44) |
| MOE (D) | 0.15 (0.57) | 0.22 (0.67) | 0.62 (-0.19 to 0.32) | 0.073 (0.73) | 0.17 (0.59) | 0.52 (-0.20 to 0.39) |
| CI | 1.07 (0.27) | 1.08 (0.31) | 0.89 (-0.11 to 0.13) | 1.03 (0.34) | 1.07 (0.29) | 0.58 (-0.099 to 0.18) |
| IOS | 0.34 (0.21) | 0.38 (0.24) | 0.46 (-0.059 to 0.13) | 0.51 (0.23) | 0.38 (0.20) | 0.53 (-0.12 to 0.063) |
| COA | 1.00 (0.31) | 1.01 (0.56) | 0.58 (-0.13 to 0.24) | 1.20 (1.06) | 1.05 (0.20) | 0.41 (-0.51 to 0.21) |

Table 2: Outcomes at 4-weeks and 6-months follow-up between the two groups.

SD=Standard deviation; CI=Confidence Interval; OTS=Off The Shelf; FT=Fully Tailored; UDVA=Uncorrected distance visual acuity; BDVA= Best-corrected distance visual acuity; K=Keratometry; D=Dioptres; IOP=Intraocular Pressure (measured using icare); VAS=Visual Analogue Scale; TIA=Target Induced Astigmatism; SIA=Surgically Induced Astigmatism; DV=Difference Vector; AOE=Angle of Error; MOE=Magnitude of Error; CI=Correction Index; IOS=Index of Success; COA=Coefficient of Adjustment.
Unpaired t-test used to compare means between two groups. Mean (+/-Standard Deviation)