



The Regulation and
Quality Improvement
Authority

Optical Express
RQIA ID: 10634
32 Donegall Place
Belfast
BT1 5BB

Inspector: Jo Browne
Inspection ID: IN022108

Tel: 028 90437768

**Announced Care Inspection
of
Optical Express**

11 August 2015

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
Tel: 028 9051 7500 Fax: 028 9051 7501 Web: www.rqia.org.uk

1. Summary of Inspection

An announced care inspection took place on 11 August 2015 from 09.45 to 12.45. Overall on the day of the inspection the establishment was found to be delivering safe, effective and compassionate care. The outcome of the inspection found no areas for concern.

This inspection was underpinned by The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments.

1.1 Actions/Enforcement Taken Following the Last Care Inspection

Other than those actions detailed in the previous QIP there were no further actions required to be taken following the last inspection.

1.2 Actions/Enforcement Resulting from this Inspection

Enforcement action did not result from the findings of this inspection.

1.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	0	0

This inspection resulted in no requirements or recommendations being made. Findings of the inspection can be found in the main body of the report.

2. Service Details

Registered Organisation/Registered Person: Optical Express Limited Ms Mary Spellman	Registered Manager: Mrs Gail Caldwell
Person in Charge of the Establishment at the Time of Inspection: Ms Mary Spellman	Date Manager Registered: 28 September 2012
Categories of Care: AH (DS) – Acute Hospital Day Surgery, PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PD Private Doctor (Other)	

Laser Equipment

Excimer Laser

Manufacturer: VisX
 Model: Star 4
 Serial Number: 5629
 Laser Class: Class 4
 Wavelength: ArF (193nm)

Intralase Laser

Manufacturer: Intralase
 Model: IFS
 Serial Number: 0107-40185
 Laser Class: Class 3b
 Wavelength: Nd: Glass (1053nm)

Laser Protection Advisor (LPA) – Dr Roy Henderson (Bioptica)

Laser Protection Supervisor (LPS) – Ms Gail Caldwell

Medical Support Services – Medical Advisory Board -
 Mr David Teenan – UK Medical Director
 Mr Steve Schallhorn – Chief Medical Officer

Clinical Authorised Users - Mr Stefan Klopper

Non-Clinical Authorised Users - Mrs Gail Caldwell
 Ms Wendy Coffey
 Ms Helga Walsh

Types of Treatment Provided – Refractive eye surgery - LASIK and LASEK

3. Inspection Focus

The inspection sought to assess progress with the issues raised during and since the previous inspection and to determine if the following standards have been met:

- Standard 4 – Dignity, Respect and Rights
- Standard 5 – Patient and Client Partnerships
- Standard 7 – Complaints
- Standard 48 – Laser and Intense Light Sources

Other areas inspected: Incidents, insurance arrangements and RQIA registration.

4. Methods/Process

Specific methods/processes used in this inspection include the following:

Prior to the inspection the following records were analysed: pre-inspection information and complaints return.

During the inspection the inspector met with Ms Mary Spellman, registered person and Mrs Gail Caldwell, registered manager.

The following records were examined during the inspection:

- Six patient care records
- Laser safety file
- Laser risk assessment
- Policies and procedures
- Patient feedback questionnaires
- Incident/accident records
- Local rules
- Medical treatment protocols
- Equipment service records
- Complaints records

5. The Inspection

5.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced care inspection dated 21 May 2014. The completed QIP was returned and approved by the care inspector.

5.2 Review of Requirements and Recommendations from the Last Care Inspection dated 21 May 2014

Previous Inspection Statutory Requirements		Validation of Compliance
Requirement 1 Ref: Regulation 8 (1) Stated: First time	The responsible person must ensure that the Patient Guide contains all information outlined in Regulation 8 of The Independent Healthcare Regulations (Northern Ireland) 2005.	Met
	Action taken as confirmed during the inspection: Review of the Patient Guide confirmed that it was updated following the last inspection and contained all of the information required by legislation.	

5.3 Standard 4 – Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the consultation and surgery, with the registered persons confirmed that patients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient and the optometrist. The surgery is provided within a designated laser suite.

It was confirmed that patient care records were stored securely in locked filing cabinets. Arrangements are also in place for off-site secure archiving facilities.

Is Care Effective?

It was confirmed through the above discussion and observation that patients are treated in accordance with the DHSSPS standards for Improving the Patient & Client Experience.

Patients meet with the surgeon on the planned day of surgery and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

A range of policies and procedures are in place which promote the rights of patients. A sample selection of policies were reviewed during the inspection.

Is Care Compassionate?

Discussion with staff and review of six patient care records confirmed that patients are treated and cared for in accordance with legislative requirements for equality and rights.

There were no patients being treated at the time of the inspection.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.4 Standard 5 – Patient and Client Partnership

Is Care Safe?

Patients are asked for their comments in relation to the quality of treatment provided, information and care received.

The information from patients' comments are collected in an anonymised format, summarised and used by the establishment to make improvements to services.

Is Care Effective?

Optical Express obtains the views of patients on a formal and informal basis as an integral part of the service they deliver.

All patients complete an online satisfaction questionnaire while they are in the establishment. The questionnaire is completed following consultation, treatment and review.

The information received from the patient feedback questionnaires is collated into an annual summary report which is made available to patients and other interested parties to read in the waiting area of the establishment.

The inspector reviewed the summary reports from January 2015 – July 2015 and found that patients were highly satisfied with the care and treatment provided. No comments from patients were recorded within the survey.

It was confirmed through discussion that comments received from patients are reviewed on a monthly basis by senior management and an action plan is developed and implemented to address any issues identified.

Is Care Compassionate?

Review of the patient satisfaction survey confirmed that patients have the opportunity to comment on the quality of care and treatment provided, including their interactions with staff who work within the establishment.

Review of care records and discussion with the registered persons confirmed that treatment and care are planned and developed with meaningful patient involvement; facilitated and provided in a flexible manner to meet the assessed needs of each individual patient.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.5 Standard 7 - Complaints**Is Care Safe?**

Review of complaint records and found that complaints are investigated and responded to within 28 working days (in line with regulations) or if this is not possible, complainants are kept informed of any delays and the reason for this.

Discussion with the registered persons confirmed that information from complaints is used to improve the quality of services.

Is Care Effective?

It is not in the remit of RQIA to investigate complaints made by or on the behalf of individuals, as this is the responsibility of the providers. However, if there is considered to be a breach of regulation as stated in The Independent Health Care Regulations (Northern Ireland) 2005, RQIA has a responsibility to review the issues through inspection.

A complaints questionnaire was forwarded by RQIA to the establishment for completion. Discussion with the registered persons and review of the documentation indicated that complaints have been managed in accordance with best practice.

The establishment operates a complaints policy and procedure in accordance with the DHSSPS guidance on complaints handling in regulated establishments and agencies and the legislation.

The registered persons demonstrated a good understanding of complaints management.

Review of the complaints register and complaints records evidenced that all complaints were well documented, fully investigated and had outcomes recorded in line with the complaints procedure and legislation. Complaints records were observed to be stored securely in line with data protection legislation.

A complaints audit is undertaken monthly. The audit information is used to identify trends and enhance services provided as part of the establishment's quality assurance arrangements.

The complaints procedure is contained within the Patient Guide; copies of which are available in the waiting area for patients to read.

Is Care Compassionate?

A copy of the complaints procedure is provided to patients and to any person acting on their behalf.

The complainant is notified of the outcome and action taken by the establishment to address any concerns raised.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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5.6 Standard 48 - Laser and Intense Light Sources.

Is Care Safe?

Patients have an initial consultation with a fully qualified optometrist who discusses their treatment options and the cost of the surgery.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The LPA's certificate of competence was not available at the time of the inspection; however this was forwarded to RQIA on 13 August 2015.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by the medical advisory board in December 2014. Systems are in place to review the medical treatment protocols on an annual basis.

The medical treatment protocol set out:

- Indications
- Contraindications
- Technique
- Pre-treatment tests
- Pre-treatment care
- Post-treatment care
- Recognition of treatment related problems
- Procedure if anything goes wrong with the treatment
- Permitted variation on machine variables
- Procedure in the event of equipment failure

The establishment has local rules in place which have been developed by their LPA on 16 April 2014 which expire on 16 April 2017.

The local rules cover:

- The potential hazards associated with lasers
- Controlled and safe access
- Authorised operator's responsibilities
- Methods of safe working
- Safety checks
- Personal protective equipment
- Prevention of use by unauthorised persons
- Adverse incidents procedures

The laser protection supervisor has overall responsibility for safety during refractive eye surgery as recorded within the local rules.

A list of clinical and non-clinical authorised users is maintained and authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

Patients are provided with clear post-operative instructions along with contact details for a senior optometrist if they experience any concerns. There are systems in place for the senior optometrist to refer patients directly to a consultant ophthalmologist if necessary.

The establishment's LPA completed a risk assessment of the premises on 16 April 2014, which expire on 16 April 2017 and no recommendations were made. It was advised that the LPA should include the date of renewal on the risk assessment.

The authorised users have completed training in core of knowledge and the safe use and application of the laser equipment.

Review of the training records confirmed that all authorised users had also undertaken the following required mandatory training in line with RQIA guidance:

- Basic life support annually
- Fire safety annually
- Infection prevention and control annually

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training. Confirmation of this training was forwarded to RQIA on 13 August 2015.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to areas, when surgery is being carried out.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

Laser safety warning signs are illuminated when the laser equipment is in use described within the local rules.

Protective eyewear is available as outlined in the local rules for laser technicians/surgical assistants if required.

The door to the laser suite is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using a keys, key cards and passwords. Arrangements are in place for the safe custody of the laser keys and key cards when not in use.

Is Care Effective?

The establishment has a laser surgical register which is completed every time the equipment is operated and includes:

- The name of the person treated
- The date
- The operator
- The treatment given
- The precise exposure
- Any accident or adverse incident

Review of the laser surgical register during the inspection found it to be comprehensively completed.

The care records of six patients were reviewed and found to be comprehensively completed. There was a clear patient pathway recorded within the care records from the initial consultation, to pre-operative, intra-operative and post-operative care. Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

There was evidence of signed consent forms within the care records reviewed which clearly outlined the associated risks and complications of refractive eye surgery. A completed patient health questionnaire was also available.

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service report of 6 August 2015 was reviewed as part of the inspection process.

A laser safety file is in place which contains all of the relevant information in relation to laser. Advice was given in relation to archiving old information from the file.

Is Care Compassionate?

As previously stated patients meet with their surgeon, on the day of surgery, to discuss their individual treatment and any concerns they may have. Arrangements can be made for the patient to meet with the surgeon earlier if necessary.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment.

The establishment has a list of fees available for each type of surgical procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the individual patient's prescription and surgery options available to them.

Number of Requirements:	0	Number of Recommendations:	0
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5.7 Additional Areas Examined

5.7.1 Management of Incidents

The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA.

No adverse incidents have occurred within the establishment since the last inspection. However systems are in place to manage, document, fully investigate incidents and disseminate the outcomes.

5.7.2 RQIA registration and Insurance Arrangements

Discussion with the registered persons regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The certificates of RQIA registration and insurance were clearly displayed in the waiting area of the premises.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements	0	Number Recommendations:	0
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5.8 Laser Protection Report

A laser protection report prepared by Dr Ian Gillan, RQIA's medical physics expert has been appended to this report and outlines any deficits in laser safety arrangements within the establishment.

All issues identified by Dr Gillan have been fully addressed and supporting evidence forwarded to RQIA on 13 August 2015.

6. No requirements or recommendations resulted from this inspection.

I agree with the content of the report.			
Registered Manager	J. Carlowan	Date Completed	23/8/15
Registered Person	none	Date Approved	2/10/15
RQIA Inspector Assessing Response	Go Braine	Date Approved	7/10/15

Please provide any additional comments or observations you may wish to make below:

Please complete in full and returned to Independent.Healthcare@rqia.org.uk from the authorised email address

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the service. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations.