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# 'Off the shelf' Toric Intraocular Lenses for patients in the National Health Service: Preliminary Data of a Randomised Controlled Trial

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## Introduction

- Cataract surgery is one of the most common elective operations performed in the United Kingdom National Health Service (NHS), with 21% of NHS patients have a pre-operative astigmatism of over 1.5DC.
- Compared to standard monofocal intraocular lenses (IOLs), Toric IOLs (TIOLs) implantation is associated with higher rates of spectacle independence, better quality of life scores, and a lower lifetime economic burden for patients.
- TIOLs are available in only a small proportion of NHS hospitals due to increased associated costs.
- An in-house bank of TIOLs can reduce additional time and financial expenditure, allowing public healthcare patients routine access to TIOLs and their associated visual and refractive benefits.
- We present preliminary data of a randomised controlled trial comparing outcomes with 'fully-tailored' (FT) TIOLs, and an 'off the shelf' (OTS) approach with 2.00 or 4.00 dioptre cylinder (DC) corrections only, with additional OCCIs where required.

## Methodology

Single-blind, prospective randomized control study

Fully tailored TIOL

2.00DC / 4.00DC TIOL ± OCCIs

**Inclusion Criteria**:
- Full Capacity
- Visually significant cataract
- Age >18 years
- >1.50DC Regular Astigmatism

**Exclusion Criteria:**
- Irregular astigmatism
- Visual impairing ocular or neurological co-morbidities
- Previous ocular surgery

Biometric Keratometry readings used to calculate TIOL lens power using Rayner Toric calculator (RayOne Toric Lens)

**Visits**: Baseline, 4/52 post-op & 6/12 post-op

**Primary Outcomes**:
- Subjective Refractive Error
- UCVA (logMAR)
- BCVA (logMAR)

**Secondary Outcomes**:
- Vector analysis (Alpins Method)
- Peri- & Post-operative complications
- Quality of Life Outcomes (CAT-PROM 5 & EQ-5D-3L)
- Adverse Events

## Results

### Baseline Demographics

Baseline Demographics

| Variable | Fully Tailored Group (n=20) Mean (+/- SD) | 'Off the Shelf' Group (n=21) Mean (+/- SD) | *p*-value (95% Confidence Interval) |
|---|---|---|---|
| Gender (Male: Female) | 5:15 | 13:8 | 0.039 |
| Age (years) | 69.1 (9.72) | 68.95 (14.37) | 0.97 (-7.64 to 7.94) |
| Eye (Int: 2nd) | 11:9 | 19:2 | 0.027 |
| UCVA (logMAR) | 0.66 (0.58) | 0.86 (0.41) | 0.17 (-0.49 to 0.09) |
| BCVA (logMAR) | 0.32 (0.32) | 0.48 (0.30) | 0.12 (-0.041 to 0.35) |
| Spherical Equivalent Aim (D) | -0.145 (0.11) | -0.15 (0.11) | 0.94 (-0.074 to 0.070) |
| Biometric Corneal Astigmatism (D) | 2.31 (0.58) | 2.35 (0.72) | 0.86 (-0.38 to 0.45) |
| Pentacam Corneal Astigmatism (D) | 2.16 (0.58) | 2.14 (0.70) | 0.41 (-0.22 to 0.53) |
| Pre-operative Refractive Cylinder (D) | 2.48 (1.06) | 2.06 (1.33) | 0.28 (-1.18 to 0.35) |
| IOP (mmHg) | 14.8 (3.24) | 14.67 (4.79) | 0.92 (-2.73 to 2.46) |
| Endothelial Cell Count (cells/m²) | 2452.9 (288.58) | 2563.52 (229.63) | 0.26 (-78.81 to 252.1) |
| CATPROM-5 Rasch-calibrated Score | -1.18 (2.18) | 0.41 (2.78) | 0.048 (-3.18 to -0.012) |
| EQ-5D-3L Visual Analogue Score | 80.95 (16.04) | 82.86 (20.35) | 0.74 (-13.52 to 9.78) |
| EQ-5D-3L Index Score | 0.79 (0.31) | 0.92 (0.14) | 0.093 (-0.28 to 0.02) |

### Baseline vs Post-operative Outcomes

| Fully Tailored | Baseline | 4/52 (n=20) | *p*-value | 6/12 (n=13) | *p*-value |
|---|---|---|---|---|---|
| UCVA (logMAR) | 0.66 | 0.2 | 0.0018 | 0.16 | 0.0014 |
| BCVA (logMAR) | 0.32 | 0.0035 | 0.0007 | 0.017 | 0.0033 |
| Residual Refractive Cylinder (D) | 2.31* (Biometric Astimgatism) | 0.93 | <0.0001 | 0.69 | 0.0001 |
| CATPROM | -1.18 | -4.93 | 0.0001 | -4.73 | 0.0001 |
| EQ-5D-3L SCORE | 0.79 | 0.92 | 0.08 | 0.835 | 0.63 |
| EQ-5D-3L RAW | 80.95 | 84 | 0.49 | 86.08 | 0.34 |

| 'Off The Shelf' | Baseline | 4/52 (n=21) | *p*-value | 6/12 (n=12) | *p*-value |
|---|---|---|---|---|---|
| UCVA (logMAR) | 0.86 | 0.14 | <0.0001 | 0.15 | 0.0001 |
| BCVA (logMAR) | 0.48 | 0.0095 | <0.0001 | -0.025 | 0.0001 |
| Residual Refractive Cylinder (D) | 2.35* (Biometric Astimgatism) | 0.6 | <0.0001 | 0.96 | 0.0001 |
| CATPROM | 0.41 | -4.44 | 0.0001 | -6.89 | 0.0001 |
| EQ-5D-3L SCORE | 0.92 | 0.95 | 0.31 | 0.882 | 0.51 |
| EQ-5D-3L RAW | 82.86 | 87.67 | 0.33 | 89.17 | 0.36 |

### Fully Tailored vs 'Off the Shelf' Outcomes at 4-week and 6-month Follow-up

| Fully Tailored 4/52 (n=20) | | 'Off the Shelf' 4/52 (n=21) |
|---|---|---|
| 0.20 | UCVA (logMAR) *p*=0.12 | 0.14 |
| 0.0035 | BCVA (logMAR) *p*=0.85 | 0.0095 |
| 0.93 | Residual Refractive Cylinder (D) *p*=0.021 | 0.60 |
| -4.93 | CATPROM *p*=0.86 | -4.44 |
| 0.92 | EQ-5D-3L Score *p*=0.35 | 0.95 |
| 84 | EQ-5D-3L RAW Score *p*=0.28 | 87.67 |

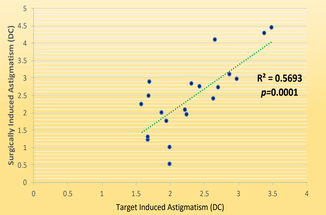
| Fully Tailored 6/12 (n=13) | | 'Off the Shelf' 6/12 (n=12) |
|---|---|---|
| 0.15 | UCVA (logMAR) *p*=0.87 | 0.16 |
| 0.017 | BCVA (logMAR) *p*=0.22 | -0.025 |
| 0.69 | Residual Refractive Cylinder (D) *p*=0.061 | 0.96 |
| -4.73 | CATPROM *p*=0.039 | -6.89 |
| 0.835 | EQ-5D-3L SCORE *p*=0.49 | 0.882 |
| 86.08 | EQ-5D-3L RAW Score *p*=0.59 | 89.17 |

### Vector Analysis at 6-month follow-up

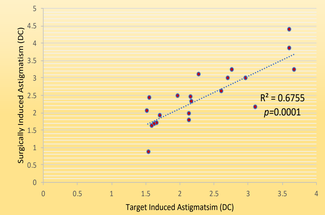
| Variable | Fully Tailored Group (n=13) Mean (+/- SD) | 'Off the Shelf' Group (n=12) Mean (+/- SD) | *p*-value (95% Confidence Interval) |
|---|---|---|---|
| Magnitude of Target-induced Astigmatism (D) | 2.4 (0.47) | 2.46 (0.77) | 0.81 (-0.59 to 0.46) |
| Magnitude of Surgically-induced Astigmatism (D) | 2.43 (0.86) | 2.74 (1.15) | 0.45 (-1.15 to 0.53) |
| Difference Vector (D) | 0.69 (0.34) | 0.96 (0.33) | 0.061 (-0.55 to 0.014) |
| Correction Index | 1.0 (0.25) | 1.11 (0.32) | 0.36 (-0.35 to 0.13) |
| Index of Success | 0.3 (0.18) | 0.42 (0.17) | 0.12 (-0.26 to 0.031) |
| Angle of Error (degrees) | 1.15 (8.67) | 3.5 (9.59) | 0.53 (-9.90 to 5.21) |
| Magnitude of Error (D) | 0.03 (0.60) | 0.28 (0.7) | 0.35 (-0.79 to 0.29) |
| Torque (D) | 0.36 (0.26) | 0.56 (0.35) | 0.36 (-0.35 to 0.13) |
| Flattening Effect (D) | 2.36 (0.92) | 2.64 (1.2) | 0.53 (-1.15 to 0.61) |

## Target Induced Astigmatism vs Surgically Induced Astigmatism (4 week follow-up)

4/52 Post-operative Target Induced Astigmatism vs Surgically Induced Astigmatism in Fully-Tailored Group




4/52 Post-operative Target Induced Astigmatism vs Surgically Induced Astigmatism in Off the Shelf Group




## Discussion

- Our preliminary data suggests that 'off the shelf' 2.00DC and 4.00DC TIOLs with additional OCCIs improves UCVA and allows patients to achieve spectacle independence for distance vision.
- There were no cases needing further surgery to reposition a TIOL.
- Our preliminary results suggest that the off the shelf model may not be inferior to a fully tailored approach.
- Having a bank of 2.00DC and 4.00DC TIOLs in-house may allow the majority of patients with regular astigmatism to achieve spectacle independence in a public healthcare setting.

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