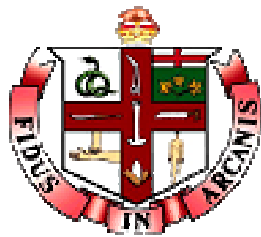


Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Laser Treatment of Benign Vascular Lesions

3rd Edition, March 2009



**THE COLLEGE OF
PHYSICIANS &
SURGEONS
OF ONTARIO**

The College of Physicians and Surgeons of Ontario

Vision Statement

Quality Professionals, Healthy System, Public Trust

Our Mandate

Build and maintain an effective system of self-governance.

The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves.

It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek.

Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes.

We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we, as caring professionals, are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation.

The public, through legislation, has empowered the profession to regulate itself through the College.

Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system.

To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

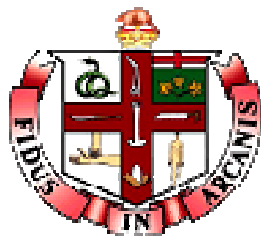
Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

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**THE COLLEGE OF
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SURGEONS
OF ONTARIO**

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Table of Contents

PREFACE

Role of the College of Physicians and Surgeons	ii
Responsibilities of the College	iii
Updating this Document	iii

VOLUME I FACILITY STANDARDS

CHAPTER 1 STAFFING.....	1
Overview.....	1
Physician Qualifications	1
Quality Advisor.....	1
Medical Director	3
<i>Responsibilities Related to Patient Care</i>	3
<i>Responsibilities Related to Staff Members</i>	4
<i>Responsibilities Related to the Facility</i>	5
Nurse.....	5
<i>Recommendations for Training</i>	6
<i>Nursing Practice</i>	7
<i>Administration of Laser Treatments</i>	7
<i>Responsibilities of RN in the Facility</i>	8
<i>Standard of Nursing Care During Laser Treatment</i>	9
<i>Summary of Essential Recommendations for Nurses</i>	10
Laser Safety Officer (LSO).....	10
CHAPTER 2 POLICIES AND PROCEDURES	13
Overview.....	13
Facility Management Policies and Procedures	13
Patient Related Policies and Procedures	14
CHAPTER 3 FACILITIES, EQUIPMENT AND SUPPLIES	15
Overview.....	15
General Design Requirements	15
Infection Control.....	16
Electrical Requirements	17
CHAPTER 4 HEALTH RECORDS	19
Overview.....	19
Health Records.....	19
CHAPTER 5 PROVIDING QUALITY CARE	21
Overview.....	21
Monitoring Quality of Care	21
Assessment of Outcome.....	22

VOLUME II CLINICAL PRACTICE PARAMETERS

CHAPTER 6 INTRODUCTION	23
Objective	23
Preamble	23
Definition	23
Rationale	24
<i>Scope</i>	24
<i>Issue</i>	26
History	27
Optimal Laser Parameters for the Treatment of Vascular Lesions	28
<i>Critical Parameters Summarized</i>	28
Rationale For Current Therapy	29
Current Technology	30
<i>Longer Pulsed Flashlamp Dye Laser</i>	30
<i>Long Pulsed KTP Laser</i>	30
<i>Long Pulsed Alexandrite</i>	30
<i>Pulsed Near Infrared (800 nm) Diode Laser</i>	30
<i>Long Pulsed Nd:YAG Laser</i>	31
Conclusions	31
CHAPTER 7 TREATMENT MANAGEMENT	33
Type One Facility Local Anesthesia Only	33
Pre-treatment Care	33
<i>Treatment Procedure</i>	34
<i>Anaesthesia</i>	34
Treatment Setting	34
Post-treatment Care	34
<u>APPENDIX I INDEPENDENT HEALTH FACILITIES ACT ONTARIO REGULATION</u>	
57/92 -AMENDED TO O. REG. 14/95	35
General	35
Quality Advisor and Advisory Committee	35
Standards	36
Records of Employees	36
Patient Records	37
Books and Accounts	39
Notices	40
Miscellaneous	41
ENDNOTES & REFERENCES	43

Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessments in Independent Health Facilities. Regulation changes were introduced in 1999. These out-of-hospital facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine, pulmonary function, and sleep studies.
- in treatment of surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynecology, dermatology, nephrology, ophthalmology, and their related anesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health and Long-Term Care, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program supports this process by developing and implementing detailed provider and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients and promoting continuous quality improvement. As well it outlines consensus recommendations pertaining to the prevention and/or treatment of life threatening conditions that may arise in the course or as a consequence of surgical interventions.

It is expected that practitioners will manage medical and surgical conditions encompassed within the general domain of their specialty certification. They shall practice according to the basic principles of medical and surgical therapeutics inherent in their surgical training and consider the application of clinical practice parameters based on current available research and professional consensus.

The primary purpose of this document is to assist physicians in developing their own quality management program and to act as a guide for assessing the quality of care provided in the facilities. When a facility is licensed by the Ministry of Health and Long-Term Care it receives the appropriate parameters and standards. To further the role of the facilitator the College works with and assists physicians in developing their own quality management and improvement programs.

Role of the College of Physicians and Surgeons

At the beginning of this process, the College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

The Task Force members' initial work, distributed in March 1991, was sent to the following organizations for their review and comments:

- all relevant specialty physicians in Ontario, national specialty societies and specialty sections of the Ontario Medical Association
- Ontario Chapter of the College of Family Physicians of Canada
- Canadian Medical Association
- American Medical Association
- Canadian Council on Health Facilities Accreditation
- College of Nurses of Ontario

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with “cookbook formulas.”
- parameters will need to be regularly updated based on appropriate research studies.
- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- monitoring service results in facilities. The College's information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America, requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Updating this Document

These parameters and standards are subject to periodic review, and amendments in the form of replacement pages may be issued from time to time. Such pages will be mailed automatically to all relevant independent health facilities. It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

**Independent Health
Facilities: Clinical Practice
Parameters and Facility
Standards:**

*Laser Treatment of Benign
Vascular Lesions*

Volume 1

Facility Standards

Chapter 1 Staffing

Overview

The laser treatment of benign vascular lesions and related services should be provided to patients by appropriately qualified personnel.

Physician Qualifications

A physician with qualifications as a Dermatologist certified by the Royal College with a current certificate of registration in good standing from the College of Physicians and Surgeons of Ontario (CPSO).

or

In the case of a physician who is trained and examined in Dermatology but who is not certified by the Royal College of Physicians and Surgeons of Canada (RCPSC), the physician's knowledge, skills and judgment will have been demonstrated to be equivalent to that of the RCPSC and approved by the Registration Committee of the College of Physicians and Surgeons of Ontario. Documentation must be available to demonstrate full compliance with any term, condition or limitations of their registration with the CPSO, including any supervision requirement or scope of practice definition.

It is important to understand that frequently the tissue is altered or destroyed by the laser without pathologic confirmation. Because of this, it is imperative that the physician has the clinical expertise in the diagnosis of cutaneous lesions with a level of proficiency that meet the minimal specific qualifications as listed below.

- It is appropriate for a laser physician to have formal training as defined previously.
- Documented training with at least two years of laser experience. The experience must use a preceptorship and proctorship setting where the trainee uses appropriate vascular lasers and maintains a logbook recording all cases treated.

or

- A 1 year fellowship with a significant component of laser experience.

Quality Advisor

As outlined in the IHF Regulations (see Appendix I) "Every licensee shall appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility."

Every Quality advisor shall:

- be physically present at the independent health facility on a regular basis, at least once every six months and be available for consultation at any time when services are provided with documentation kept of all visits
- seek advice from other health professionals where necessary to ensure that all aspects of the services provided through the independent health facility are provided in accordance with generally accepted professional standards
- consult with the quality advisory committee at least semi-annually if the independent health facility has more than six full-time staff equivalents including the quality advisor, otherwise at least annually, and to document the substance of the discussion, the actions agreed upon and the completion date for any actions agreed upon
- obtain a copy of any assessment reports from the owner/operator and approve and sign any written plan of action submitted to the College. Documentation of this activity must be maintained as part of the Quality Advisory Committee meetings

The Quality Advisor shall advise the facility licensee and document this advice concerning the following:

- qualifications, selection and ongoing education of the professional and technical staff working in the independent health facility
- whether adequate and appropriate staffing, equipment and procedures are available to ensure patient and staff safety in the independent health facility
- testing being performed on a periodic basis to ensure the accuracy and reliability of the independent health facility's equipment
- proper design of consultation requests, performance protocols (including, where appropriate, reference values for procedures), documentation and reports used at the independent health facility
- facility's policies regarding the maintenance of all appropriate clinical records, including their maintenance for the required length of time
- standards of care required for the proper management of benign vascular lesions as detailed in this document.
- supervision of technical and professional activities.
- establishing and maintaining systems for monitoring the results of the service(s) provided in the facility.
- ensuring that no procedure is carried out in the facility unless it is included in the approved list for that facility.

Every licensee shall have a written agreement with the Quality Advisor requiring and authorizing the Quality Advisor to fulfill the requirements as set out above.

Whenever the Quality Advisor has reasonable grounds to believe the conduct of the laser services and ancillary measures might jeopardize the safety of patients or the proper management and where, in the judgment of the Quality Advisor, he or she is constrained from correcting the perceived deficiencies by actions taken or not taken by the licensee, then the Quality Advisor reports those concerns in writing to the Director of Independence Health Facilities as required by the Regulations under the Independent Health Facilities Act.

It is understood that the sections above do not in any manner remove for the licensee or impose upon the Quality Advisor the obligation or responsibility for operating the facility; it being understood that the Quality Advisor's sole responsibility is to provide advice to the licensee on the matters specified.

Note: The Quality Advisor may also be the Medical Director in an Independent Health Facility for laser treatment of benign vascular lesions.

Medical Director

The requirements for a Medical Director are as follows:

- A physician must meet the requirements/physician qualifications as outlined on page 1 of this chapter.
- The Medical Director must have undergone specific educational activity in cutaneous laser medicine. This training may be fulfilled by completion of a formal fellowship in cutaneous laser medicine. Alternatively, individual study, in the form of cutaneous laser preceptorships, attendance at scientific laser meetings, and / or laser workshops must be documented (minimum 60 hours).
- The Medical Director must have at least 2 years experience in the management of benign vascular lesions, particularly capillary malformations and haemangiomas.

Note: The Medical Director can be the Quality Advisor. For this type of facility a separate QA requires the same requirements.

Responsibilities Related to Patient Care

The Medical Director is responsible for:

- ensuring that the medical status of each patient is appropriate for treatment in an Independent Health Facility (IHF) and that the degree of medical supervision is appropriate to the patient's health status.
- ensuring that all patients have appropriate primary care physician coverage and maintains communication with that physician.

- supervising the review of the clinical, social, and emotional status of all patients at regular intervals.
- seeing themselves as a patient advocate.
- providing primary dermatologic care for patients when necessary until the patient can be managed as a return or referred patient to a dermatologist or family physician.
- ensuring that the practice of the primary laser therapists- physicians and nurse practitioners acting as physician extenders, meets all the current standards.
- ensuring that all patients are either under the direct care of the Medical Director or are followed by an associate physician.
- ensuring that the technology used to treat patients within the IHF meets the current standard for the treatment of benign vascular lesions, and is maintained through a service program to deliver optimal performance.
- ensuring that a Laser Safety Program meeting the criteria defined by American National Standards Institute (ANSI) in the Z136 series of laser safety standards is actively integrated into the daily practice of patient care, which prevents any injury from laser beam or non-beam laser hazards to patients and staff.

Responsibilities Related to Staff Members

The Medical Director is responsible for:

- providing input into staff hiring.
- providing leadership and resolving difficulties that arise between the patients and staff.
- acting as a resource for patients and staff with respect to medical issues within the unit.
- relating to the, Nursing Supervisor and the Administrative Supervisor within a formal system of performance appraisals for all medical and support staff.
- ensuring that the practice applied to all patients in the IHF meets all current standards.
- supervising the training, or delegating such supervision to the management staff and/or the Quality Advisor, when these are physicians with the required expertise.
- ensuring that the proficiency of each RN acting as a physician extender in performing delegated laser treatments meets the same level as required for a physician, and provides each patient with the best standard of care.

- developing and participating in a program of CME in laser medicine, dermatology and related areas, such as the use of local anaesthetic agents, advances in technology and laser safety.
- ensuring that this CME syllabus utilizes relevant aspects (Sections 1-6) in the MOCOMP program of the RCPSC, to allow all physicians to meet the requirements, and to train and integrate nurses acting as physician extenders into the curriculum, as deemed to be appropriate.

Responsibilities Related to the Facility

The Medical Director is responsible for:

- setting the medical policies for the facility.
- playing an active role with management staff and/or Quality Advisor in decisions concerning equipment and disposable purchases, taken or not taken by the licensee.
- acting on any issues or concerns reported by the Quality Advisor or the Laser Safety Officer, or any member of staff relating to conditions within the facility affecting the quality of any aspect of patient care.
- overseeing the general operation of the facility and ensuring that adequate quality assurance measures are in place.
- a framework of ongoing assessment that monitors and records important aspects of quality assurance, including but not limited to, all medical complications or adverse effects experienced by patients.
- ensuring that all medical advances in the management of benign vascular lesions are analyzed using an evidence based approach and implemented in the facility where appropriate.
- reviewing nursing policies and procedures and ensures that they are in keeping with current legislative standards.

Nurse

All nurses (registered nurses, registered practical nurses.) (RN, RPN) need to possess the necessary skills and knowledge to use lasers for patient treatment in a laser treatment center.

It is the nurse's responsibility to ensure they have knowledge of their scope of practice and the requirements of the facility and College of Nurses of Ontario.

Training programs should consist of a laser course that is in accordance with applicable standards, the facility's policies and procedures and federal and local regulations.

Programs include hands-on practical application and written test. A passing grade on the written test is considered necessary for competency.

Continuing education should be mandatory and be made available as necessary (to include outside training sessions) to help insure adequate performance. Specific credit hours and requirements will be determined by the individual facility.

Entry Qualifications for Registered Nurses working in a cutaneous laser unit:

- Current certification of registration from the College of Nurses of Ontario
- Minimum of two (2) years nursing experience
- Current certification in Basic Cardiopulmonary Life Support (BCLS)
- Experience in cutaneous laser surgery is preferred but not mandatory
- BScN is preferred but not mandatory

Note: Only a nurse with the designations RN or Nurse Practitioner (NP) can function as a Nursing Supervisor and be trained as a Laser Safety Officer

Recommendations for Training

- Basic training program devoted to the principles of laser, their laser instrumentation, physiological effects and safety requirements. Basic training to include a minimum of 16 hours.
- Advanced laser training program where a course is of a minimum 8 hours dedicated to each specific laser type (e.g. Pulsed Dye Laser.)
- Preceptor training program with a minimum period of one week with hands on experience. The trainee needs to perform satisfactorily under the supervision of the preceptor. Written documentation of laser competency is required. All of the training shall be documented and kept on file.
- Continuing education should be mandatory and be made available with reasonable frequency to help ensure adequate performance, especially when new lasers are introduced into the clinic.

Training Program should include, but is not limited to:

- Basic laser physics: Definitions and explanations of laser terminology, electromagnetic energy, wavelength, laser systems, types of lasers, beam characteristics, and tissue responses.
- Laser energy delivery systems: The components of laser energy delivery systems, (fiber optics, and sheathed fibers, hand pieces etc.).
- Clinical Applications: In-service training should be geared towards specific lasers in the clinic as well as the specific indications for laser treatment.

- Safety: Should cover regulatory agencies or standards such as ORNAC (Operating Room Nurses Association of Canada), classification of lasers, procedure safety and equipment checks, major hazards associated with lasers in a clinic, eye protection, window coverings, warning signs and systems, electrical / water safety, fire prevention, emergency laser shutdowns, airway management, safety with gases, smoke evacuation, and laser safety publications.
- Policies and Procedures: Set of policies and procedures should be documented in the clinic to include; laser policies and standards in general, personnel training, safety, equipment operation and maintenance, responsibility of staff members and current laser resource information.

Nursing Practice

The nurse is responsible and accountable for all nursing functions for all patients assigned to their care.

The nurse must always consider the patient's risk factors. Their presenting clinical picture should be assessed prior to laser use.

The nurse should be knowledgeable about expected outcomes, resulting from administering the specific laser treatment to the patient.

It is inappropriate and inconsistent with the generally accepted standards of nursing practice for a nurse to administer a medication or perform a treatment or perform any nursing function, which is beyond the parameters for the RN or RPN education, capabilities and experience.

Administration of Laser Treatments

- The nurse may act on the physician's orders only after the patient has been assessed and evaluated by the physician.
- The nurse may only implement the selective laser treatment when the physician is physically available to the practice setting.
- Physician's orders should include: type of selective laser, the fluence of the laser beam, laser beam (spot size), wavelength, pulse width, description, location and size of the area to be treated, and utilization of any topical anaesthetic agent.
- Written policies and procedures within the office setting shall guide the nurse for each specific laser type/treatment administered.
- The written policies and procedures should include equipment and operator safety, patient education, patient assessment, emergency procedures, and monitoring guidelines.

The nurse administration of laser treatment shall be a component of a written process for continuous quality monitoring of expected patient outcomes.

The health facility should have an educational and credentialing mechanism, which includes a process for educating and verifying the nurse's education; training and clinical competency to perform specifically identified selective laser treatments.

The nurse is also required to have knowledge of laser equipment and techniques, necessary skills to perform patient assessment, knowledge of monitoring and evaluating the patient during the treatment, able to provide patient education specific to the selected laser treatment, and the ability to maintain both patient and operator safety while utilizing the laser equipment.

Responsibilities of RN in the Facility

- Participate in new employee education programs and mentoring staff
- Participate in mandatory in-services, nursing rounds, continuing education, conferences and seminars.
- Participates in continuous quality improvement activities
- Participates in all CME programs as determined by the Medical Director

Onsite training program shall include a 3-month preliminary period utilizing a preceptorship and proctorship format under the auspices of the Medical staff, where a logbook is kept as a record of all treatments performed.

At the conclusion of the 3-month period the nurse will be required to write a multiple choice exam and obtain a passing grade.

A further 9-month training period that includes increasing responsibility for patient care, attendance at the ASLMS course for laser nurses or its equivalent, ongoing logbook documentation and regular reading of all relevant articles in specified journals.

The nurse is required to become a member of ASLMS

The nurse administering the selected laser treatment is required to have the same knowledge base regarding this treatment and its effect, as with any other specialized treatment she would administer to another patient in a practice setting. This knowledge base would include, but is not limited to:

- Knowledge of anatomy and physiology specific to selected laser treatment.
- Expected effect of selected laser.
- Potential side effects of the treatment.
- Contraindications to the administration of the selected laser treatment

- Ability to recognize and anticipate potential complications of the selected laser treatment.
- Ability to recognize emergency situations and institute appropriate nursing interventions.
- Preparation and operation of the laser equipment.
- Continuing education specific to selected laser treatment and development of new laser technology.
- The nurse shall document completely the administration of the physician's order, the patient's response to the treatment, patient safety measures taken and education delivered to the patient.

Standard of Nursing Care During Laser Treatment

1. Pre-treatment Patient Care:

- a) Be aware of patient's medical history, including allergies, current medications, and skin type.
- b) Explain and answer patient and/or family members' questions on how the laser works (tissue response and post care).
- c) Ensure an **informed** consent is signed and photo documentation completed.
- d) Review that discussion of risks versus benefits has been discussed with patient. Discussion and documentation of adverse affects such as pigmentation changes and scarring noted.
- e) Ensure the patient has realistic goals and expectations of outcome.

2. Intra-treatment Patient Care:

- a) Ensure all necessary equipment and supplies are provided in room.
- b) Ensure patient comfort during procedure
- c) Ensure that safety standards are adhered to at all times.

3. Post-treatment Patient Care:

- a) Application of ointment/dressing as ordered and post-treatment skin care is reviewed with patient and/ or family.
- b) Review of discharge instructions including expected outcomes and side effects. Written instructions should be given.
- c) Answer questions; provide the patient with reassurance to decrease anxiety. Relay all patient concerns to physician.

- d) Coordinate proper scheduling of return visits or ancillary measures to meet the individual treatment program developed for each patient by the medical team
- e) Provide patient with contact numbers.

Summary of Essential Recommendations for Nurses

- Nurses should demonstrate continued competency commensurate with their responsibilities.
- Education programs taken by nurses should be specific to the laser systems used and procedures performed in the facility.
- Nurses should be required to demonstrate laser competency periodically and prior to new laser equipment accessories or safety equipment purchased.
- The laser safety program should provide and include maintenance of a safe environment during laser procedures.
- Nurses should document all laser procedures including type of laser used, safety measures implemented.
- Educational activities should be documented, dated and maintained on file in the clinic.
- Policies and procedures for laser safety should be developed; applicable standards and regulations should be reviewed periodically, revised as necessary and made available to the nurse.

Laser Safety Officer (LSO)

The LSO in this type of unit could be:

- Any member of the medical team.
- The Nursing Supervisor.

The ideal person in this type of laser unit for enforcement as the LSO is the Quality Advisor/ Medical Director. The daily responsibility of implementation and for monitoring the laser safety program is best delegated to the Nursing Supervisor as the Associate LSO.

An LSO does not assume clinical responsibility for monitoring treatment protocols or for advising physician or nurse therapists on the correct clinical use of laser equipment. There is a distinct difference between hazards related to laser safety and those related to patient treatment.

The LSO is responsible for:

- Developing with the Medical Director a laser safety program that meets the general requirements of the ANSI Z136 series of laser safety standards and specific precautions relating to the use of each vascular laser system.
- Mandating compliance among staff, visitors and patients.
- Delegating responsibility for implementation and monitoring compliance to the Associate LSO.
- Final enforcement within the framework of provincial and national regulations and international standards.

Any Laser Safety Program must be designed according to existing national and professional standards and consider that:

- Many standards and guidelines such as ANSI are not regulatory, and cannot mandate compliance and enforcement.
- The program must be comprehensive and must include beam and non-beam hazard prevention and control, audit and recording provisions, education and training of operational and support staff, and emergency fire procedures.
- That hazard controls must include administrative, engineering or technical, and procedural components.
- Successful prevention of exposure to laser hazards and injury to patients or personnel is best achieved with general measures being complemented with a mindset of “safety first” among all personnel, which is communicated to patients and visitors.
- General measures, such as controlled access to laser treatment areas, use of specific signs and eyewear must end with each laser therapist performing a procedure adopting the role of a “field LSO”, and stringently observes the precautions for that specific wavelength and laser.

Chapter 2 Policies and Procedures

Overview

Policies and procedures are established and written in accordance with the applicable legislation. Policies and procedures are reviewed at least annually and revised as necessary and are available for reference by all employees.

Facility Management Policies and Procedures

Policies and procedures are written and include, but are not limited to:

- internal disaster, including fire and evacuation
- bomb threat
- managing needlestick injuries
- workplace hazardous materials information systems (WHMIS)
- employment practices
- certification for Controlled Acts and/or specialized nursing skills
- evaluation and continuing education of staff
- staff orientation program
- standards for documenting clinical health records
- contracted services, including services to be provided, qualifications of service provided, reporting mechanisms, and compliance with relevant standards
- incident and medication error reporting
- diagnostic testing including who, when, and the quality assurance mechanism
- routine practices for infection control are described in detail in the CPSO guidelines “Infection Control in the Physician’s Office”, 2004 Edition booklet that is available for all physicians (an electronic version is available at www.cpsso.on.ca)
- quality management systems including responsibility, documentation, and outcomes
- preventive maintenance program including the training and qualifications of personnel carrying out the program
- power failure
- drug storage, preparation, and administration.

Patient Related Policies and Procedures

Policies and procedures are written and include, but are not limited to:

- patient consent
- cardiac arrest protocols
- orientation of the patient and family to the program
- managing complications
- medication review
- caring for the patient receiving hazardous drugs
- nurse initiated diagnostic tests
- medical directives

Chapter 3 Facilities, Equipment and Supplies

Overview

Issues related to laser safety and local fire codes that involve the layout of the laser dermatology unit must meet ANSI¹ standards and incorporate the requirements for an emergency evacuation plan. A general layout described here is meant to be a guideline that facilitates the important objectives for patient care in the treatment of benign vascular lesions. Some of these considerations are as follows:

- Some patients may have disfiguring lesions and in addition to the usual measures to protect privacy require “visual “privacy. These patients may remain in the reception area briefly and have only initial contact with the receptionist.
- Although patients with extensive lesions may spend up to 4 hours in the unit, there are usually no more than 2-3 patients present simultaneously- the patient scheduled for treatment in a given time slot, and the patient to be treated next. Topical agents used for treatment or nerve blocks usually do not involve any recovery care and the sporadic use of sedation or oral analgesia rarely requires that a patient remains for the appropriate observation.
- Pre-treatment measures such as the application of topical anaesthesia may be carried out in the privacy of pre-treatment or the actual treatment room. The relatively low volume of patients seen on a daily basis allows privacy and efficient care to be provided by two rooms that function as pre-treatment and treatment rooms. It is unlikely that under the present system there will ever be more than one laser (a flashlamp pulsed-dye laser) used for treatment.
- A separate medical secretary working in another area usually proximate to the work station used by the physicians and nurses is required to coordinate matters involved in the care of patients from Northern Ontario, Indian Affairs, NDMC and some referred from out-of-province. Many other patients require referral to radiology and assistance with travel and hotel accommodations that are best dealt with separately from reception.
- Most patients receive dedicated attention from the nurse who receives them in the reception area. The physician and assigned nurse directly perform all aspects of care other than photography until the patient is taken personally to the secretary who coordinates the ongoing care requirements of each individual patient.

General Design Requirements

The suggested layout affords the delivery of care in a largely private and streamlined setting that ensures the efficient use of personnel and laser equipment.

¹ ANSI Z136.3-2005 and ANSI Z136.1-2007 (American National Standard for Safe Use of Lasers in Health Care Facilities)

- The reception area should be staffed at all times. To provide comfort, function and privacy a minimum area of 15' x 20' is usually required.
- A formal office area usually 12' x 15' that allows the Medical Director to perform consults, counselling with audio-visual aids to patients and family, and perform an examination. This is separate from the laser treatment room, although there needs to be a work area in the treatment room where some of this activity may be carried out.
- Two rooms of minimum size 12' x 15' to function as treatment or pre-treatment facilities. Storage of relevant supplies, medication and patient interview areas can exist here.
- A work station that medical staff use to chart and provide various aspects of care to patients proceeding for treatment or leaving to arrange follow-up measures with the secretary. This station also houses emergency and procedural manuals with appropriate drugs, equipment and supplies.
- A properly equipped photographic lab usually 10' x 10' with lighting and camera equipment required for the specialized reproduction of vascular lesions.
- A nursing office that allows the staff to carry out their administrative and miscellaneous clinical duties such as call-backs, counselling etc. in a setting that affords maximum privacy to patients. It also provides them with a space to perform educational activities or reading required in the daily performance of their clinical duties.
- Dedicated washroom facilities are required that allow the vascular patient sufficient time to remove make-up or apply topical agents and re-apply makeup or camouflage after treatment.
- There is no need for separate locker room provisions if each patient remains segregated in a specific room during their entire stay.
- Rooms require sound-proof construction for noise abatement and to protect patient privacy.
- All patient care areas must be handicap accessible.
- The facility must comply with all applicable provincial fire and building codes.

Infection Control

Needles and other “sharps” are disposed or placed in appropriate containers. Linen soiled with blood rarely occurs in this type of unit but must be treated as contaminated. Proper care and cleansing/sterilization of specific handpieces should be integrated into the treatment protocols. Medical waste, disposal of syringes must be treated as biomedical waste and disposed of accordingly. (*Routine practices are described in detail in the*

CPSO guidelines “Infection Control in the Physician’s Office”, 2004 Edition booklet that is available for all physicians)

Electrical Requirements

The electrical specifications vary with different laser units. Plug configuration, receptacles and wiring must meet the specific manufacturers’ requirements and conform to provincial and relevant CSA standards. Most pulsed dye lasers operate optimally at 220-240 volts. Commercial voltage in Ontario may cycle around 207 volts and special voltage transformers may be required. Other equipment such as forced air coolers used for analgesia have standard electrical requirements.

Chapter 4 Health Records

Overview

Health records are maintained as required by the regulations under the Independent Health Facilities Act (Ontario Regulation 57/92 Amended to O. Reg. 14/95) (*see Appendix 1*)

Health Records

The patient's health record includes the:

- patient's name and home address, date of birth, health number
- name of any attending physician or practitioner
- name of any referring physician or practitioner
- patient history including allergy status/adverse reactions, blood group, and family/social related information.
- a record of any orders for examinations, tests, consultations, or treatments
- particulars of any examination of the patient
- reports of examinations, tests or consultations including any imaging media from examinations and any physicians' reports
- reports of treatment including any physicians' operative reports
- any orders for reports of any discharge of the patient from supervised care
- any consents
- any relevant diagnoses
- medications administered to the patient including name, dosage, time and route of administration, and signature of person administering the medication.
- Every part of the patient's health record has a reference on it identifying the patient or the record.

Note: If information in a patient's record is kept in the form of a chart, each entry in the chart is dated and initialled by the person authorizing the entry.

Chapter 5 Providing Quality Care

Overview

A Quality Advisory Committee is established as per the IHF Act. The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility. Regular meetings are held and minutes maintained (IHF Act Regulation 57/92).

To provide quality of care, there is evidence that patients' needs for laser dermatology services are assessed. The services planned and provided are consistent with those needs and assure therapeutic reliability and patient safety.

Monitoring Quality of Care

The facility establishes and maintains a system to monitor the results of the services provided.

The facility establishes a quality management program appropriate to the size, volume and types of services provided. It is recognized that quality management programs will vary depending on the facility size, scope of practice, and geographical considerations. Each facility has written goals and objectives as part of their quality management program.

Components of quality management include a review of:

- goals and objectives
- policies and procedures
- incidents, adverse drug reactions, complications
- clinical data e.g. assessing accuracy of interpretation, appropriateness of procedures.
- staff performance appraisals
- in service education using recent patient records
- patient and referring physician surveys.

All staff of the facility receive the results of such reviews.

Staff participate in the planning strategies to overcome any deficiencies to continually improve the services provided to patients.

Assessment of Outcome

Evaluation of the degree of fading by clinical assessment is performed in conjunction with pre and post treatment photographs. Ideally the assessment could be carried-out by an independent observer.

Response graded as:

- 0 - 25% fading
- 26 - 50% fading
- 51 - 75% fading
- 76 - 100% fading

A colour chart is useful in grading exposure.

Precise documentation of adverse patient outcomes:

- Temporary
 - blistering
 - excessive scabbing/crusting
 - delayed healing
 - infection
 - pigment change
 - hyperpigmentation
 - hypopigmentation or vitiligo
- Long-term or Permanent
 - Hypertrophic/keloidal scarring
 - atrophic scarring
 - pigment change
 - hyperpigmentation
 - hypopigmentation or vitiligo

It is recommended that a properly designed patient survey to assess the quality of care being provided be utilized.

**Independent Health
Facilities: Clinical Practice
Parameters and Facility
Standards:**

*Laser Treatment of Benign
Vascular Lesions*

Volume 2

Clinical Practice Parameters

Chapter 6 Introduction

Objective

These Clinical Practice Parameters and Facility Standards are intended to provide guidelines for standards of care which ensure that the management of benign vascular lesions using laser procedures and adjunctive measures is provided by qualified professionals in the safest and most effective manner. Any treatment program must take account of the natural biologic course of the specific lesion or malformation. Proper management begins with accurate diagnosis and the supervising physician must have formal training in cutaneous medicine.

Preamble

These guidelines have been developed by a panel of experts in the field of cutaneous laser medicine and surgery using an evidence and consensus based approach,. They attempt to define the principles of practice that would address the requirements of the majority of patients presenting for this therapy. The essential elements should provide guidance for the pattern of practice and not for the care of a particular individual. The ultimate judgment regarding the method and propriety of care for a particular patient must be made by a qualified physician, carefully considering the specific circumstances presented by the patient.

Clinical practice parameters identify characteristics and components required to provide the best standards in the laser treatment of benign vascular lesions. These guidelines reflect a comprehensive review of the current body of knowledge about the clinical condition and the technology being utilized. They are based on the best available clinical and scientific data as interpreted by the panel. In some instances, the evidence is particularly persuasive, and provides clear guidance from randomized prospective clinical trials. In other instances the panel relies more heavily on their collective opinion when there is no evidence, or the data is open to interpretation. Therefore, these parameters must be updated as new knowledge dictates and altered when it is appropriate.

Definition

Laser surgery for the treatment of benign vascular lesions involves the use of lesion specific lasers, which use the principle of selective photothermolysis to destroy abnormal microvasculature. A precise, controlled, intravascular coagulation destroys the vessel wall without the transfer of heat to the surrounding dermis or epidermis. The risk of scarring associated with continuous wave lasers can be reduced using best practices models.

Rationale

Scope

Prevalence

Capillary Malformations (otherwise known as Port wine stains – PWS) are most commonly treated in lighter skin types (1-3) because:

- 1) the cosmetic abnormality is more apparent in lighter skin
- 2) the results of laser treatment are easier to achieve and with better results
- 3) there is less risk of pigmentary change

Indications

The use of a particular laser system must be based on the biologic, cellular and morphologic characteristics of the lesion. Laser parameters should be matched to the type of vessel and its morphology, such as vessel diameter and wall thickness. Laser therapy is most appropriate for benign vascular lesions that respond well to treatment with selective laser systems:

- Capillary Malformations (PWS)
- Superficial Hemangiomas
- Acquired Benign Vascular Lesions
 - Telangiectasia
 - Diffuse
 - Linear
 - Matted
 - Spider Nevi
 - Angiokeratomas
 - Vascular components of rosacea (eg. fixed erythema or telangiectasia)

Note: Other conditions with a prominent vascular component such as recalcitrant warts, hypertrophic scars and keloids can respond to treatment with vascular lasers.

A photographic record is required to document the lesions prior to, during and after therapy. Photographs are technically state of the art and performed by an experienced dermatological photographer.

Certain benign vascular lesions respond poorly to selective yellow light lasers used to treat PWS. For mixed or venous malformations and deeper lesions yellow light at 585 nm. may not be absorbed adequately or achieve the required depth of treatment. New technology with longer wavelengths within the yellow (590-600 nm) and near infrared

portions of the spectrum (750-1064 nm.), are now available in the longer pulsed widths between 1 to 50 milliseconds suitable for deeper venous lesions.

- Venous Malformations
- Mixed Venous - Lymphatic Malformations
- Blue Rubber Bleb Syndrome
- Leg Veins

Other vascular lesions require investigation and treatment with other methods which may include more destructive laser treatment. They respond poorly, if at all, to selective lasers:

- Deep Hemangiomas
- Arterio-vascular Malformations
- Pyogenic Granulomas

For example, A-V malformations require angiography and special investigations. Embolization may be preferable to laser treatment although the long-pulsed Nd: YAG laser may be used for deep ablation in selected cases. Some complicated hemangiomas require treatment with steroids given by the oral or intralesional route, or interferon in rare cases. In rare cases deep excision may be required in stable lesions with non-selective destructive lasers or surgery.

The aetiology of PWS birthmarks and other vascular malformations remains unclear although basic research in this area is still ongoing. At birth, histological abnormalities usually are absent or minimal. Progressive ectasia of mature dermal vessels begin in the superficial dermis and may extend to deeper layers. The precise cause is unclear. It was previously suggested that a defect in collagen was involved, but recent studies did not detect any abnormalities in collagen or ground substance. Older theories suggested a neurogenic basis and even attributed PWS to neurologic birth trauma. Contemporary studies using electron microscopy demonstrate an absence of adrenergic nerves in the perivascular bundle. This results in a lack of neuronal modulation and loss of vasomotor tone, which lead to progressive dilatation (ectasia). However, until the exact cause is uncovered, there is little that can be done in the area of prevention.

The treatment of PWS birthmarks becomes necessary in order to avoid the morbidity from psychological trauma in patients who develop disfiguring and visible lesions. Early treatment prevents the occurrence of emotional and personality disorders which is seen in some of these patients. There is a psychosocial and economic impact associated with these disorders. Early treatment may prevent soft tissue hypertrophy and be a cost saving measure by avoiding the use of health care resources, such as extensive plastic or dental reconstruction, and psychosocial services. Many patients experience discrimination and psychological trauma. Patients should be encouraged to contact support groups such as the Sturge-Weber Foundation.

Early treatment is required for some superficial haemangiomas when they are in the “flat/pink” stage, as this may abort the development of symptomatic and disfiguring lesions. In children, lesions can be complicated by bleeding, infection, and ulceration which require more urgent treatment.

The treatment of hemangiomas should be correlated to their natural biologic course. The cellular biology of a hemangioma argues for a different clinical approach from a PWS. Juvenile hemangiomas are true tumours, not malformations like PWS. They resemble the fetoplacental trophoblast and have cell mediated protection during their growth phase from the host immune and defence system. Involution or apoptosis occurs when this immune privilege disappears for unknown reasons. Immune rejection occurs and host cells and enzymes regulating cellular immunity produce cell death within the hemangioma.

The cellular biology of hemangiomas dictates that laser treatment should trigger apoptosis or assist immune mediated regression. Laser pulses should produce focal injury in phase with the cellular kinetics. Low fluences in short pulses induce apoptosis and best achieve the response that liberates the cells required for the immune process. It is a mistake to approach treatment in the same way one treats a PWS. Pulsed dye lasers were never designed to treat even a superficial hemangioma containing clumps of tangled blood vessels. These lesions are thicker than PWS and beyond the effective depth for green or yellow light lasers. Unlike PWS where dilated small calibre vessels are dispersed within intervening stroma, hemangiomas are tortuous masses of larger vessels with little or no connective tissue or stroma. Yet superficial lesions in the early growth stage can be cleared completely by the flashlamp pulsed dye laser. However, adverse effects can occur, when lasers are used at the same levels as for treating PWS, particularly without cryogen cooling of the epidermis.

Hemangiomas (like hypertrophic scars) respond better to yellow or near infra-red pulses at low energy and short pulses. The use of aggressive laser therapy with any wavelength at higher fluences is imprudent and should be avoided.

Issue

Use of the FLASHLAMP pulsed dye laser was a major advance in cutaneous laser surgery within the decade of the 1980's. The development of this laser system illustrates the use of classic scientific principles elucidated by meticulous research in the development of medical technology. With respect to laser systems as they apply to this particular area of laser surgery, widespread confusion may still exist among primary care physicians and specialists. The important distinction between pulsed technology with short exposure times (usually less than 40 milliseconds), and continuous wave systems which utilize longer exposure times, was clouded by improper or imprecise use of terminology. A historical perspective is required to understand the basis for this confusion and the evolution of the current technology now used for the treatment of benign vascular lesions.

History

In 1983 Anderson and Parrish proposed a scientific model for the ideal vascular laser. They suggested an optimal choice of colour and pulse duration to maximize selectivity and specificity which they termed selective photothermolysis (SPTL). They postulated that the use of pulsed technology or exposure times between 300 microseconds to 5 milliseconds would prevent non-selective thermal injury.

The early work of Anderson and Parrish was confirmed by other studies that framed the scientific principles required for vessel treatment without scarring. The literature available in the decade of the eighties provided an evidence based model that suggested laser systems must meet certain specifications to produce selective vascular injury with minimal risks of scarring.

The body of literature over the past 25 years is consistent in confirming all of these scientific principles. The limitations of Argon laser or other continuous or quasi-continuous wave lasers, and their significant risk of scarring is now understood and generally accepted. Numerous studies documented a risk of hypertrophic scarring reported to reach 40% in children. Argon laser produced scarring in treated skin which was rarely, if ever, identical in colour and texture to normal skin. Early studies describing the clinical outcome with Argon laser also documented the extensive histological damage showing marked necrosis and fibrosis. Other studies showed that the injury produced by continuous wave lasers was similar - manifest as a diffuse coagulation necrosis. Carbon dioxide and Argon lasers produced non-specific vessel injury. A block of tissue was destroyed by thermal injury. Repair of such injuries resulted in fibrosis and scar tissue.

The underlying principle was that all continuous wave lasers were associated with exposure times far in excess of the safe maximum (10 ms). Flashlamp pulsed dye laser technology was researched and developed to meet all of the ideal requirements previously described.

In 1986 Tan et al suggested that pulsed yellow laser radiation offered a more selective, less traumatic, and probably superior form of treatment. In a few years, clinical and basic research confirmed that prediction and validated the original scientific model. Subsequently numerous other studies documented that it was safer for children and established its clinical effectiveness, and the risk of scarring to be less than 1%.

The Argon pumped tunable dye laser, the Copper Vapour laser and the carbon dioxide laser are no longer acceptable as a standard of care for the treatment of typical capillary malformations and benign vascular lesions with small vessel diameter. Although the long pulsed Nd:YAG laser can be used for the treatment of such benign vascular lesions, the risk of scarring is highest compared to other vascular laser systems

Optimal Laser Parameters for the Treatment of Vascular Lesions

This technology for laser treatment of benign vascular lesions has changed significantly since the first pulsed dye laser using yellow light at 585 nm. in a fixed pulse width of 0.45 milliseconds was the gold standard for therapy. Several systems from different manufacturers now allow the delivery of light in the 585-595 nm. band, in exposure times generally up to 40 milliseconds. Green light 532 nm. lasers and infra-red Nd:YAG lasers are appropriate in certain instances. These parameters refer to our current understanding and may likely change as new data becomes available.

Treatment of PWS is still based on the theory of selective photothermolysis, which requires that certain objectives be achieved for optimal results.

- A wavelength that is preferentially absorbed by the target chromophore.
- An exposure time equal to or less than the thermal relaxation time of the target tissue.
- A fluence which produces a temperature above the threshold for irreversible vessel damage
- An optimal combination of these parameters that confine heat to the target structure and minimizes non-selective injury to the surrounding skin.

Critical Parameters Summarized

Wavelength

585 and 595 nm. wave lengths are ideal for the typical PWS or lesions with capillary type microvessels. Longer wavelengths within yellow (590-600 nm) or infrared (750-1064nm) may be useful for resistant or hypertrophic PWS, venous malformations, and deeper lesions.

Pulse Width

- Pulse durations of 450 microseconds up to 3 milliseconds are used for typical PWS.
- Pulse durations up to 10 milliseconds are used for capillary telangiectasia, small calibre vessels.
- Pulsations up to 40 milliseconds are used in the treatment of large vessels.

Fluence

Fluences of 5-8 joules/cm² with a pulsed dye laser operating at 585 nm and 450 microseconds were initially used when the systems available were limited to this pulse duration. Current technology now allows for the use of higher fluences delivered in longer pulse widths with an appropriate method of epidermal cooling.

Spot size

5-10 mm spot sizes are commonly used with pulsed dye lasers at a suitable wavelength. Fluence levels need to be reduced as spot size is increased.

Epidermal Cooling

New devices use various methods of epidermal cooling (cryogen, contact, cooled air) to reduce the risk of epidermal injury. This measure is required particularly with higher fluences, larger spot sizes and longer wavelengths.

Rationale For Current Therapy

The concepts of matching pulse duration to vessel diameter, wavelength to dermal thickness, lesion architecture, and vessel characteristics are now well established in the literature. New systems are now available which allow these principles to be applied to the treatment of microvascular lesions. The wavelength should be selected on the basis of the type of vessel being treated. Small capillaries which contain relatively well oxygenated hemoglobin are best treated using the absorption band at 585-595 nm. These vessels are generally small in calibre (less than 150 microns) and relatively superficial. As vessels become more ectatic in a PWS, they become more venous in nature.

Deoxygenated hemoglobin shows a better absorption at longer wavelengths between 590-600 nm in the yellow and 700-1100 nm in the infrared portions of the spectrum. There is no advantage in using a longer wavelength to treat the typical PWS or small capillary telangiectasia. If longer wavelengths are used to treat small capillaries, the decreased absorption requires a compensatory increase in fluence. For deeper, bluer, or venous vessels better penetration is required. This may first be achieved by using a larger spot size but may eventually require the use of a longer wavelength. At any wavelength pulse duration should be selected by considering the thermal relaxation time of the target vessels.

The use of any laser system for the treatment of PWS, haemangiomas, other vascular malformations, and other benign vascular lesions (telangiectasia, venous lakes, etc.) should be based on applying the general principles outlined above. A brief review of new technology and their applications are outlined below.

Current Technology

Longer Pulsed Flashlamp Dye Laser

A laser with a 1.5 – 40 millisecond pulse width is available. Several spot sizes -5,7,10, 12 and an elliptical 3x10mm, deliver energy at a selected wavelength of 585, 590, or 595 nm. The 3x10 mm elliptical hand piece is designed especially for the treatment of larger calibre telangiectasia on the face and legs. Systems are fitted with an epidermal cooling device which increases safety when delivering fluences up to 40 joules/cm². Studies suggest moderate efficacy comparable to sclerotherapy in the treatment of some leg telangiectasia.⁴²

Longer wavelengths offer a theoretical advantage in the treatment of PWS, particularly resistant or non-responsive lesions. There are new systems that combine yellow pulsed light in a dual platform mode with infrared Nd:YAG where the first yellow light pulse is followed immediately by an infra-red pulse.

Long Pulsed KTP Laser

Laser systems operating at the 532 nm wavelength are available in various pulse configurations. There is some early evidence that using 532 nm with a 10 mm. spot size, at 10 millisecond, in low fluences may be useful to treat pediatric pink-macular PWS. There are no studies that compare use of these systems to standard treatment with pulsed yellow light, but treatments seem to be tolerated well and are associated with less purpura. These systems may be used to treat erythema, various forms of telangiectasia, but their exact role in the treatment of PWS or hemangiomas remains to be determined.

Long Pulsed Alexandrite

Current systems use pulse durations of 2-20 milliseconds. These systems employ a method to cool the epidermis and can deliver up to 100 joules/cm². These lasers are currently being used for laser-assisted hair removal and are being investigated for the treatment of vascular lesions, particularly venous or larger calibre leg telangiectasia. They may offer certain advantages for hypertrophic or nodular PWS, resistant PWS and venous malformations. Little, if any, information on their use in these conditions is presently available in the published literature.

Pulsed Near Infrared (800 nm) Diode Laser

This wavelength provides good absorption by hemoglobin and deeper penetration into the skin to a depth of several millimeters. This should allow for selective vascular injury of deeper and larger leg veins. Theoretical considerations suggest that they may be useful in the treatment of thick PWS, hemangiomas, and venous malformations.

Long Pulsed Nd:YAG Laser

The 1064 nm. wavelength produces deep penetration and may be specially suitable for large reticular veins and leg telangiectasia. New systems allow for extremely high fluences in selected combinations of spot size and pulsewidth delivered over exposure times of 1-100 milliseconds. These systems may have a role in the treatment of venous malformations; reticular veins < 5mm. in diameter, and venous lakes. They have a limited role in the treatment of PWS where the treatment of hypertrophic or resistant stains should be performed with extreme caution. The risk of scarring using this laser is the highest compared to other vascular laser treatments.

Conclusions

It is now accepted that pulsed yellow light lasers operating in the 1-10 millisecond domain is the standard of therapy for the typical capillary malformation, hemangiomas and superficial vascular lesions. For adult patients with capillary malformations relatively short pulses of 1.5-3 millisecond exposures, delivered with 7-12 mm spot sizes at an appropriate fluence is the preferred approach to treatment. In children the standard approach to use the 585 nm at submillisecond pulses is being replaced with the use of the longer 595 nm wavelength at longer exposure times with larger spot sizes. Clinical evidence suggests that these treatments produce better clearing if performed at monthly intervals instead of the traditional 2-3 months.

All the various alternative treatment protocols, including multiple pulsing, stacked pulses, dual passes, longer infrared systems, and longer pulses exceeding 10 millisecond cannot be assigned a definite role in the standard of care. Each method may be useful in selected patients with specific lesional characteristics. There are few, if any, randomized studies that compare the outcome for various methods of treatment. There is no available evidence to suggest that any of these alternative treatments should replace pulsed yellow light as the preferred standard of care for typical capillary malformations.

Chapter 7 Treatment Management

Type One Facility Local Anesthesia Only

All Type One surgical facilities using local anesthesia, local infiltration or peripheral nerve blocks have:

- adequate space and equipment to ensure safe and aseptic treatment of the patient.
- adequate space for surgery, proper lighting, flooring and smooth walls that are easy to wash.
- adequate hand-washing facilities and proper towel usage and disposal.
- openings to the outer air effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means.
- accessible and properly maintained anaesthetic material and equipment.
- proper cleaning equipment
 - *Dry dusting and sweeping cannot be utilized.*
- blood pressure monitoring equipment.
- adequate waiting area space for accompanying people.
- a business office facility which is separate from the area used for surgery.
- written treatment protocols for the management of anaphylactic reactions.
- required emergency drugs and intravenous set-up.

Pre-treatment Care

Pre-treatment care includes:

- Assessment of the vascular lesion, including history and physical examination, by a dermatologist (as previously defined).
- Discussion and documentation of exclusion criteria and risks or complications related to the use of certain drugs or a history of keloidal scarring.
- Expected outcomes, alternative treatments, the risks, and possible complications of laser surgery.
- Discussion and documentation of adverse effects including temporary changes in pigmentation and permanent scarring. Scarring should be defined and discussed with an estimate of the risk provided.
- A signed Informed Consent duly witnessed and dated

- Proper clinical photographs to complement the clinical assessment and diagnosis.

Treatment Procedure

While the flashlamp pulsed dye laser therapy is, at present, the method of choice due to efficacy and reduced risk of scarring compared to other laser systems, other systems may be used, subject to indications as previously specified.

Anaesthesia

Anaesthesia is usually not required. However it may be required for use in some children and for treating sensitive areas in adults such as periorbital and perioral regions. When anaesthesia is needed topical anaesthesia is preferred. A nerve block to the appropriate branch of sensory nerve may be used for facial lesions in some patients. Adjunctive sedation may be given orally (intravenous administration is appropriate only in a Type II facility as defined by the CPSO)

These agents should be used in the facility that meets the minimal requirements for a Type I Facility as defined by the CPSO.

Treatment Setting

The treatment facility meets standards for laser safety in health care facilities as required by the Canadian Standards Association and Health and Welfare Guidelines for Laser Services in Health Facilities (1991) and complies with specific regulations as per the Independent Health Facilities Act. (see Appendix I- IHFA Ontario Regulations 57/92- Amended to O. Reg 14/95)

Post-treatment Care

Patients are provided with verbal and written instructions relating to skin care of the treated area. The post-treatment instruction sheet should also include:

- Advice for dealing with minor side effects and clear instructions on how to recognize more serious side effects that require calling the treating or covering physician.
- Reminders about the timing of follow-up or repeat treatments and the designated telephone numbers for routine matters and emergency needs.
- A computer generated call back program is recommended, where a nurse therapist calls the patient 3 days after treatment, to assess morale, specific concerns, and to provide any relevant advice or instructions.

Appendix I Independent Health Facilities Act - Ontario Regulation 57/92 -Amended to O. Reg. 14/95

General

Quality Advisor and Advisory Committee

- 1** (1) Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.
- (2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.
- (3) The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.
- (4) It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.
- (5) In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.
- (6) A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O Reg 57/92, s.1.
- 2** (1) Every licensee shall appoint an advisory committee to advise the quality advisor.
- (2) The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.
- (3) The quality advisor shall be the chair of the advisory committee.
- (4) Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O Reg. 57/92, s.2.
- 3** (1) Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall inform the Director in writing forthwith.

(3) Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3

Standards

- 4** (1) Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.
- (2) Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.
- (3) If the quality advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.
- 5** Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.
- 6** (1) Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a laboratory for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.
- (2) The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

- 7** (1) Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee's qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.
- (2) Every licensee shall retain an employee's employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.
- 8** (1) Every licensee of an independent health facility shall maintain a record of qualifications and work history for:
- (a) each person the licensee contracts with to manage the facility; and

(b)each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.

(2)The record shall include a record of any registration with or licensing by the governing body of a health profession.

(3)Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.

9 (1)Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.

(2)A declaration of professional standing must include the following information:

1. The physician's name
2. The physician's registration number with the College of Physicians and Surgeons of Ontario
3. The physician's number registered with the Health Insurance Division of the Ministry of Health.
4. The class of the physician's licence issued under Part III of the *Health Disciplines Act* and any terms and conditions attached to it.
5. The physician's specialty.

(3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).

(4)Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.

(5)Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O. Reg. 57/92, s.9.

Patient Records

10 (1)Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.

(2)A patient's health record must include:

- (a) the patient's name and home address
- (b) the patient's date of birth
- (c) the patient's health number
- (d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (e) the name of any referring physician or practitioner and his or her number as

registered with the Health Insurance Division of the Ministry of Health

- (f) a history of the patient
- (g) a written record of any orders for examinations, tests, consultations or treatments
- (h) particulars of any examination of the patient
- (i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports
- (j) any reports of treatment including any physicians' operative reports
- (k) any orders for and reports of any discharge of the patient from supervised care
- (l) any consents; and
- (m) any diagnoses of the patient.

(3) A patient's health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received only such services.

(4) Every licensee shall ensure that every part of a patient's record has a reference on it identifying the patient or the record.

(5) If information in a patient's record is kept in the form of a chart, each entry in the chart must be dated and it must be initialled by the person authorizing the entry. O. Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

- (a) the patient's last visit; or
- (b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

- (a) the patient's last visit; or
- (b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O. Reg. 57/92, s.11.

12 (1) No licensee shall allow any person to examine a patient's health record or give any person any information, copy or thing from a patient's health record except as required by any Act or regulation made under an Act or as required or allowed by this section. O. Reg. 57/92, s.12(1).

(2) Every licensee shall provide copies from a patient's health record to any of the following persons on request:

1. The patient.
2. A personal representative who is authorized by the patient to obtain copies from the record.

3. If the patient is dead, the patient's legal representative
4. If the patient is incapable of giving an authorization described in paragraph 2,
 - i. a lawfully authorized substitute decision maker
 - ii. a person to whom the patient is married
 - iii. a person of the opposite or same sex, with whom the patient is living in a conjugal relationship outside marriage if the patient and the person:
 - A. Have cohabited for at least one year
 - B. Are together the parents of a child, or
 - C. Have together entered into a cohabitation agreement under section 53 of the *Family Law Act*
 - iv. the patient's child if the child is sixteen years old or older
 - v. the patient's parent. O. Reg. 57/92, s. 12(2); O. Reg. 14/95, s.1

(3)A licensee may provide copies from a patient's health record to any person authorized by a person to whom the licensee is required to provide copies under subsection(2).

(4)A licensee may, for the purpose of providing health care, or assisting in the provision of health care, to a patient, allow a health professional to examine the patient's health record or give a health professional any information, copy or thing from the health record.

(5)A licensee may provide to the person described in subsection (6) information or copies from a patient health record if anything which could identify the patient is removed from the information or copies.

(6)Subsection (5) applies to:

1. Any person if the information or copies are to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.
2. The Ontario Cancer Treatment and Research Foundation.

(7)A licensee may charge a reasonable fee for any information, copies or thing provided under this section. O. Reg. 57/92, s.12(3-7).

Books and Accounts

12.1(1)This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled "Schedule of Facility Fees".

(2) Every licensee shall keep the following records in relation to the independent health facility:

1. Current financial records showing:
 - i. the amounts paid by the Minister to the licensee under section 24 of the Act.
 - ii. the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee's licence, and
 - iii. the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.
2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee's licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.
3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph
4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

(3) Every licensee shall ensure that the records required under section (2)

- (a) are kept in the independent health facility; and
- (b) are kept in a bound or looseleaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4) Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5) Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act*. O. Reg. 283/94, s.1, *part*.

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/ 94, s.1, *part 3*

Notices

13. Every licensee of an independent health facility,

- (a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and
- (b) who ceases operate the facility shall give the Director, within seven days after the

date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14. Every licensee of an independent health facility shall give the Director:

- (a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and
- (b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/ 92, s.14.

Miscellaneous

15. It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.

16 (1) The fee for a licence is \$100.

(2) The fee for the transfer of a licence is \$100.

(3) The fee for the renewal of a licence is \$100. O. Reg. 57/92, s.16.

17. The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

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