

# ANALYSIS

## NHS comparison with Optical Express clinical outcomes

**Steve Schallhorn** compares the results of an independently audited data analysis of Optical Express intraocular lens and cataract outcomes with a recently published study of NHS cataract outcomes

A recently published study of cataract surgery performed in the NHS represents a benchmark for the ophthalmology industry.<sup>1</sup> This comprehensive analysis was part of the Royal College of Ophthalmologists' National Ophthalmology Database (RCO NOD) and included 180,114 primary intraocular lens (IOL) and cataract procedures at 28 UK Trust sites undertaken between August 2006 and November 2010.

### MATCHED GROUP ANALYSIS

A series of analyses were performed to compare the results of 68,153 primary Optical Express IOL procedures to the NHS benchmark data. This included visual outcomes and complication rate comparisons between the RCO NOD and Optical Express as well as visual outcomes of more recently conducted Optical Express procedures.

To help ensure an adequate comparison of visual outcomes, only primary treatments of the same type and performed during the same time period (August 2006 to November 2010) and with

similar post-operative follow-up (three months) were included (matched group analysis). In addition, only those eyes that did not have pre-existing ocular co-morbidity were included from both groups. Ocular co-morbidity for exclusion included diseases of the eye which could impact vision, including macular degeneration, glaucoma and diabetic retinopathy. For the RCO NOD there were 113,610 eyes without co-morbidity and for Optical Express this included 11,978 eyes. Table 1 displays the demographics of the treatments. The relative young age at Optical Express was primarily due to patients requesting privately-funded visual improvement to support their work and lifestyle needs.

For the complication analysis, all treatments reported by the RCO NOD (180,114 eyes) and all IOL/ataract procedures conducted by Optical Express from August 2006 to July 2015 (68,153 eyes) were included. This provided the largest possible dataset for the inclusion of complications that occur with a very low incidence. The Optical Express treatments were performed in 18 centres across the UK and Ireland.

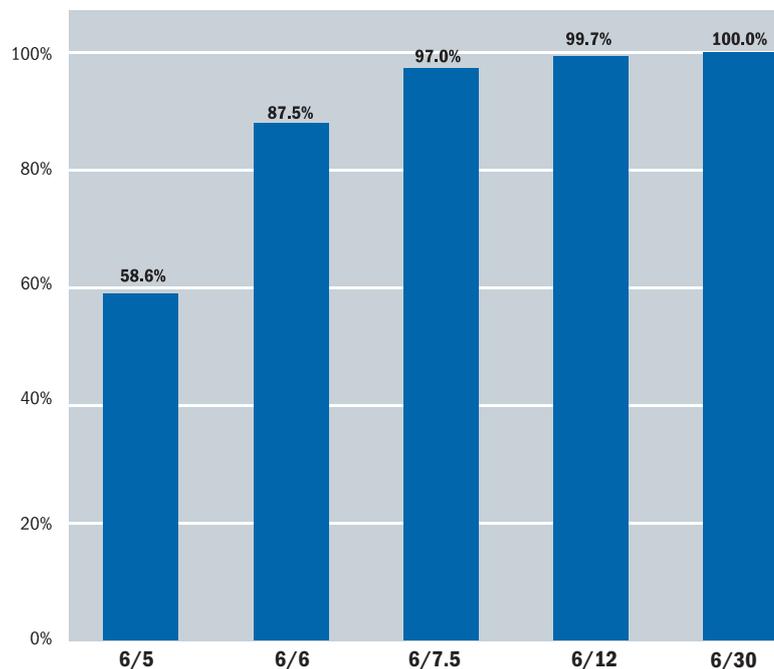
The final analysis consisted of the visual outcomes of more recently conducted IOL/ataract procedures conducted at Optical Express (December 2010 to July 2015). This consisted of 55,623 eyes of which 54,227 eyes did not have ocular co-morbidity.

Surgical indications for RCO NOD patients were where they presented with visually significant cataracts and, for patients at Optical Express, this included visually significant cataracts as well as presbyopia with age-related lens changes where there was a desire for improvement in unaided vision. All of the procedures (RCO NOD and Optical Express) included removal of the natural crystalline lens using phacoemulsification and implantation of an IOL. There was a very wide range of pre-operative refraction with spheres ranging from -18.50DS to +10.00DS. Most of the patients at Optical Express elected to have a multifocal IOL to provide functional distance, intermediate and near vision. It is worth noting that multifocal IOLs are mostly unavailable for implantation under the NHS due to their much higher cost and hence monofocal lenses are usually used.

### RESULTS – VISUAL OUTCOMES

The visual outcomes of matched patients treated at Optical Express were significantly better than reported in the RCO NOD as shown in Table 2. In the NHS patients with no pre-existing eye problems, 27.3% of eyes achieved 6/6 uncorrected distance visual acuity, while a much higher percentage of Optical Express eyes achieved this result (51.3%). While 80.9% of NHS eyes were able to read letters equivalent to the established driving standard after

**FIGURE 1** Postoperative binocular unaided distance vision after more recent OE treatments



their procedure (6/12), significantly more eyes at Optical Express (91.5%) exceeded this minimum standard for driving without the need for spectacles or contact lenses.

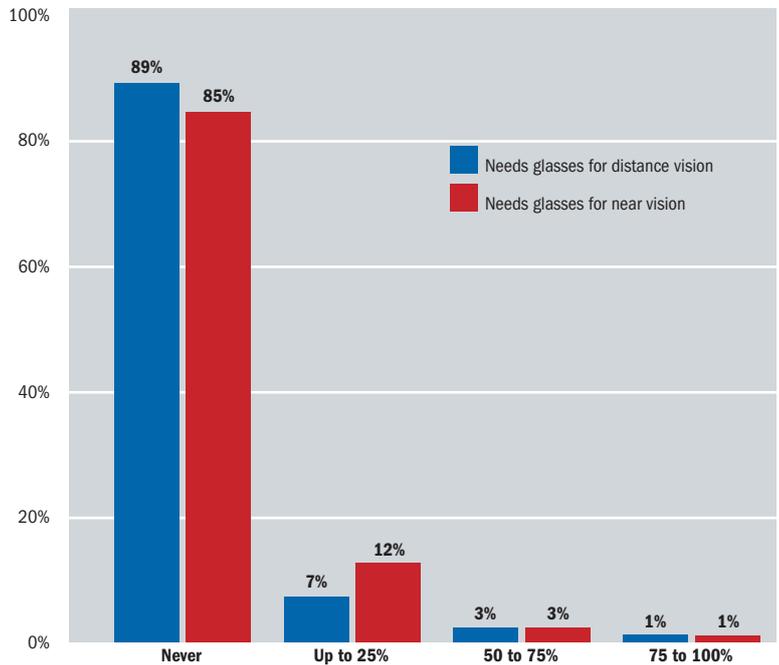
More recent procedures resulted in even better visual outcomes. For treatments conducted between December 2010 and July 2015, 68.7% of Optical Express eyes had unaided distance vision of at least 6/6 while the great majority (96.7%) achieved 6/12 or better vision (Table 2). These results are for monocular vision (vision measured in only one eye). When surgery is performed on both eyes, binocular vision may be a better metric to indicate visual function. For more recently conducted IOL/cataract procedures, 87.5% of Optical Express patients achieved 6/6 unaided binocular distance vision and most (99.7%) achieved 6/12, as shown in Figure 1. In addition, there was an average of 6 line pre-op to post-op improvement in unaided near vision; this was primarily because most patients elected to have a multifocal lens implanted.

The good visual acuity outcomes of more recent procedures was reflected in a questionnaire that is routinely given to all post-operative patients. Most patients (89%) reported that after surgery they never wore glasses for distance vision as shown in Figure 2. Similarly, 85% of patients report no need for near vision spectacles. Only 4% reported that they wore spectacles for more than half of the time. Patient satisfaction was high and 92.1% of patients reported that the surgery had improved their life.

**RESULTS - COMPLICATIONS**

While visual outcomes provide a valuable measure of efficacy, an analysis of complications is necessary to understand the safety of the procedures performed. The likelihood of an intraoperative

**FIGURE 2 Use of spectacles one year after OE lens replacement surgery**



complication was low at the NHS but even lower when the procedures were conducted at Optical Express, as shown in Table 3.

One of the most feared eye postoperative complication of an IOL/cataract procedure is endophthalmitis. Endophthalmitis →

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**TABLE 1 Demographic comparison of UK NOD and OE**

	RCO NOD IOL	OE IOL surgery at same time period as NOD report	OE IOL surgery performed more recently
Number (all eyes)	111,114	12,530	55,623
Number (eyes) without pre-existing ocular co-morbidity	113,610	11,978	54,227
Treatment time period	Aug 2006 to Nov 2010	Aug 2006 to Nov 2010	Dec 2010 to Jul 2015
Age at surgery (mean)	77.1 years	55.4 years*	57.0 years
Male / female (%)	40.6 / 59.4	46.1 / 53.9	47.7 / 52.3
Procedure technique	100% Phaco	100% Phaco	100% Phaco
EMR system	Medisoft Limited, UK	Proprietary	Proprietary

\*The relative young age is primarily due to patients requesting privately-funded visual improvement. This includes patients with cataracts as well as those with age-related lens changes that were not yet visually significant, but in whom cataract progression was likely, and thus better served with an IOL replacement procedure instead of a corneal refractive procedure (such as LASIK).

**TABLE 2 Comparison of UK NOD & OE visual outcomes**

Without ocular co-morbidity	RCO NOD IOL	OE IOL surgery at same time period as NOD	OE IOL surgery performed more recently
Eyes	113,610	11,978	54,227
Post-op best corrected vision			
6/12 or better (20/40)	94.6%	98.0%	99.3%
6/6 or better (20/20)	50.8%	79.6%	89.8%
Post-op uncorrected vision			
6/12 or better (20/40)	80.9%	91.5%	96.7%
6/6 or better (20/20)	27.3%	51.3%	68.7%

**TABLE 3 Comparison of UK NOD OE intraoperative complications**

	RCO NOD IOL (180,114)	OE IOL* (68,153)
No complications	95.8%	96.3%
Posterior capsular rupture	2.00%	1.10%
Iris trauma/prolapse	0.50%	0.02%
Corneal oedema	0.14%	0.12%
Anterior Chamber haemorrhage	0.05%	0.03%
Choroidal haemorrhage	0.05%	0.02%

\*Includes all eyes that underwent a IOL replacement / cataract procedure (Aug 2006 to Jul 2015)

can result in significant vision loss and can be difficult to treat. Fortunately, this is very rare in the NHS with a rate of 0.03% (1 in 3,000 cases), and at Optical Express just 0.02% (1 in 5,000 cases), as shown in Table 4. Similar differences favouring Optical Express are seen for another serious condition, retinal detachment, where the prevalence at the NHS is 0.03% versus Optical Express 0.02%. The requirement to perform an intraocular lens exchange (removal and replacement of the IOL) due to issues such as incorrect lens power, malposition of the lens or lens movement, was slightly lower at Optical Express (0.10% vs 0.13%).

Another safety indicator is the incidence of visual loss after a procedure. Vision loss, as defined by the RCO NOD analysis, is a pre-operative to post-operative loss of three or more lines of best-spectacle corrected visual acuity (BCVA). Regardless of the pre-operative vision and of whether there was pre-existing ocular

co-morbidity, there was a significantly lower rate of vision loss for procedures conducted at Optical Express than at the NHS, as shown in Table 5.

## CONCLUSIONS

The results of this comparison analysis showed that patients treated at Optical Express had a higher likelihood of excellent visual outcomes with a lower chance of suffering either an intraoperative or post-operative complication. In addition, while the risk of vision loss is low for patients treated through the NHS, it is even lower for procedures performed at Optical Express.

When comparing more recent procedures performed at Optical Express, the visual outcomes are even better. The vast majority of patients (99.7%) met or exceeded the minimum standard for driving in the UK (6/12 or better) without the assistance or reliance on spectacles and / or contact lenses. Almost nine in 10 patients achieved 6/6 unaided binocular vision. Likewise, almost nine in 10 patients reported being spectacle-free. In those patients who elected to receive a newer multifocal IOL, almost nine in 10 patients reported being free of reading spectacles.

The differences in visual outcomes and complication rates could be attributed to several factors, the most important likely being surgical experience. The 180,114 NHS procedures were performed by consultants (58.4%), independent non-consultants (31.3%), and trainees (10.3%). While no data was provided in the RCO NOD report, it is possible that the visual outcomes of the trainees were not as good as the consultants or independents. But the relatively low number of procedures from the trainees (10.3%) would not likely be enough to significantly alter the comparison. The complication rates for the trainees in the RCO NOD report were higher than the consultants. Clearly surgeon experience can reduce the complication rate and Optical Express surgeons are highly experienced with many having conducted over 25,000 IOL/Cataract procedures.

The type of intraocular lenses can affect outcomes. Multifocal and toric lenses, not readily available through the NHS because they are significantly more expensive than monofocal IOLs and require more clinical expertise, are routinely implanted at Optical Express. These lenses have advanced aspheric designs which can correct corneal astigmatism and presbyopia, leading to improved outcomes.

Another factor in the improved outcomes at Optical Express is the electronic medical record system and the ability of a dedicated biostatistics team to perform continuous and complete outcome audits.

This type of monitoring and surgeon feedback is an important element of quality improvement and can directly improve outcomes.

## STUDY LIMITATIONS

For transparency and scientific rigour, there are potential study limitations to discuss. The first is that the analysis used retrospective data from both the RCO NOD and Optical Express. Retrospective data does not carry the same study strength as a prospective, randomised trial. However, the sheer size of the sample size offsets many of the concerns of smaller retrospective studies. Both datasets included over 10,000 treatments, significantly greater than almost all previous studies. In addition, an electronic data entry system was used for the RCO NOD study to reduce transcription errors while a very robust direct-entry electronic medical record system was used at Optical Express.

There was a significant difference in the average age of the two

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**TABLE 4 Comparison of UK NOD & Optical Express postoperative complications**

	RCO NOD IOL (180,114)	OE IOL (68,153)
Lens exchange*	0.13%	0.10%
Endophthalmitis	0.03%	0.02%
Retinal detachment	0.03%	0.02%

\*Excluding Quality of Vision issues directly attributed to a multifocal lens design resulting in a like-for-like comparison

**TABLE 5 Comparison of UK NOD & Optical Express postoperative loss of vision**

Significant vision loss defined as post-operative loss of  $\geq 0.03$  logMAR of best spectacle corrected vision compared to preop (3 or more lines lost).

	RCO NOD IOL	OE IOL
Pre-op BCVA $\leq 6/6$ (20/20)		
No ocular co-morbidity	5.7%	1.7%
With ocular co-morbidity	10.2%	3.0%
Pre-operative BCVA $\leq 6/12$ (20/40)		
No ocular co-morbidity	2.4%	1.6%
With ocular co-morbidity	4.2%	2.8%

groups. The difference was due to differences in surgical indications (cataract vs pre-cataract refractive lens exchange) and that patients requested privately-funded visual improvement. Older patients are more likely to have other ocular conditions which could affect vision.

To mitigate against the potential impact of this age difference, only eyes that did not have ocular conditions that could possibly affect visual outcomes were analysed. These ocular co-morbidities are well established in the ophthalmic community, such as macular degeneration, glaucoma and diabetic retinopathy. In other words, the outcomes of otherwise healthy eyes with the same visual potential after an IOL/cataract procedure were compared.

## BACKGROUND ON IOL/CATARACT PROCEDURES

The IOL/cataract procedures at Optical Express compare with NHS procedure in that they are performed under local anaesthesia, and all surgeons are supported by a consultant anaesthesiologist who aids the comfort of patients throughout the procedure. A low efficacy and short-lasting sedative is offered to patients which aids their surgery experience.

IOL/cataract lens replacement is a form of surgery that is performed within the eye. The treating doctor undertakes the procedure through a microscopic incision that is made at the limbal margin, typically less than 3.0mm in size.

The procedure involves phacoemulsification (phaco) where an ultrasonic device is used to break up and then remove the natural lens before the insertion of an artificial IOL. Phaco surgery is used to treat both cataract and as an alternative form of vision correction for presbyopic patients who require glasses for their near vision as well as their distance vision. ●

**Mr Steve Schallhorn is a consultant ophthalmologist and global medical director for Optical Express**

## REFERENCE

- Day AC, Donachie PHJ, Sparrow JM and Johnston RL; The Royal College of Ophthalmologists National Ophthalmology Database Study of Cataract Surgery Report 1, Visual Outcomes and Complications; *Eye* 2015; (29), 552 – 560.