Inspection Report

21 March 2023

Optilase Therapie

Type of service: Independent Hospital – Cosmetic laser/intense pulse light (IPL) and refractive eye laser service
Address: 36 Ann Street, Belfast, BT1 4EG
Telephone number: 0800 012 1565

Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/, The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

1.0 Service information

Organisation/Registered Provider: Optilase (UK) Limited **Responsible Individual:** Mr Phillip Mc Glade	**Registered Manager:** Mr Kyle Apsley (application submitted)
Persons in charge at the time of inspection: Ms Aoife Kelly, applicant registered manager for Optilase Belfast	
Categories of care: Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PT(L) Prescribed techniques or prescribed technology: establishments using intense light sources PT(IL) Private Doctor (PD)	
Brief description of how the service operates: Optilase Therapie is registered with the Regulation and Quality Improvement Authority (RQIA) as an Independent Hospital (IH) with the above categories of care. The cosmetic laser and IPL service treatments are offered from the ground floor of the building and a refractive laser eye surgery service from the first floor. Optilase (UK) Limited is the registered provider for Optilase Therapie and Mr Phillip McGlade is the responsible individual. Mr McGlade is also the responsible individual for three other services registered with RQIA. During the previous RQIA inspection it was highlighted that the cosmetic laser service and the refractive eye service were being managed and operated as two separate distinct services. It was agreed that RQIA would review this arrangement and arranged to meet with Mr McGlade. On 15 August 2022 RQIA met with Mr McGlade and the managers of the refractive laser eye service and the cosmetic laser service. RQIA proposed that the registration of Optilase Therapie was reviewed to facilitate the refractive laser eye service and the cosmetic laser service to be registered as two separate services. Mr McGlade and the managers accepted this proposal and stated that the cosmetic laser/IPL service would remain as Optilase Therapie and that a new registration application would be submitted in respect of the refractive laser eye service to be known as Optilase Belfast. An application to register Optilase Belfast (the refractive laser eye service) as a separate entity was received by RQIA on 16 December 2022.	

When RQIA planned to undertake this inspection the Optilase Belfast registration application was incomplete, therefore a decision was made that the inspection for the 2022/23 inspection year of Optilase Therapie would consist of two separate inspections; one for the refractive eye service and one for the cosmetic laser service.

This inspection focused solely on the refractive eye laser service and an inspection of the cosmetic laser service will be undertaken on a separate date.

Equipment available in the service:

Refractive Laser Eye Surgery Equipment

Manufacturer:	Schwind A
Laser Class:	Class 4
Model:	Armaris 500E
Serial Number:	M110

Manufacturer:	Abbott Medical Systems (AMO)
Laser Class:	Class 3B
Model:	Intralase IFS Advanced Femtosecond
Serial Number:	F50511-70169

Laser protection advisor (LPA):
Mr Alex Zarneh

Laser protection supervisor (LPS):
Ms Lisa McDowell

Clinical authorised operator:
Dr Mehul Damani (Consultant Ophthalmologist)

Medical support services:
Dr Alex George
Dr Katilal Jan
Dr Karim Tourkmani

Non clinical authorised operators:
Ms Lisa McDowell
Ms Danielle Grier

Types of treatment provided:
Refractive laser eye surgery - Lasix and Lasex

2.0 Inspection summary

This was an announced inspection undertaken on 21 March 2022 from 10.00 am to 2.15 pm. The RQIA's Laser Protection Advisor, accompanied the care inspector and reviewed the laser equipment and the laser safety arrangements pertaining to the refractive laser eye service only. Their findings are appended to this report. All recommendations made by RQIA's LPA have been addressed following the inspection.

The purpose of this inspection was to assess progress with any areas for improvement identified during and since the last inspection and to assess compliance with the legislation and minimum standards.

There was evidence of good practice concerning staff recruitment; authorised operator training; safeguarding; laser safety; the management of the patients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the clinic's adherence to best practice guidance in relation to COVID-19; the management of clinical records; clinical and organisational governance; and effective communication between patients and staff.

Additional areas of good practice identified included maintaining patient confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

No immediate concerns were identified regarding the delivery of front line patient care.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

This inspection was facilitated by Ms Kelly, applicant registered manager for Optilase Belfast; the surgery manager for Optilase Belfast; the compliance manager; and the operations manager for Optilase (UK) Limited.

The information obtained is then considered before a determination is made on whether the establishment is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the quality improvement plan (QIP).

4.0 What people told us about the service?

Posters were issued to the service by the RQIA prior to the inspection, inviting patients and staff to complete an electronic questionnaire. No completed questionnaires were submitted to RQIA prior to this inspection.

Patient feedback was further assessed by reviewing the most recent patient satisfaction surveys compiled by Optilase Therapie. The clinic actively seeks the views of patients about the quality of care, treatment and other services provided. Patient feedback regarding the service was found to be very positive in all aspects of care received and it reflected that the team deliver a very high standard of care.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since the last inspection?

The last inspection to Optilase Therapie was undertaken on 2 and 3 March 2022; no areas for improvement were identified.

5.2 Inspection outcome

5.2.1 How does the service ensure that staffing levels are safe to meet the needs of patients and that staff are appropriately trained to fulfil the duties of their role?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of one consultant ophthalmologist, four optometrists, two nurses and laser technicians/surgical assistants. It was confirmed that all staff have specialist qualifications and skills in refractive laser eye surgery patient care.

The clinic staff take part in ongoing training to update their knowledge and skills, relevant to their role. Induction programmes relevant to roles and responsibilities are required to be completed when new staff join the team. A review of documentation evidenced that a new staff member recently recruited had completed an induction programme.

A system was in place to monitor all aspects of ongoing professional development and a record was retained of all training and professional development activities. A review of the records confirmed that all staff had undertaken training in keeping with RQIA training guidance.

Discussion with Ms Kelly and review of documentation identified that arrangements were in place to check the registration status for all clinical staff on appointment and on an ongoing basis. The arrangements for monitoring the professional indemnity of all staff were also in place, as was a system for the monitoring of any practicing privileges (discussed further in section 5.2.9).

Discussion with staff confirmed there are good working relationships. Staff spoke positively regarding the clinic, felt valued as members of the team and confirmed they were supported by management.

It was determined that appropriate staffing levels were in place to meet the needs of patients and the staff were suitably trained to carry out their duties.

5.2.2 How does the service ensure that recruitment and selection procedures are safe?

The arrangements in respect of the recruitment and selection of staff were reviewed.

A recruitment and selection policy and procedure, which adhered to legislation and best practice guidance was in place.

The staff register reviewed was found to be up to date and included the names and details of all staff in keeping with legislation. It was noted that two new staff members had been appointed since the previous RQIA inspection.

A review of both new staff members' personnel files evidenced that all recruitment documentation, as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, had been sought and retained for inspection.

It was determined that recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance should staff be recruited in the future.

5.2.3 How does the service ensure that it is equipped to manage a safeguarding issue should it arise?

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies 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 were included for onward referral to the local Health and Social Care (HSC) Trust should a safeguarding issue arise.

Ms Kelly and staff informed us that treatments are not provided to persons under the age of 18 years. Discussion with staff confirmed that they were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Clinics July 2014.

Ms Kelly as the safeguarding lead for the clinic had completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards.

It was also confirmed that a copy of the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) was available for reference.

The service had appropriate arrangements in place to manage a safeguarding issue should it arise.

5.2.4 How does the service ensure that medical emergency procedures are safe?

The arrangements in respect of the management of medical emergencies were reviewed.

The British National Formulary (BNF) and the Resuscitation Council (UK) specify the emergency medicines and medical emergency equipment that must be available to safely and effectively manage a medical emergency.

There was a medical emergency policy and procedure in place and a review of this evidenced that it was comprehensive, reflected legislation and best practice guidance. Protocols were available to guide the team on how to manage recognised medical emergencies.

Robust systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date and are immediately available.

Discussions with staff confirmed they were able to describe the actions they would take, in the event of a medical emergency, and were familiar with the location of medical 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.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency should one arise.

5.2.5 How does the service ensure that it adheres to infection prevention and control and decontamination procedures?

The arrangements for IPC procedures throughout the clinic were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised. There were IPC policies and procedures in place that were in keeping with best practice guidance.

A tour of the premises was undertaken and areas reviewed were found to be clean, tidy and uncluttered. Cleaning schedules were in place and records were completed and up to date. Staff described the procedure to decontaminate the environment and equipment between patients and this was in keeping with best practice.

A review of training records confirmed that staff had received IPC training commensurate with their roles and responsibilities. Staff spoken with on inspection demonstrated good knowledge and understanding of IPC procedures.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance and according to the treatments provided. The laser suite and cosmetic laser treatment rooms provided dedicated hand washing facilities and hand sanitiser was available throughout the clinic.

The service had appropriate arrangements in place in relation to IPC and decontamination.

5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular, businesses need to consider the risks to their patients and staff.

The management of operations in response to the COVID-19 pandemic were discussed with staff who outlined the measures taken to ensure current best practice measures are in place. Appropriate arrangements were in place in relation to maintaining social distancing; implementation of enhanced IPC procedures; and the patient pathway to include COVID-19 screening prior to attending appointments.

The management of COVID-19 was in line with best practice guidance and it was determined that appropriate actions had been taken in this regard.

5.2.7 How does the service ensure that laser procedures are safe?

The arrangements in respect of the safe use of the laser equipment for the refractive laser eye service were reviewed.

The refractive laser eye service has one laser suite and various consultation/treatment rooms. It was confirmed that refractive laser eye procedures are carried out by the consultant ophthalmologist acting as the clinical authorised operator assisted by laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the lasers was maintained and kept up to date.

A review of the laser safety file found that this contained all of the relevant information in relation to the lasers. There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis and the service level agreement between the clinic and the LPA was up to date. The clinic's LPA had completed a risk assessment of the premises and any recommendations made were actioned.

Up to date local rules were in place for the refractive laser eye service that had been developed by the LPA. The local rules contained the relevant information about the laser equipment being used and all appropriate authorised operators had signed to state that they had read and understood these.

Protective eyewear was available for the non-clinical authorised operators, if required, as outlined in the local rules.

Staff told us that refractive eye surgical procedures are carried out in accordance with the identified medical treatment protocols that contain the relevant information about the treatments being provided. The medical treatment protocols had been produced by named registered medical practitioners and systems were in place to review the medical treatment protocols when due.

It was confirmed that a laser surgical register is retained and updated with the relevant information every time the laser machines are operated. The register included:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure given
- any accidents or adverse incidents

A review of the laser surgical register found this to be comprehensively completed.

The laser suite where the laser equipment is used was found to be safe and controlled to protect other persons while treatments are in progress. Discussion with staff confirmed that the 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 lasers are operated using keys and passwords that unauthorised staff do not have access to. There were arrangements in place in relation to the safe custody of the keys and passwords of all laser equipment for the refractive eye lasers.

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service reports of the laser equipment were reviewed and found to be appropriately dated.

It was determined that appropriate arrangements were in place to safely operate the laser equipment.

5.2.8 How does the service ensure patients have a planned programme of care and have sufficient information to consent to treatment?

Staff confirmed that all patients have an initial consultation with an optometrist who discusses their treatment options and the cost of the surgery.

During the initial consultation, patients are asked to complete a health questionnaire. Systems were in place to contact the patient's general practitioner (GP), with their consent, for further information if necessary.

The clinic 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.

In accordance with General Medical Council (GMC) and the Royal College of Ophthalmologists guidance, patients meet with their surgeon on a separate day in advance of surgery, to discuss their individual treatment and any concerns they may have. They also meet the surgeon again on the day of surgery to complete the consent process for surgery.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment. Patients are also provided with clear post-operative instructions along with contact details if they experience any concerns. Systems were in place to refer patients directly to the consultant ophthalmologist if necessary.

Staff informed us that systems were in place to review the patient following surgery at regular intervals if necessary.

Two patient care records reviewed were found to be well documented, contemporaneous and clearly outlined the patient journey.

It was determined that appropriate arrangements were in place to ensure patients have a planned programme of care and have sufficient information to consent to treatment.

5.2.9 Are robust arrangements in place regarding clinical and organisational governance?

Organisational Governance

Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within Optilase Therapie.

Where the entity operating the service is a corporate body or partnership or an individual owner who is not in day to day management of the service, Regulation 26 unannounced quality monitoring visits must be undertaken and documented every six months.

The clinic manager had overall responsibility for the day to day management of the establishment and is responsible for reporting to the registered provider.

Optilase Therapie is operated by Optilase (UK) Limited and Mr McGlade as the responsible individual, nominates a member of the senior management team to monitor the quality of services and undertake a visit to the premises at least every six months in accordance with legislation.

The most recent unannounced monitoring visit had been undertaken as required and the report was available for inspection. It was confirmed that all reports are sent to Mr McGlade to enable him to monitor progress with the identified actions if required.

Clinical and medical governance

As previously discussed, the team consists of a consultant ophthalmologist, four optometrists, two nurses and laser technicians/surgical assistants who have evidence of specialist qualifications and skills in refractive laser eye surgery work in the clinic.

The consultant ophthalmologist is considered to be a private doctor as they no longer hold an elective post in the HSC sector in Northern Ireland (NI) nor are they on the GP performer list in NI. Review of the consultant ophthalmologist's record confirmed evidence of the following:

- confirmation of identity
- current 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
- ongoing annual appraisal by a trained medical appraiser
- an appointed responsible officer (RO)
- arrangements for revalidation

As previously discussed the consultant ophthalmologist has completed training in accordance with RQIA's training guidance for private doctors and is aware of their responsibilities under GMC Good Medical Practice.

All medical practitioners working within the clinic must have a designated RO. An RO is an experienced senior doctor who works with the GMC to make sure doctors are reviewing their work. In accordance with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they're doing well and how they can improve. As part of the revalidation process RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work. The consultant ophthalmologist working within the clinic has a designated external RO due to their prescribed connection with another health care organisation and has revalidated accordingly.

The minimum standards specify establishments registered as IH's state that, where appropriate, the establishment should have a medical advisory committee (MAC) appointed and describes the responsibilities of the MAC. Through discussion it was established that Optilase Therapie/Optilase Belfast do not have a medical director and therefore do not have a MAC. This area will be discussed with Mr McGlade during the registration process in respect of Optilase Belfast.

Practising Privileges

The only mechanism for a clinician to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the clinic.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.

A policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place. A review of practising privileges records in respect of the PD confirmed that all required documents were in place, that the practising privileges agreement is updated every two years and the most recent agreement was signed and dated by the PD and a senior representative of Optilase Therapie.

A review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of appropriate medical governance arrangements within the organisation.

Quality assurance

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals. The results of audits are analysed and actions identified for improvement are embedded into practice. If required, an action plan is developed to address any shortfalls identified during the audit process.

A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate and made available to key staff in a timely manner.

The statement of purpose and patient's guide had been developed in respect of the refractive eye service. It was confirmed that both documents would be kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately and current insurance policies were in place. Observation of insurance documentation confirmed that current and appropriate insurance policies were in place.

Notifiable Events/Incidents

A robust system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

The surgery manager confirmed that any learning from incidents would be discussed with staff. There was a process in place for analysing incidents and events to detect potential or actual trends or weakness in a particular area in order that a prompt and effective response can be considered at the earliest opportunity.

Complaints Management

A copy of the complaints procedure was available in the clinic and was found to be in line with the relevant legislation and Department of Health (DoH) guidance on complaints handling.

The surgery manager confirmed that a copy of the complaints procedure is made available for patients and/or their representatives on request and staff demonstrated a good awareness of complaints management.

It was confirmed that one complaint had been received since the previous inspection. A review of records and discussion with the surgery manager demonstrated that the complaint was being appropriately managed in line with the clinic's complaints policy and procedures. It was confirmed that any information gathered from complaints would be used to improve the quality of services provided.

In the main the governance structures within the clinic provided a level of assurance to the senior management team. The arrangements concerning medical governance should be further strengthened in accordance with the minimum standards as outlined above.

5.2.10 Does the service have suitable arrangements in place to record 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 with the surgery manager.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

6.0 Quality Improvement Plan/Areas for Improvement

	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 Kelly and the surgery manager, as part of the inspection process and can be found in the main body of the report.

Appendix 1

Carmel McKeegan
Inspector/Quality Reviewer
The Regulation and Quality Improvement Authority
James House
2-4 Cromac Avenue
Gasworks
Belfast
BT7 2JA

7 April 2023

Laser Protection Report

Site Details:
Optilase
36-40 Ann Street
Belfast
BT1 4EG

Laser Protection Adviser appointed by site:

Dr Alex Zarneh, Chelbourne LPA

Laser/IPL Equipment:

Make	Model	Class	Serial Number	Wavelength(s)
Schwind	Amaris 500E	4	M110	193 nm (ArF)
Intralase	FS	3B	0511-70169	1053 nm (Nd:Glass)

Introduction

A Laser Protection Adviser inspection of Optilase was performed on 21 March 2023. This report summarises the main aspects of the inspection and document review where improvements may be required. The findings are based on the requirements of the Minimum Care Standards for Independent Healthcare Establishments published July 2014 by the Department of Health, Social Services and Public Safety (DHSSPSNI) and other relevant legislation, guidance notes and European Standards.

The LPA inspection included a review of:

- Protective eyewear
- Environment/signage
- Training records and user authorisation
- Laser device markings
- Maintenance Records
- Treatment protocols
- Risk assessments
- Local rules
- Appointment of duty holders (LPS/LPA)

Comments / Recommendations:

1. **Treatment Protocols:** In accordance with standard 48.3 of The Minimum Care Standards for Independent Healthcare Establishments, details should be added to the treatment protocol detailing the procedure if anything goes wrong with the treatment, and procedures in event of laser equipment failure.

2. **Laser Local Rules**

The following updates required to the local rules were discussed with the clinic on the day of inspection for remedial action:

a. An additional signature page should be added to the local rules for assisting laser staff to confirm that they have read, understood and will comply with the local rules.
b. The local rules should be updated with details of the illuminated laser warning sign in the department, as the illuminated sign pictured in the local rules is different from the one in use.

The clinic should inform RQIA when the above points have been addressed.

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Mrs Jane Brown
Laser Protection Adviser to RQIA

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Assurance, Challenge and Improvement in Health and Social Care