

Announced Care Inspection Report 15 March 2019



Optimax Laser Eye Clinic

**Type of Service: Independent Hospital (IH) – Cosmetic
Laser Service**

Address: 7 Derryvolgie Avenue, Belfast, BT9 6FL

Tel No: 02890661118

Inspector: Elizabeth Colgan

Dr Ian Gillan, RQIA's Medical Physics Advisor

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



2.0 Profile of service

This is a registered independent hospital providing refractive laser eye surgery.

Laser equipment

Manufacturer: Schwind
 Model: 250
 Serial Number: 5244
 Laser Class: 4

Manufacturer: Intralase
 Model: FS/F530
 Serial Number: 0506-40039
 Laser Class: 4

Laser protection advisor (LPA) - Dr Sandy Mosse

Laser protection supervisor (LPS) - Mrs Susan Moffatt

Medical support services - Clinical Director Optimax Ltd

Clinical authorised operators - Dr M Ghassan - Ayoubi

Non –clinical authorised operators - Mrs Susan Moffatt
 Ms Valerie Smyth
 Ms Kelly Braniff
 Ms Fiona Quinn

Types of treatment provided - Lasik, Lasek, Epi-lasek and Photorefractive Keratectomy

3.0 Service details

Organisation/Registered Provider: Optimax Laser Eye Clinic	Registered Manager: Ms Susan Moffatt
Responsible Individual Mr James Lee Rowley	
Person in charge at the time of inspection: Ms Susan Moffatt	Date manager registered: 15 March 2019
Categories of care: (IH) Independent Hospital PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PD Private Doctor	

4.0 Inspection summary

An announced inspection took place on 15 March 2019 from 09.50 to 13.05.

Dr Ian Gillan, RQIA’s Medical Physics Advisor attended on the 14 March 2019 to review the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, 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 (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidence in all four domains. These included the arrangements for managing medical emergencies; clinical records; the environment; infection prevention and control; maintaining client confidentiality; ensuring the core values of privacy and dignity were upheld; authorised operator training and providing the relevant information to allow clients to make informed choices.

There were no areas requiring improvement identified.

Patients who submitted questionnaire responses indicated that they were either very satisfied or satisfied with the services provided in Optimax Laser Eye Clinic.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and clients experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Ms Susan Moffett, registered manager, as part of the inspection process and can be found in the main body of the report.

4.2 Action/enforcement taken following the most recent care inspection dated 28 September 2017

No further actions were required to be taken following the most recent inspection on 28 September 2017

5.0 How we inspect

Prior to the inspection a range of information relevant to the service was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of RQIA. Returned completed clients questionnaires were analysed prior to the inspection. RQIA invited staff to complete an electronic questionnaire prior to the inspection. Four completed staff questionnaires were received.

A poster informing clients that an inspection was being conducted was displayed.

During the inspection the inspectors met with Ms Moffatt, registered manager; and two nurses, a non-clinical operator. A tour of the premises was also undertaken.

The following records were examined during the inspection:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- information provision
- care pathway
- management and governance arrangements
- maintenance arrangements

The findings of the inspection were provided to Ms Moffett at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 28 September 2017

The most recent inspection of the establishment was an announced care inspection.

6.2 Review of areas for improvement from the last care inspection dated 28 September 2017

There were no areas for improvement made as a result of the last care inspection.

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Discussion with Ms Moffatt, confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and patients. This includes an ophthalmic surgeon, an optometrist, a nurse and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery.

It was confirmed that refractive laser eye procedures are only carried out by a trained medical practitioner acting as clinical authorised operator and laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised users for the laser is maintained and kept up to date.

It was confirmed no new staff have been recruited since the previous inspection.

A review of training records evidenced that all authorised operators have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control, fire safety and safeguarding.

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, have received laser safety awareness training.

Evidence was available that confirmed that staff who have professional registration, undertake continuing professional development (CPD) in accordance with their professional body's recommendations.

Discussion with staff and review of documentation confirmed that there are rigorous systems in place for undertaking, recording and monitoring all aspects of staff supervision, appraisal and ongoing professional development.

A review of two ophthalmic surgeons' details confirmed there was evidence of the following:

- confirmation of identity
- current General Medical Council (GMC) registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- there was evidence of ongoing annual appraisal by a trained medical appraiser
- an appointed responsible officer
- arrangements for revalidation

Evidence was available that staff who have professional registration undertake continuing professional development (CPD) in accordance with their professional body's recommendations. Discussion with Ms Moffett confirmed that authorised operators take part in appraisal on an annual basis.

Recruitment and selection

There have been no authorised operators recruited since the previous inspection. During discussion Ms Moffatt confirmed that should staff be recruited in the future robust systems and processes have been developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

Safeguarding

It was confirmed that refractive laser eye procedures are not provided to persons under the age of 18 years.

Staff were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. Staff were aware of who the nominated safeguarding lead was within the establishment.

Review of records demonstrated that all staff in the establishment had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Following the inspection it was confirmed that adult safeguarding training in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) had been undertaken by Ms Moffatt as the safeguarding lead.

Policies and procedures were in place for the safeguarding and protection of adults at risk of harm. The policy included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

Laser safety

A laser safety file is in place which contains all of the relevant information in relation to laser equipment.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires on June 2021.

Refractive eye surgical procedures are carried out by an ophthalmic surgeon in accordance with medical treatment protocols produced by the medical directors of Optimax in February 2019. Systems are in place to review the medical treatment protocols on an annual basis.

Up to date local rules are in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser equipment being used.

The establishment's LPA completed a risk assessment of the laser service and no recommendations were made.

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

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

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.

The keypad doors to the laser suite are 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 keys and passwords. Arrangements are in place for the safe custody of the laser keys when not in use.

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

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

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

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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service report for October 2018 and February 2019 were reviewed as part of the inspection process.

Management of emergencies

A review of medical emergency arrangements evidenced that an anaphylaxis kit is in place, however only one dose of 300mcgs was in place. It was recommended that the clinic has the adult dose of 500mcgs in sufficient quantities to give 2 doses. Ms Moffett confirmed by electronic mail on 22 March 2019 that these will be obtained. Oxygen and an automated external defibrillator (AED) were retained. A robust system was in place to ensure that emergency medicines and equipment do not exceed their expiry date. There was an identified individual with responsibility for checking emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance. It was confirmed the nurse and the ophthalmic surgeon have undertaken immediate life support training in the last year. It was confirmed a resuscitation drill is carried out on a three monthly basis.

There was a resuscitation policy in place.

Infection prevention and control and decontamination procedures

The treatment room was clean and clutter free. Discussion with Ms Moffett evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As discussed previously, authorised operators have up to date training in infection prevention and control.

Environment

The premises were maintained to a good standard of maintenance and décor. Cleaning schedules for the establishment were in place.

Observations made evidenced that a carbon dioxide (CO2) fire extinguisher is available which has been serviced within the last year.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to staff recruitment, induction, training, supervision and appraisal, adult safeguarding, laser safety, management of emergencies, infection prevention and control, risk management and the environment.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

Patients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes.

The establishment has a list of fees available for each laser procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the type of treatment provided and the individual requirements of the client.

During the initial consultation, clients are asked to complete a health questionnaire. There are systems in place to contact the client’s general practitioner, with their consent, for further information if necessary.

It was confirmed 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 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.

Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

Five client care records were reviewed. There is an accurate and up to date treatment record for every client which includes:

- client details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

Observations made evidenced that client records are securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Discussion with Ms Moffett, staff and review of the management of records policy confirmed that patients have the right to apply for access to their clinical records in accordance with the General Data Protection Regulations that came into effect during May 2018 and where appropriate ICO regulations and Freedom of Information legislation.

The establishment is registered with the Information Commissioners Office (ICO).

Ms Moffett confirmed that that the establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records.

The establishment also has a policy statement in place for clinical record keeping in relation to patient treatment and care which complies with GMC guidance and Good Medical Practice.

Communication

As discussed, there is written information for patients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The establishment has a policy for advertising and marketing which is in line with legislation.

Staff confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Staff confirmed that there are good working relationships and there is an open and transparent culture within the practice.

Areas of good practice

There were examples of good practice found in relation to the management of clinical records, the range and quality of audits, health promotion strategies and ensuring effective communication between clients and staff.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with Ms Moffatt and staff regarding the consultation and surgery 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.

Information is provided to the patient in verbal and written form at all consultations to allow the patient to make choices about their care and treatment and provide informed consent. Patients meet with the surgeon on a separate day in advance of surgery and are fully involved in decisions regarding their treatment. Patients’ wishes are respected and acknowledged by the establishment.

Appropriate measures are in place to maintain patient confidentiality; and observations made evidenced that care records were stored securely in locked filing cabinets and electronic records are password protected.

Patient satisfaction surveys are carried out by the establishment on an annual basis and the results of these are collated to provide a summary report which is made available to patients and other interested parties. The survey includes patient’s opinion on how their privacy and dignity was respected. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that patients were highly satisfied with the quality of treatment, information and care received.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining client confidentiality ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Staff confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Arrangements were in place to facilitate annual staff appraisal.

Ms Moffatt is the nominated individual with overall responsibility for the day to day management of the service. Mr James Rowley, the registered person, monitors the quality of services and undertakes a visit to the premises at least every six months in accordance with legislation. Reports of the unannounced monitoring visits were available for inspection.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a three yearly basis. Staff spoken with were aware of the policies and how to access them.

Discussion with Ms Moffatt demonstrated that arrangements were in place to review risk assessments. The risk register is audited three monthly.

A copy of the complaints procedure was available in the establishment. Discussion with Ms Moffatt demonstrated good awareness of complaints management.

Ms Moffatt confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

Discussion with Ms Moffatt confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. It was confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

The following audits were reviewed:

- medication
- bi- annual IPC
- bi- annual environmental
- display screen equipment (DSE)
- handwashing

Ms Moffatt outlined the process for granting practising privileges and confirmed medical practitioners meet with the medical directors prior to privileges being granted.

The ophthalmic surgeon’s details were reviewed and confirmed that there was a written agreement between him and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

There are systems in place to review practising privileges agreements every two years. A policy and procedure was in place in place which outlined the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

Ms Moffatt demonstrated a clear understanding of her role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. It was confirmed that the statement of purpose and patient’s guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

Observation of insurance documentation confirmed that current insurance policies were in place.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to governance arrangements, management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.8 Equality data

Equality data

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed. Discussion with Ms Moffett confirmed that the equality data collected was managed in line with best practice

6.9 Client and staff views

Fourteen patients submitted questionnaire responses to RQIA. All 14 indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All patients indicated that they were very satisfied or satisfied with each of these areas of their care.

Comments included in the submitted patient questionnaire responses are as follows:

- “The care I received was excellent; I was kept fully informed at all times. Wish I had come to Optimax sooner”.
- “Excellent from start to finish. Very professional staff, couldn’t do enough for you.”
- “Everything was excellent”.
- “I can’t say I have a single thing to say about Optimax. Went to another clinic first. Comparing the two Optimax just felt more professional and comfortable. I am a very shy and nervous person and the staff really put me at ease”.
- “I have had two treatments with Optimax. The care and professionalism from all staff from the consultant to aftercare has been superb. I would not hesitate to contact them again or recommend them in the future”.
- “Great clinic, very professional, helpful, would highly recommend”.
- “A lovely experience from start to finish. Would recommend Optimax to anyone. Great staff”.
- “Fabulous service, very professional”.
- “Staff are brilliant, staff and doctor really put me at ease for the whole process”.

Four staff submitted questionnaire responses to RQIA. All 4 indicated that they felt patient care was safe, effective, that patients were treated with compassion and that the service was well led. All staff indicated that they were very satisfied with each of these areas of patient care.

Comments included in the submitted staff questionnaire responses are as follows:

- “No concerns.”
- “We provide a very professional and caring service.”

7.0 Quality improvement plan

There were no areas for improvement identified during this inspection, and a quality improvement plan (QIP) is not required or included, as part of this inspection report.

14th March 2019

Mrs E Colgan
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Mrs E Colgan

Laser Protection Report

Optimax, 7 Derryvolgie Avenue, Belfast BT9 6 FL

Introduction

Further to today's inspection visit to the above premises this report summarises any laser protection aspects where improvement may be required. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Comments

The Laser safety arrangements in the clinic are of a high standard.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

Optimax, 7 Derryvolgie Avenue, Belfast BT9 6 FL

Laser Systems

Ophthalmology – Ar F Excimer laser

Manufacturer: Schwind
Model: Amaris 750
Serial No: S244
Class of Laser: Class 4

Ophthalmology – Nd YLF laser

Manufacturer: Intralase
Model: FS/F530
Serial No: 0506-40039
Class of Laser: Class 3B

Laser Protection Adviser

Sandy Moss, UCLH Laser Protection Services



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