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The Beneficial Effects Of Fractional CO_2 Laser Treatment On Perineal Changes During Puerperium And Breast Feeding Period

A Dissertation Submitted to the Institute of Laser for Postgraduate Studies, University of Baghdad in Partial Fulfillment of the Requirements for the Degree of Higher Diploma in Laser in Medicine / Gynaecology

.

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2022 AD **1443 AH**

بِسْمِ اللَّهِ الرَّحْمَٰنِ الرَّحِيمِ

﴿اللَّهُ نُورُ السَّمَاوَاتِ وَالْأَرْضِ ۚ مَثَلُ نُورِهِ كَمِشْكَاةٍ فِيهَا مِصْبَاحٌ ۖ الْمِصْبَاحُ

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Dedicated to

My wonderful

family

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Abstract

Background: The postpartum period or puerperium, normally continues for 6 weeks and is the phase of adjustment post-delivery when the physiological and anatomic variations of pregnancy are restored to normal, pre-pregnant state.

The Objectives: The aim of the present study was to evaluate the efficacy and of fractional CO_2 laser in the treatment of the postpartum perineal changes throughout the breast feeding and puerperium period.

Materials and Methods : The study was carried out over five months from September 2021 to January 2022 in private gynaecology clinic in Tikrit city, Iraq. It is a case-control study where in 25 women were involved. Fifteen women were enrolled in the treatment group and 10 women were enrolled in the control group for studying postpartum perineal changes during puerperium and breast feeding. In the treatment group, the individuals were treated with fractional CO_2 laser. While, the control group was treated with lubricant (without laser treatment). Various symptoms such as dyspareunia, perineal pain, dryness, pruritus, burning and pH were evaluated on the visual analog scale score. The enrolled patients were given treatment in the three sessions. Every treatment session followed by a 4 weeks gap. Fractional CO_2 laser parameters were 40 watt power, 1 ms pulse duration, and 1 mm distance for vaginal treatment. While, for vulvar treatment, parameter were 25 watt power, 0.5 ms pulse duration and 0.5 mm distance.

Results: The dyspareunia (6.60-2.30) (p= 0.001), perineal pain (5.93-2.10) (p-003), dryness (4.13-1.60) (p = 0.000), pruritus (4.26-1.00) (p = 0.000), burning (4.53-1.33) (p = 0.000) and pH (7.20-5.86) (p = 0.000) were found to be improved significantly in the laser treatment group as compared to the control group. Normal vaginal delivery (NVD) episiotomy showed around 62.5% and

37.5% correlation with less than 3 months and more than 3 months delivery time, respectively. While, breast feeding showed around 23.07% and 76. 92% correlation with less than 3 months and more than 3 months delivery time respectively.

Conclusion: this study has shown the fractional CO_2 laser treatment is an easy to use , effective and minimally invasive in postpartum perineal changes .

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LIST OF ABBREVIATIONS

Abbreviations	Item
A	After
ANSI	American National standard Institute
ATP	Adenosine triphosphate
B	Before
°C	Celsius
C/S	Cesarean section
CDRH	Center for devices and Radiological Health
Cm	Centimeter
CO_2	Carbon dioxide
EH&S	Environmental, health and safety
FDA	U.S Food and drug administration
GUE	General urine examination
Hz	Hertz
IR	Infrared
ISSVD	International Society for the Study of Vulvovaginal diseases
J	Joule
LLLT	Low level laser therapy
LSO	Laser safety officer
M	Meter

µm	Micrometer
µs	Microsecond
MASER	Microwave Amplification by Stimulated Emission of Radiation
min	Minute
mm	Millimeter
MPE	Maximum permissible exposure
MTZ	Microscopic Thermal zone
N	Number
nm	Nanometer
NVD	Normal vaginal delivery
PDT	Photo dynamic therapy
PPE	Personal protective Equipment
PPS	Pulse per second
P-value	Probability value
RCOG	Royal College of Obstetricians and Gynaecologists
SD	Standard deviation
Sec	Second
SOP	Standard operating procedure
UV	Ultraviolet
PV	Provoked vastibulodynia
VV	Vulvular vestibulitis

W	Watt
λ	Lambda

Chapter One

Introduction

And

Basic Concepts

1. INTRODUCTION

The postpartum period or puerperium, normally continues for 6 weeks and is the phase of adjustment post -delivery when the physiologic and anatomic variations of pregnancy are restored to normal, pre-pregnant state. Childbirth and pregnancy, in spite of being physiological incident, constitute a very delicate time in the life of the woman's, as they disclose to crucial valve-personal injuries. The pain in the pelvis following every delivery, whether surgical (caesarean section) or spontaneous do not ends in the afterbirth first day but, relying on the research, becomes continuing in a very varied cases percentage. This pain, even may last for months, creating remarkable issues for women who frequently have to go through lengthy procedures prior to arrive at an accurate diagnosis and accordingly a selected therapy.

Actually, various clinical research has indicated that pregnancy and the childbirth characterizes a highly exposed temporal window to sexual dysfunction of female, of which the commonest is the vulvular pain. The vaginal vestibule (80% cases) as defined by the ISSVD (International Society for the Study of Vulvovaginal diseases) says that the site where the postpartum pain and burning is concentrated; in such cases we talk about VV (vulvular vestibulitis), and VP (provoked vastibulodynia).

Postpartum pain takes place under several manifestations, but the more dominant cannotations include chiefly the introital dyspareunia (even occasionally the deep area), the chronic pelvic pain and the vulvular pain. Prevalence research shows that postpartum pain is one of the worst outcomes in the first day post child birth and that it can be observed in 88% women who have currently given birth.[1,2]

1.1 Postpartum period

The period of post partum is designated as the “labor’s fourth stage”, and is having 3 different but continuous phases. The acute or initial period includes the first postpartum of 6-12 hours. This is the rapid change time having a potential for instant crises like eclampsia, amniotic fluid embolism, uterine inversion and postpartum hemorrhage.

The second phase is the period of subacute post partum which continues for 2-6 weeks. Throughout this phase, the patient body is going through major variations in terms of emotional status, metabolism, genitourinary recovery and hemodynamics. Nevertheless, the variations are less quick than in the phase of acute postpartum and the patient is normally efficient of self recognizing problems. These can run the gamut via the usual troubles regarding perineal discomfort to serious postpartum depression or peripartum cardiomyopathy.

The third phase is the detained postpartum phase, which may last for about 6 months .[3] Variations throughout this period are gradual extremely, and pathology is scarce. This is the restoration time of connective tissue and muscle tone to the prepregnant condition. Even though, a variation is subtle throughout this phase.

1.2 Puerperium

Puerperium is the time, following delivery throughout which pregnancy influenced maternal physiological and anatomical changes restoring to the non-pregnant condition. Its duration is inexact understandably, but is recognized to scale among 4 to 6 weeks. Nevertheless, it generally involve 6 successive weeks of delivery. [4]

The puerperium word is acquired from puer-Latin word meaning child and parus meaning bringing forth. Basically, these variations involve the maternal organs return to about pre-pregnant functions and sizes, endocrine variations Start immediately following of loss of the placenta, and the lactation onset.

There are specific risks connected with the puerperal period, specifically infection, psychosis and hemorrhage, which speaks to the demand for advanced healthcare, help and education, even when gestation has concluded with the healthy baby delivery. [4]

The period of post-partum is connected with superstition and tradition as the new infant health is very critical to the any family survival. Puerperium establishes as early as the placenta is ejaculated and continues for 6 weeks roughly when the uterus almost return to the non pregnant size.

The puerperium may be divided into:

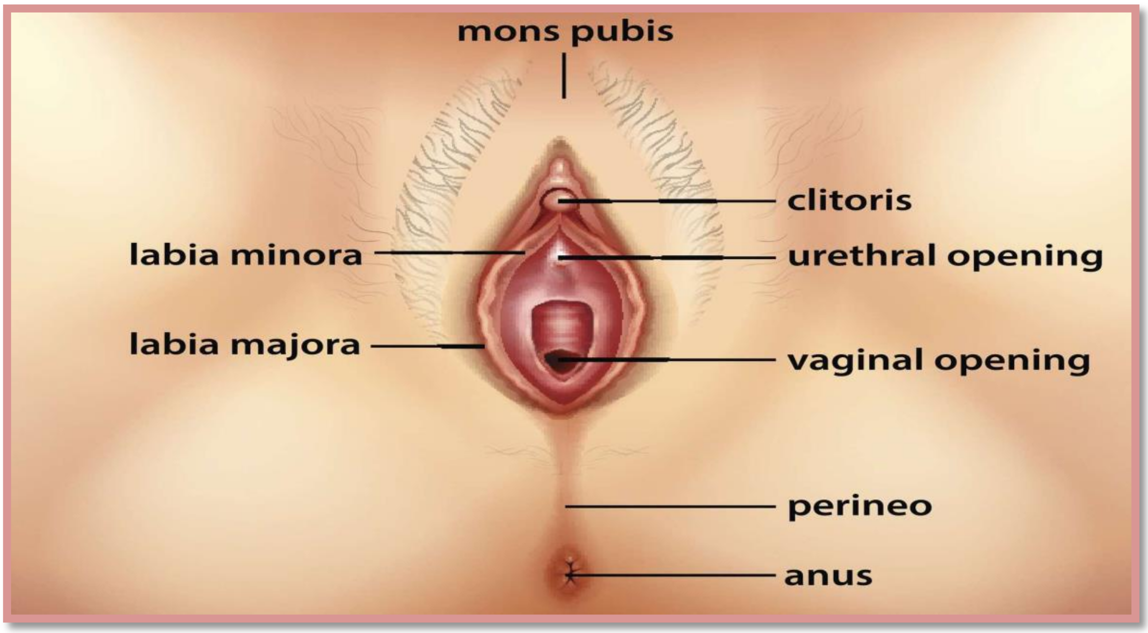
a) Immediate- in 24 hrs
b) Early- up till 7 days
c) Remote- up till 6 weeks

1.3 Anatomy of female genitalia

In this section, the anatomy of female genitalia described briefly.

A- Anatomy of female external genitalia

The perineum may be objectified as a space of diamond shape forming pelvis outlet Figure (1.1). It is restricted within the below given boundaries: 1) anterolaterally, by the pubic symphysis inferior margin and the ischiopubic rami borders; 2) posterolaterally, by the sacrotuberous ligaments (enveloped by the muscles of gluteus maximus) and coccyx, and; 3) laterally *via* the 2 ischial tuberisities. It may be bifurcated into 2 triangles, anteriorly the urogenital triangle and posteriorly the anal triangle.[2, 3]



Figure(1.1) Female external genitalia .[4]

The urogenital triangle involves the outer genital organs and the opening of the urethra, generally recognized as the vulva.

The vulva consists of the below given structures:

Mons pubis: Triangular distinction overspreading the symphysis pubis, comprising of connective and adipose tissue.

Labia majora: occupied on vaginal opening either side, the labia majora are 2 skin folds of fibro-adipose expanding from the mons pubis in a posterior orientation, unify in the at the posterior fourchette in the midline. They involve the round ligaments terminal part and the obliterated processes vaginalis, also attributed as the nuck canal. They are roughly 1-2 cm thick and 0.7-5 cm in width. Laterally the labia majora are shielded by hair and are rich in eccrine, apocrine and sebaceous glands. The labia majors subcutaneous tissue is same in constitution to the wall of the abdomen.[4]

Labia minora: immediately located median to the labia majora, there are two folds labia minora of hairless skin overspreading a fibroelastic stroma affluent in neurovascular construct, few smooth muscles, some sweat glands and sebaceous follicles. The folds merge anteriorly to form the clitoris hood, while posteriorly, they adhere on the inferior clitoris surface to form the frenulum. The area among the posterior labia minora creates the vagina vestibule.

Bartholin glands: placed on the posterolateral vestibule aspect, these glands approximately measure 0.5 to 1 cm and normally cannot be palpated. They excrete a secretion of colorless mucous among the labia minora and the hymen, chiefly to continue sufficient lubrication.

Clitoris: normally this erectile organ is 5 mm in length in prepubertal childs, and in length 1-2 cm in mature females. It is a female penis counterpart, having a same structure involving a glans, 2 corpora cavrnosa and 2 crura. It is situated above the exterior urethral opening and is hold up by a suspensary ligament which lies underneath the commissure of anterior labia.[3]

Vestibule: the vestibule is anteriorly bounded by the clitoris and posteriorly by the urethral opening, the Bartholin glands ducts, the vagina, the fourchette, and the Skene's (paraurethral) glands ducts.

Vaginal orifice: posterior to vestibule the introitus lies and is neighboured by the hymen, an insufficient membrane of mucous which matures throughout puberty under the estrogen influence, consequently becoming more elastic and fuller.

External urethral meatus: anterior promptly to the orifice of vagina, the orifice of urethra is placed around 2-3 cm posterior to clitoris. The ducts of Skene's (paraurethral) glands open on posterior facet.

Vestibular bulbs: these erectile bodies are majorly vascular structures reclining under the muscles of bulbocavernous and the vestibule lining bilaterally. They are 0.5-1 cm thick, 1-2 cm wide and 3-4 cm long in mature females. They are enveloped by the muscles of ischiocavernosus and are near to the ischiopubic rami.

Muscles: 3 muscles contain the vulva, called the superficial transverse perineal muscles, bulbocavernosus and ischiocavernosus.

B- Anatomy of perineum

The perineum is a region with diamond shape consisting of soft tissue, which seals the outlet of pelvic cavity. These regions boundaries are the ischiopubicrami and pubic arch and ischial tuberosities laterally, posterior coccyx and posterolateral sacrotuberous ligament Figure(1.2).The perineum is subdivided in to anterior triangle of urogenital and posterior anal triangle. Both the fascia and muscles of both areas centrally emerge, forming an axially located fibromuscular mass called as the perineal body.[3]

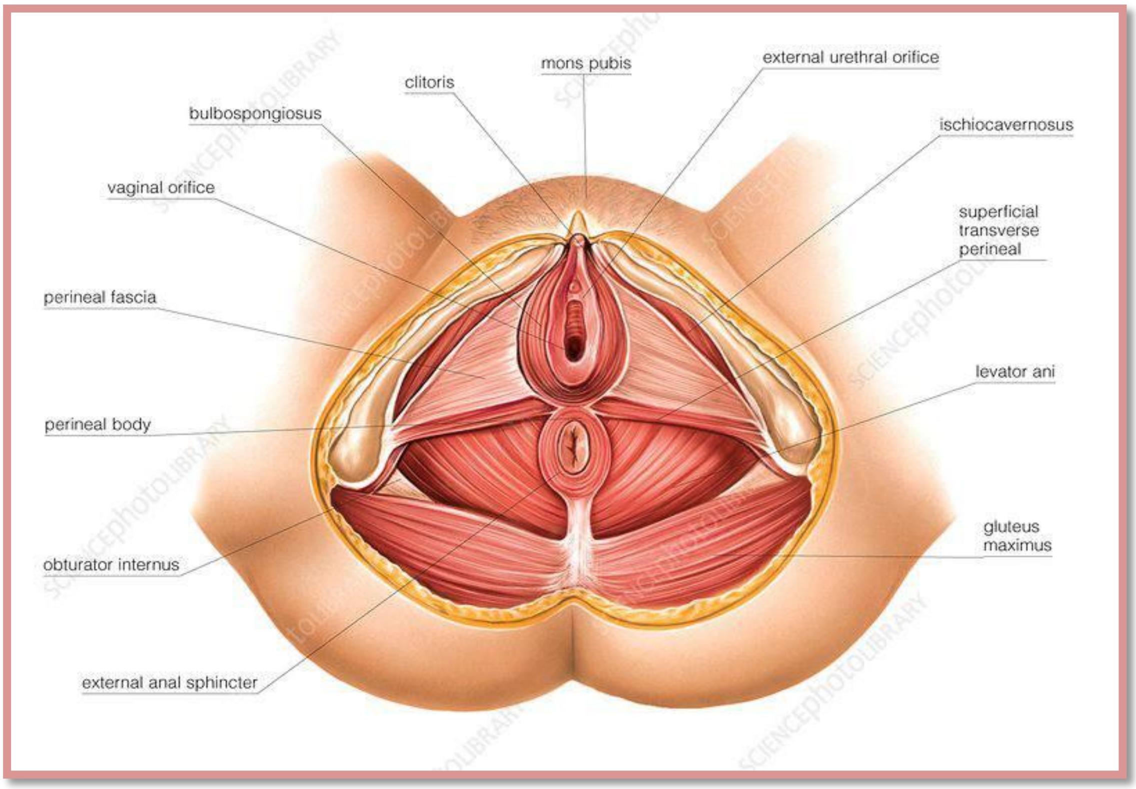


Figure (1.2) Perineum diagram [3]

1.4 Perineum changes during labor

A common type of postpartum pain (along with the uterine contractions and accompanies breast engorgement) is a perineum pain. The perineum is area between the muscle length and tissue separating the vaginal opening of woman from anus. This is purpose to stretch. Throughout the labor, baby heads exerted intense pressure for pushing up against the vaginal opening. Due to this, the perineum may get expanded and/or tear. In certain conditions, episiotomy is performed to deliver the child. Episiotomy is a procedure that involves creating a surgical incision in the perineal tissue to widen the vaginal opening.[2,3]

1.5 Role of the hormones in the postpartum period

Many hormones play an important role in the arousal and breast feeding. These hormones are estrogen, prolactin, and oxytocin. Low estrogen levels resulting from the post-partum period and breastfeeding may result in vaginal dryness, tightness, or tenderness. The breastfeeding may also cause vaginal dryness because of hormonal shift in the post pregnancy. The symptoms like pain (regardless you have sex or not), itching, soreness, burning and dryness sensation may be seen after pregnancy during breastfeeding. These symptoms may occur externally (on the vulva) and internally (in the vagina).[1,2]

1.6 Types of Lubricants

There are different types of lubricants to :

- Water-based lubricant **:** are the most common. They come in two varieties: with glycerin, which has a slightly sweet taste, or without glycerin.
- Silicone-based lubricant **:** This type of lubricant may last longer, but it’s harder to wash off, make them a good for vaginal dryness and pain during sex.
- Oil-based lubricants**:** There are two types of oil-based lubricants: natural (think coconut oil or butter) and synthetic (think mineral oil or Vaseline).
- Natural lubricant**:** They also use organic ingredients, which are better for the environment and safe of vagina.[2]

1.7 Role of CO_2 laser in the perineal Region

The carbon dioxide laser is a very effective tool for treating any conditions of this area. It offers a "no touch" method of treatment for conditions of the perineal region. There is less bleeding, less pain, less swelling with the use of the carbon dioxide laser. [5] Structural variations in the skin of different body sites can contribute to differences in barrier function, which may contribute to differences in skin sensitivity. Also, potential triggering factors for skin sensitivity would be expected to vary by body site. For example, the face is exposed to all ambient environmental conditions in the course of daily life, and to several products (e.g., cosmetics for women) and practices that may lead to adverse sensations associated with sensitive skin. In contrast, the skin of the genital area is more protected from ambient environmental conditions, but this anatomic site is almost constantly semi-occluded throughout the day.

The vulvar epithelium exhibits marked regional differences in structure [6] The cutaneous epithelium of the mons pubis and labia majora exhibit a keratinized, stratified, squamous structure similar to skin at other sites. However, skin in this area is more hydrated than skin at other body sites and, therefore, more permeable to some materials and more susceptible to friction effects . [7] Moving toward the labia minora, the degree of keratinization, and thickness of the epidermis decreases. The inner third of the labia minora is non-keratinized mucosal tissue .[8] The non-keratinized vulvar skin of the labia minora exhibits increased permeability related to the absence of keratin and a loosely packed, less structured lipid barrier.[6,7,9] In addition, the thinner, inner epithelium represents a shorter distance for penetration of substances .[6]

Vaginal atrophy is the most common indication in the treatment of vaginal rejuvenation. Its main manifestation is vaginal relaxation syndrome, which may be the early symptom of female pelvic floor dysfunction. It is a common gynecological physiological change in women. Its clinical manifestations include vaginal wall relaxation, decreased elasticity, poor dryness sensitivity, internal environment disorder, and so on. Vaginal exhaust, often combined with urinary incontinence, pelvic organ prolapse, chronic pelvic discomfort and other symptoms, seriously affecting patients' health and quality of sexual life. At present, there are many treatments for vaginal relaxation, vaginal constriction and laser therapy are the most effective and widely accepted treatments. Laser therapy with small trauma and short repair time has attracted much attention.

CO_2 fractional laser (AcuPulse) stimulates fibroblasts to synthesize and secrete collagen fibers, elastic fibers, reticular fibers and organic matrix through dot exfoliation and thermal stimulation, thus thickening the vaginal wall and achieving long-term vaginal tightening effect. The heat effect of CO_2 laser can stimulate vasodilation, increase blood flow, increase cell oxidation and nutrients, increase mitochondrial ATP release, activate cell function, enhance vaginal mucosal secretion, normalize vaginal internal environment and bacterial flora, and then reduce the probability of gynecological infection. [8]

It has been reported that the CO_2 lattice laser can stimulate collagen synthesis and rearrangement. It has also been reported that CO_2 lattice laser may have important clinical significance in improving the morphology and function of vaginal epithelial cells.[7]

With this background, the present study was designed to evaluate the effect of laser treatment on the perineal tissue after delivery. The post partum perineal changes throughout the breast feeding and puerperium as per given questionnaire were evaluated.

1.8 Laser physics

Laser physics is a branch of physics where the fundamental and the applied aspects of laser science are studied. Basically, laser physics is a part of optics which deals with the laser theory. Laser stands for light "amplification by stimulated emission of radiation". A simple laser is consisting of a medium of laser (which ascertains the system's wavelength) surrounded among 2 parallel mirrors, one of them is partly transmitting and partly reflecting. The medium is exhilarated by an electronic source up till the excited state atoms number is higher than the ground state number (inversion of population). When the medium of laser is switched on, it starts to release spontaneously the excited photons in all directions. Nevertheless, these photons small subsets travels between the laser systems centerline in a united fashion betwixt the mirrors.

Then these photons are reflected by mirrors and the stimulated emission process is amplified. The partly transmitting mirror, then permits an influential, photon cohesive beam to be rescued as laser light. Figure (1.3) demonstrates a ground state laser medium followed by atom excitation to higher levels of energy.

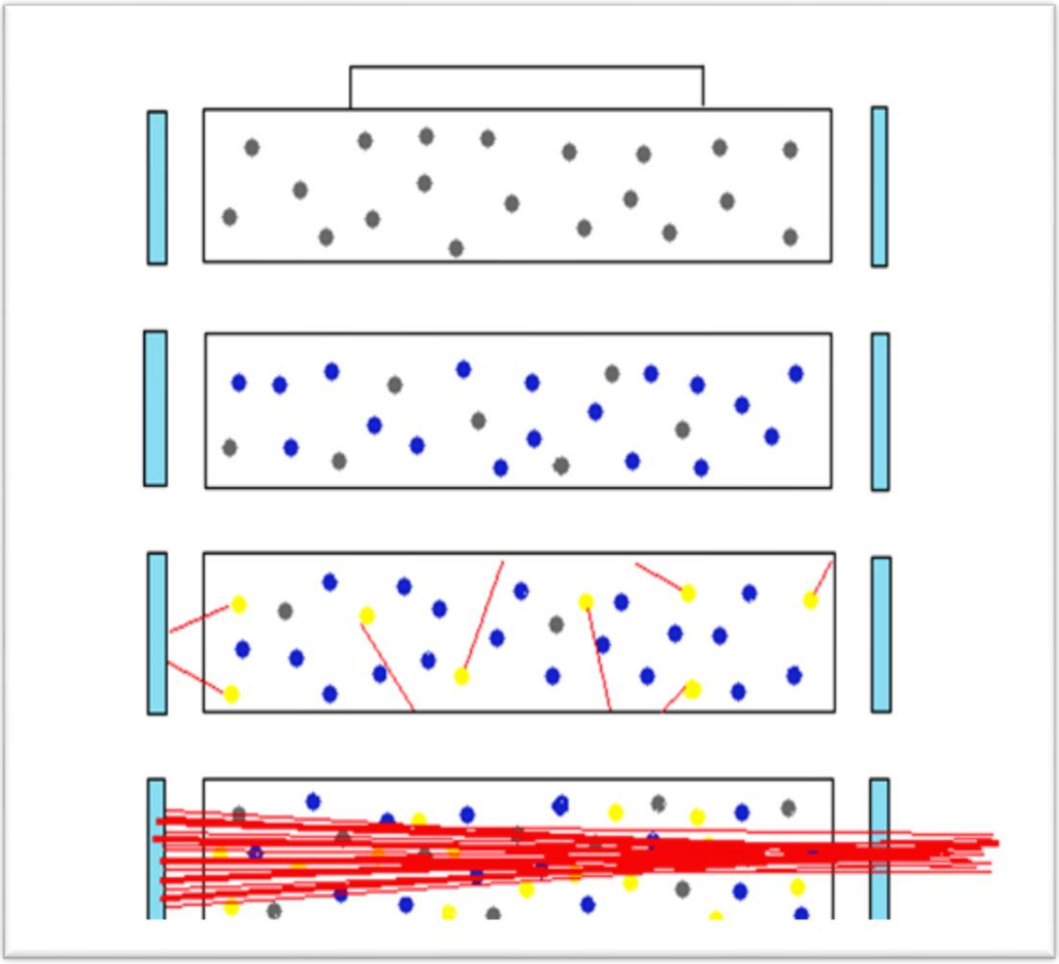


Figure (1.3) Demonstrates a ground state laser medium followed by atom excitation higher levels of energy. [9]

1.9 Laser history

The laser term indicates the critical role of the procedure of stimulated emission for the amplifiers and quantum generators of coherent light. Henceforth, the laser development history must be tracked as long as 1917 when Albert Einstein indicated that the stimulated emission procedure should exist . [10] This was the preliminary test towards the laser. In 1953, a mob at University of Columbia leaded by Charles H. Townes employed a microwave instrument which amplifies radiation by the process of stimulated emission, it was called Microwave Amplification by Stimulated Emission of Radiation (MASER) . [11]

Over the succeeding year's Schawlow and Townes created critical contributions which aid to expand these ideas via the microwave to the region of optical wavelength. These attempts concluded in July 1960, Wjen T.H. Maiman declared the pulse coherent red light generation by employing a ruby crystal the first laser. After that use of laser was begun by industry and engineering sciences. An exemplar of its usage in computer science like information security, hence making it feasible to secure information transmission via patient to store data in the health center or via one health center to another. Also in the medical engineering and electronic engineering field which made it feasible to evolve the laser device to be utilized in medical applications and medicines.[10,11]

There are no worldwide laser device or laser light parameters set for successful treatment of all medical deformities same like there is no global drug for all disorders in humans. Consequently, higher laser acceptance for medicinal treatment will arrive with better acknowledgement of proper selection of value of laser light energy required to carry out a specified treatment, when this understanding is recognized via careful scientific works in the research laboratory a laser device with safety package and system of delivery operated throughout proper conditions range will increase greatly the laser acceptance for clinical applications .[12]

1.10 Basic Laser Components

So as to handle various laser devices, 3 principal conditions should be satisfied

1-Active medium: This is ions, molecules and atoms collection, which may be plasma, gas, liquid or solid state. The lashing medium composition dictates the output wavelength and specific laser's name .[12]

2-Source of pumping: The energy source to pump the medium of laser. When the medium laser in the optical cavity is pumped, there occurred a generation of laser beam which escapes the cavity via the partly transmitive mirror via which the inversion of the population is produced in the active medium.

3-Optical resonator: This is composed of 2 mirrors. The medium of laser is located in the optical cavity and its arbor is made to coexist with the mirrors common axis. One mirror is normally completely reflective for the operation wavelength of the laser and the other is partly transmitive, via which few photon state selections and the other state's suppression may be realized [11] as indicated in Figure (1.4).

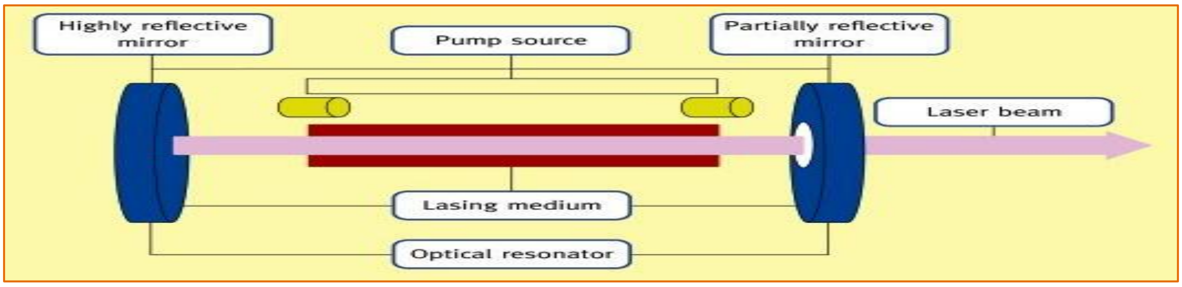


Figure (1.4) Basic laser components . [13]

1.11 Laser light properties

The laser light has some unique properties. These laser light properties are given below[11,12]

Monochromaticity: Monochromatic light is an optical radiation where the optical spectrum consists of single optical frequency. The light source is called monochromatic.

Coherence: It is a fixed relationship between the phase of waves in a beam radiation of a single frequency. Two beams of light are coherent when the phase difference between their waves is constant. The electromagnetic waves are in phase with one to the other in both time and space.

Directionality: The directionality of light is defined as the balance between the diffuse and directional components of light within an environment .[14]

Intensity or brightness: This character emerges via the collimation or parallelism of laser light as it progresses through space conserving its concentration.

1.12 Difference between laser light and ordinary light

The laser light and the ordinary (Normal) light differ with each other in their properties. These properties are chromatic properties, coherency, directionality and intensity. The laser light and the ordinary (Normal) light are depicted in the Figure (1.6).(15)

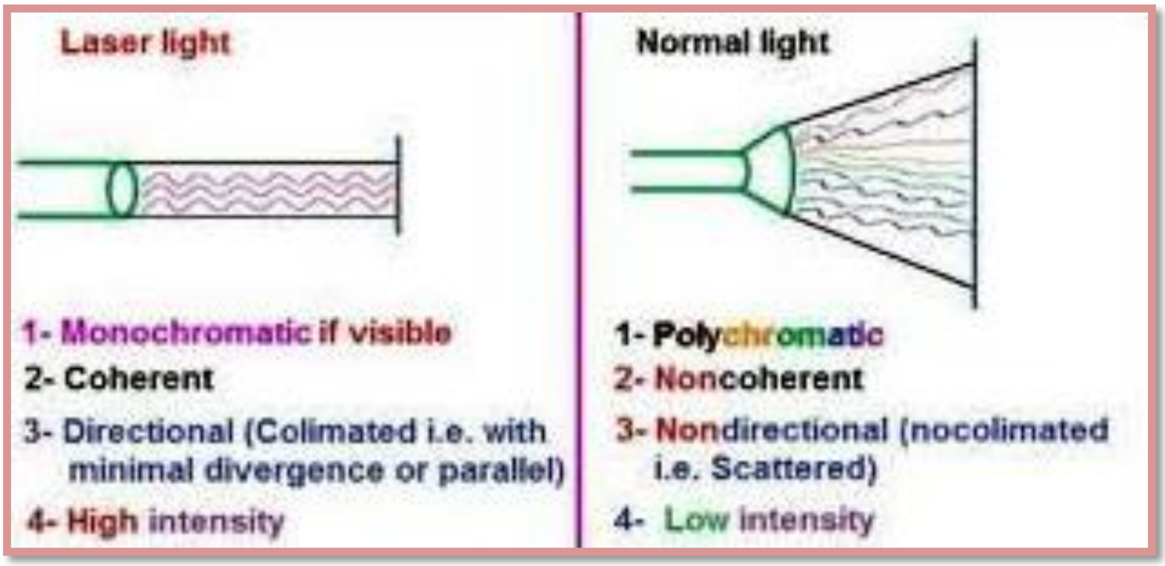


Figure (1.5). The laser light compared to ordinary light . [15]

1.13 Laser modes

Laser modes are wave like properties of the beam of light that evolve while the beam passes back and forth through the amplifier, bouncing between the mirrors. The beam grows as long as the gain in the amplifier exceeds the losses within the cavity. The development of modes involves an attempt by competing portions of the light beam having slightly different frequencies, to fit an exact number of their waves into the optical cavity with the constraint that the oscillating electric field of the light beam is zero at each of the mirrors. Most lasers have a number of modes operating simultaneously, in the form of both longitudinal and transverse modes, which give rise to a complex frequency and spatial structure within the beam in what might otherwise appear as a relatively simple, pencil-like beam of light . [16]

The lasers operate in the following modes:-

1.13.1Continuous wave mode

A continuous wave or continuous waveform (CW) is an electromagnetic wave of constant amplitude and frequency, typically a sine wave, that for mathematical analysis is considered to be of infinite duration. It is produced by continuous energy pumping into active medium to attain equilibrium among the atoms number lifted to the excited state and emitted photons number. At equilibrium like this continuous output of laser results. The span of which compasses from the second to hours Figure (1.7). [14]

1.13.2 Chopped mode

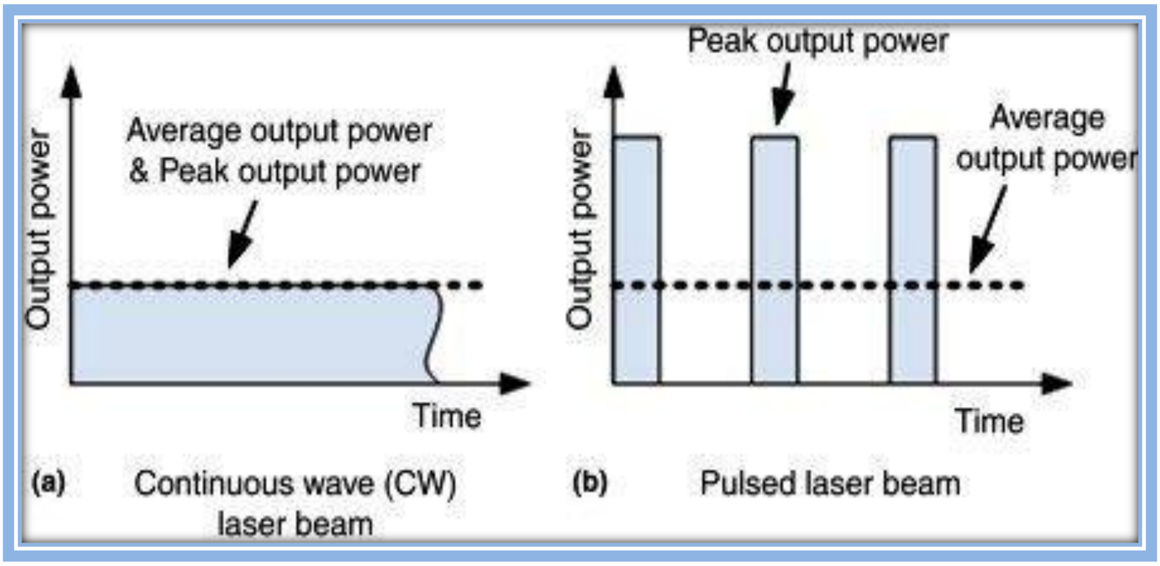
It is defined as a laser operating mode where the emission is a repetitive on and off cycle. The laser beam is actually emitted continuously, but a mechanical shutter or electronic control ‘chops’ the laser beam into pulses. The CW laser output, which chops the beam into short pulses trains. The maximal power level of every pulse is the similar as that gained in the CW mode (Figure 1.7).[16]

1.13.3 Pulsed mode

Pulsed mode is defined as a laser radiation that is emitted intermittently as short bursts or pulses of energy rather than in a continuous fashion. Gas lasers like the CO_2 laser may be pulsed or gated. Electronically the gating allows the span of the pulses to be compacted; creating a analogous growth in peak power which is much greater than it is generally accessible in the CW mode (Figure 1.6).[17]

1.13.4 Q-Switched mode

Q switching is a technique for obtaining energetic short (but not ultra short) light pulses from a laser by modulating the intracavity losses and thus the Q factor of the laser resonator. This mode is used to get shorter and intense pulse. By initiating a shutter into the cavity of the laser’s resonant, the energy of active medium has grown to an extent far beyond that is available leaving the obstruction or shutter in the system.[17]



Figure(1.6) Continuous wave (CW) and pulsed laser outputs .[17]

1.14 Laser parameters

Some unique parameters plays and important role in differentiating between the laser light and ordinary light. These parameters are the characteristics of laser light. Each parameter is explained below briefly

Wavelength: Wavelength is defined as the property of a wave in which the distance between the identical points between the two successive waves are calculated. It is the most critical determinant in how tissue is affected by light.

Energy: Energy is the ability to perform work. It is The product of power (Watts) and duration (seconds). It is calculated in joules (J) and is proportionate to the photon number.

Energy density: It is defined as a measurement of energy per area of spot size. It is expressed as Joules per square centimeter (J/cm^2). It is also known as fluence . Fluence is the delivered energy per unit area.

Duration of pulse: Pulse duration is defined as a measurement of the total amount of time that a pulse is emitted. It is also known as pulse width. This is used in pulsed lasers and confers to the completion width of pulse peak half maximum. Pulse duration is calculated in time units (femtoseconds or picoseconds, nanoseconds, microseconds, milliseconds).

Rate of Repetition: Repetition rate is known as the number of pulses per second. It is also known as pulse rate. It is calculated in Hertz (Hz) or pulses per second (PPS).[16]

Duty cycle: It is the functional laser beam proportion throughout which the light is transferred from the chopped laser. It is a unit small amount.

Power: Power is defined as an amount of work performed per unit time. It is calculated in watts (W) wherever 1 W = 1 J/sec.

Power density: The measurement of power per area of spot size, usually expressed as Watts per square centimeter (W/cm^2). It is also known as intensity, irradiance, and radiance.

Spot diameter: The spot diameter is defined as the diameter in the beam waist that contains 86.5% of the total power and corresponds to the $1/e^2$ beam diameter in the working plane for Gaussian beams .It is the target irradiated area diameter. Generally, the spot diameter units are centimeters .[17]

1.15 Hazardous effects of laser

As a result of growing popularity, laser systems are now majorly widespread in a medical environment. It is utilized by human for various purposes, *i.e.* specialized, highly in source, optics management of laser, patient treatments, etc. This has highly boosted the recognition towards laser safety issues concerned to laser beams and to rigorously evaluate the well-defined laser radiation values definitive parameters distinguishing the hazard level of source of laser .[18]

1.15.1 Types of hazards of laser identified and evaluated

Laser devices use is potentially dangerous. Effects can range from mild skin burns to irreversible injury to the skin and eye. The biological damage caused by lasers is produced through thermal, acoustical and photochemical processes. Thermal effects are caused by a rise in temperature following absorption of laser energy. The severity of the damage is dependent upon several factors, including exposure duration, wavelength of the beam, the energy of the beam, and the area and type of tissue exposed to the beam.[18]

Acoustical effects result from a mechanical Shockwave, propagated through tissue, ultimately damaging the tissue. This happens when the laser beam causes localized vaporization of tissue, causing the Shockwave analogous to ripples in water from throwing a rock into a pond. Beam exposure may also cause photochemical effects when photons interact with tissue cells. A change in cell chemistry may result in damage or change to tissue. Photochemical effects depend greatly on wavelength. Some hazardous effects are listed below

a) **Eye:** The laser beam may cause damage to the eye from direct exposure or reflection when the wearing of appropriate eyewear is not adhered to. The wavelengths in the visible to near infrared (400 - 1400 nm) may result in retinal burns in the area of the optic disk due to the relatively non-absorption by water .[19]

b) **Skin:** Skin effects can be of significant importance with the use of lasers emitting in the ultraviolet spectral region. The potential for skin injury from the use of high power lasers can also present a severe hazard. For some laser systems using an open beam, skin protection may be necessary. Covering exposed skin by using lab coats, gloves and an UV face shield can protect against UV scattered radiation. Adequate skin protection may be required for certain applications using high power laser systems.[18]

c) **Chemical:** Few lasers need toxic or hazardous substance for operations (*i.e.*, chemical dye). These chemicals are harmful for the human beings.

d) **Electric shock:** Many lasers induce high voltage during operating which may be lethal for humans.

e) **Fire hazards:** The solvents utilized in dye lasers are burnable. Flash lamps or high voltage pulse lamps can generate fire. Direct beams can burn inflammable products or a specular reflection via higher power CW infrared lasers. Other hazards include the probable inhalation of aerial biohazardous compounds which can be rescued as a consequence of the laser's surgical application .[17]

Figure (1.7) Laser loupes .[15]

1.15.2 Safety standards of laser and classification of hazard

This standard was proposed by the ANSI (American National Standard Institute) .[20] The classification is dependent on the energy or output power of beam via the laser. Primarily, the classification is utilized to outline the laser's capability to create injury to personals. The greater the number of classifications, the higher is the potential hazard [21] which is indicated in Table(1.3.)The hazard was classified in the five classes viz. Class 1, Class 2, Class 3a, Class 3b and Class 4.

Table (1.1): Classification of laser hazard. [21]

Class	Characteristics
Class 1	● Eye safe under all operating conditions ● Dose doesn't emit harmful levels of radiation during normal operation ● Includes higher class lasers completely enclosed and interlocked to prevent beam access, allowing a class 1 laser system designation; any time the higher class laser is accessible (e.g. during alignment or servicing), the higher laser class controls must be observed ● Can be used without restriction in the manner intended by the manufacturer and without special operator training or qualification.
Class 2	● Emits accessible laser light in the visible wavelength region ● Chronic exposure can cause eye damage ● In general, the human eye will blink within 0.25 seconds when exposed to class 2 laser light, this blink reflex provides adequate protection. ● Can be used without restriction in the manner intended by the manufacturer and without special operator training or qualification.
Class 3a	● Normally not hazardous when viewed momentarily with the unaided eye, but may pose severe eye hazards when viewed through collecting optics (e.g. Microscopes and binoculars).

	Power levels 1-5 milliwatt (MW) ● Same controls as class 1 and class 2 lasers for normal operations; if view through optical instruments (e.g. Binoculars, telescopes, or microscopes), contact the LSO for a hazard review.
Class 3b	● Will cause injury upon direct viewing of the beam and specular reflections ● Power output 5-500 mW for CW or less than 0.03 joule (J) for a pulsed system (*i.e.* pulse width less than 0.25 second) ● The radiation can be a hazard to the eye or skin. However, viewing of the diffuse reflection is safe
Class 4	● Includes all laser systems with power levels greater than 500mW CW or greater than 0.03J For a pulsed system. ● Pose eye hazards, skin hazards, and fire hazards. Viewing the beam or specular reflection or exposure to diffuse reflections can cause eye and skin injuries. ● All control measures explained in this document must be implemented.

1.16 Control measures

The control measures are designed to lower the skin and eye exposure possibility to hazardous laser radiation levels. The ANSI laser safety series supplies in-detail explanations of control measures . [22] The Laser Safety Officer is answerable for making confirm control measures are arranged .Control measures can be categorized into three chief types, namely, Engineering control, Procedural and administrative control and Personal protective equipment (PPE).[22]

1.16.1 Engineering control

Include design characteristic or devices related to the laser, or environment of laser that reduce or restrict irradiance subjection. Such controls involve remote monitoring and firing systems, beam attenuators and beam shutters, and the safe housing placed completely around few laser systems. [21]

a) Protective Housing, Interlocks

A protective housing is a physical barrier sufficient to contain the beam and laser radiation from exiting the laser system so that the maximum permissible exposure (MPE) is not exceeded on the outside surface. Protective housings must be interlocked so that the laser cannot operate when the housing is opened or removed. When the requirements of a protective housing are fulfilled, then the laser system is considered a Class 1 laser and no further control measures are required. [22]

b) Laser Use without Protective Housing

In the research environment lasers are often used without a protective housing in place. Typically the use of optical tables and optical devices are employed in order to manipulate the laser beam. In this environment, the EH&S Radiation Safety Office (617-496-3797) will evaluate the hazards and ensure that control measures are in place for safe operation . [20,22]

c) Access Restriction

For Class 3b and 4 laser laboratories, access controls are required to prevent unauthorized personnel from entering the area when the laser is in use. Doors need to be kept closed when the laser is in operation and locked when the laser is left unattended. A door interlocked with the laser shutter may be required. [20]

1.16.2 Procedural and administrative control

Administrative controls are methods and instructions that promote, laser safety in the laboratory.

a) Standard Operating Procedures

A written SOP must be established for normal, maintenance, and alignment operations. The SOP will be maintained with the laser equipment for reference by operators or service personnel and can be used for instructional material to train new laser users in the facility. All SOPs will be updated to reflect any changes in laboratory protocol and equipment usage.[21]

b) Warning Signs and Labels

All signs and labels must comply with ANSI Z 136.1 [20] and the FDA/CDRH standards. Signs indicating “Caution” will be posted in all entranceways into laboratories containing Class 2 and Class 3a lasers equal to or less than the MPE. For class 3a lasers exceeding the MPE for irradiance and all Class 3b and Class 4 lasers, laboratories must be posted with "Danger" signs. In accordance with ANSI Z 136.1 [20] the signs will include the laser class, wavelength, and laser output. For laboratories containing Class 3b and 4 lasers, a warning light indicating the laser "On" status must be placed at all entranceways into the laser room. Lasers are marked with the manufacturers' label according to FDA/CDRH regulations. For laser systems developed in house, call the Radiation Protection Office to evaluate the laser for proper labeling. [22]

Include information and procedures rather of mechanical systems or devices. Few critical administrative controls are reporting of labels and warning signs, initiation of SOP's and safety education.[21,22]

1.16.3 Personal protective equipment

Personal protective equipment (PPE) is worn by the individual utilizing the laser or in the laser vicinity. It involves safeguarding laser systems, class 4 and class 3b special clothing, gloves and eyewear systems.[21]

1.17 Important laser safety measure to follow

Considering all above mentioned laser hazards, it is extremely necessary to take precaution while working with lasers. Following are some suggestions about the precaution measures .[23]

- Instructions about how to keep equipment in good working order
- Training on proper procedures for the safe use of equipment
- Always put on laser security glasses while working with lasers
- Instruction and training to protect patients and clients from exposure
- Education about possible health and safety hazards to all workers
- Use genuine storage
- Accompany regulations and standards
- Work along competent personnel
- Use caution signs

1.18 Laser Tissue Interaction

Lasers are widely used in biology and medicine and the majority of the hospitals utilize modern laser systems for diagnostic and therapeutic applications.[23] The medical laser applications are defined by the type of interaction between laser light and tissues. Knowledge of laser-tissue interaction can help doctors or surgeons to select the optimal laser systems and to modify the type of their therapy.[24,25,26]

Now a day, lasers are majorly utilized in medicine and biology, and most hospitals and health centers utilize modern systems of laser therapy and diagnosis applications. Researchers have established various medicinal implementations for various lasers utilized in surgeries and other medicinal therapies. Medicinal lasers may be classified in both therapy and diagnosis branches. The chief difference between therapy and diagnosis applications is the laser-tissue interconnections type. In discovery, one attempts to organize a noninvasive technique to investigate the normal tissue behavior lacking any clear effect or damage to tissue. But in treatment, like surgery, the surgeon utilizes laser as a knife or for influencing a specified region. So, the applications of medical laser are described by the type of interaction among tissues and laser light. The laser-tissue interconnection knowledge may aid surgeons or doctors to choose the optimum systems of laser and modify the category of their treatment.[26]

1.18.1 Effect in the laser light when tumbles on tissue

Once a laser beam is produced it is aimed at tissue to perform a specific task. As the energy reaches the biological interface one of four interactions will occur; reflection, transmission, scattering, or absorption.[25]

a) **Absorption:** Specific molecules in the tissue known as chromophores absorb the photons. The light energy is then converted into other forms of energy to perform work.

b) **Reflection:** The laser beam bounces off the surface with no penetration or interaction at all. Reflection is usually an undesired effect.[24]

c) **Transmission:** The laser energy can pass through superficial tissues to interact with deeper areas. Retinal surgery is an example; the laser passes through the lens to treat the retina. The deeper penetration seen with Nd:YAG and diode lasers are an example of tissue transmission as well.[26]

d) **Scattering:** Once the laser energy enters the target tissue it will scatter in various directions. This phenomenon is usually not helpful, but can help with certain wavelength biostimulative properties.

In medicinal laser implementation, refraction plays a notable role when illuminating transparent media such as corneal tissue. In non-transparent media, generally, the refraction effect is hard to calculate due to the scattering and absorption. [27] All the light effects start with the electromagnetic radiation absorption. Throughout absorption, the incident light intensity is weakened by passing via a medium because of a partial light energy conversion into motion of heat or definite molecule vibrations of the absorbing matter. The mediums absorption ability of electromagnetic radiation relies on a various factors, chiefly the constitution of electrons of its molecules and atoms, the radiation wavelength, the absorbing layer thickness and internal parameters like concentration or temperature .[28] Figure(1.8) indicates these procedures.

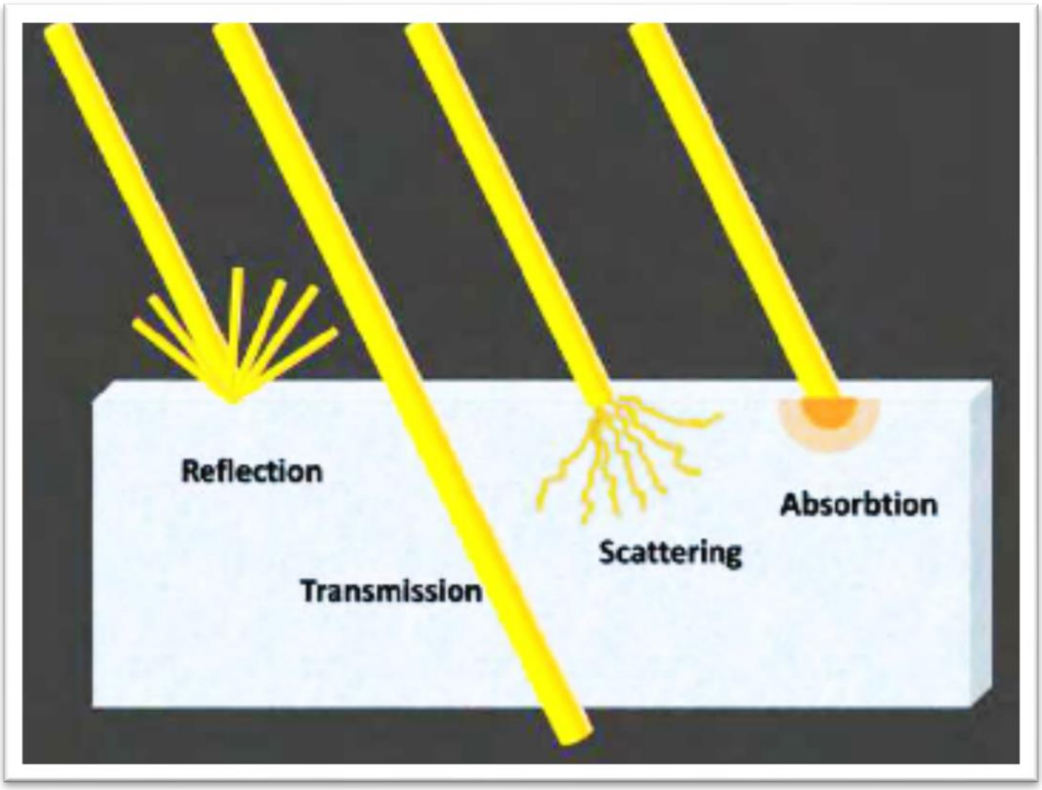


Figure (1.8) Interaction of laser and tissue surface .[28]

1.18.2 Tissue response to laser light

If laser radiation strikes biological tissue, various effects can be observed. All are caused primarily by the interaction of photons with the molecules and the molecular compounds of the tissue. [27]The resulting actions depend mainly on the application parameters, which, in turn, can be characterized by the wavelength of the applied laser, the exposure time and the power density. The action mechanisms may be divided approximately into photochemical actions, thermal processes and non-linear responses. The actions are dominated:

1) For low power densities and long exposure times by photochemical processes.
2) For average power densities and exposure times by thermal responses.

The interaction mechanisms variety can occur when laser light is applied to biological tissue because of specified tissue characters and also parameters of laser. Wavelength depended mechanism is depicted in the Figure (1.9).[26,27]

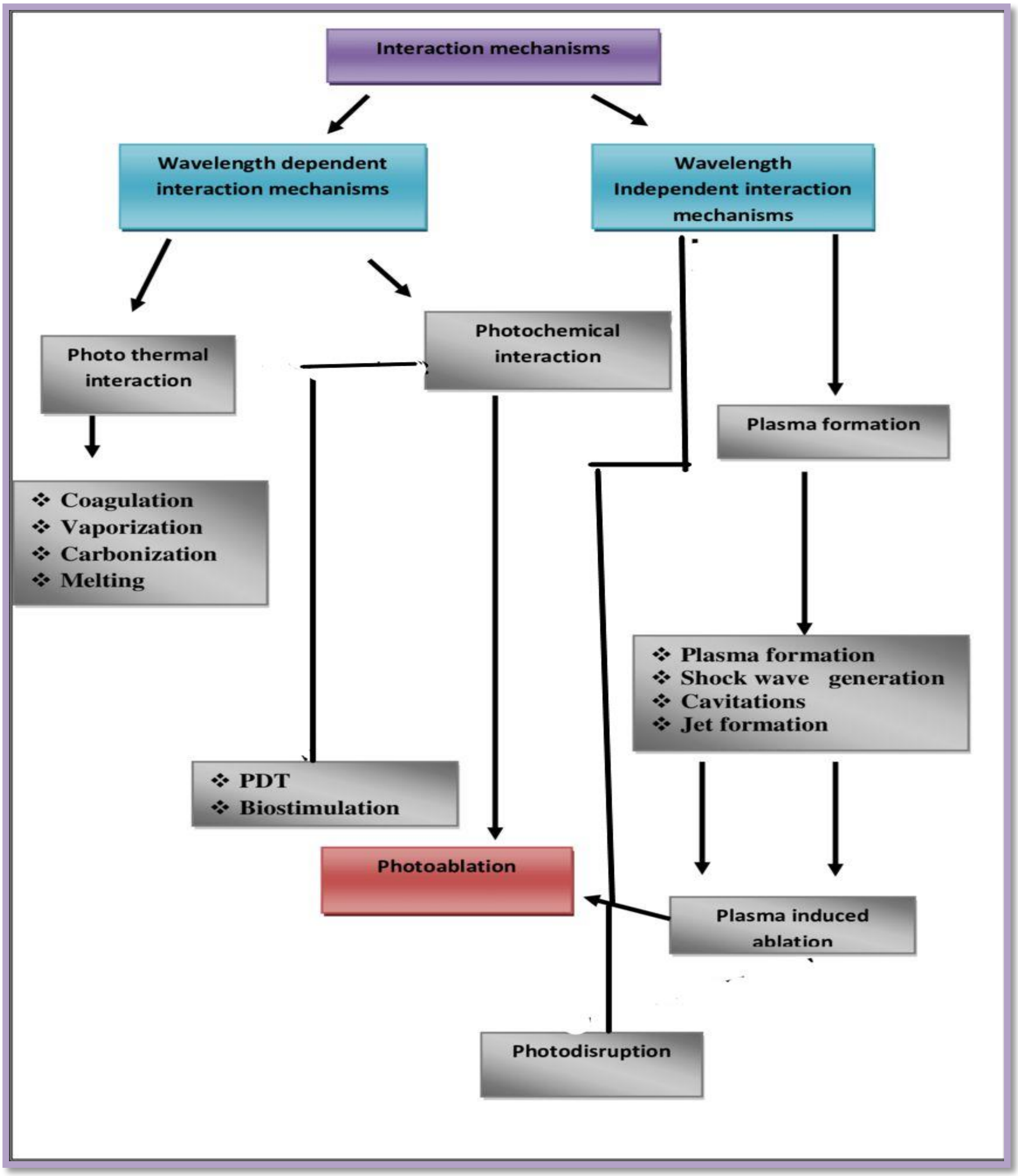


Figure (1.9) Light interaction with biological tissue (Wavelength relying mechanism) . [29]

1.18.3 Mechanisms of photothermal interaction

Increasing the body temperature leads to several effects such as hyperthermia, coagulation and other irreversible tissue effects. By increasing the temperature, the initial effect is hyperthermia. The typical range of 40-50 degrees Celsius is called hyperthermia domain within which some molecular bonds are destroyed and the membrane is altered. The reduction in enzyme activity is observed. However, the effects in this temperature range are reversible. For temperatures around 60°C, denaturation of proteins and collagen occurs which leads to the coagulation of tissue and it can necrotize cells. Several optical treatments such as hair removal aim at temperatures above 60°C. At higher temperature the equilibrium of chemical concentration is destroyed as the permeability of membrane of cells increases.[28,29]

Photons suck up by the tissue are believed to cause biological impact by nonspecified photothermal impacts caused via kinetic mechanism, the laser photons external energy is disbursed into the target matters by vibrational, rotational an transitional modes of target molecules movements. Relying on the peak value and duration of the temperature of tissue achieved, various impacts such as vaporization, carbonization, melting and coagulation can be renowned . [28]

The vaporization of water occurs at 100°C. The vaporization is sometimes referred to as the thermo mechanic procedure, because within the vaporization phase, the temperature of tissue does not alter and gas bubbles are formed. The propagation of these bubbles accompanied with the alteration of their volume causes thermal decomposition of tissue fragments. If all water molecules are vaporized, carbon atoms are released and the adjacent tissues are blackened and smoke rises from the skin. This stage is called carbonization. Finally, beyond 300°C melting might occur. Table (1.2) depicts the summarized heat effects for different temperatures. It is worth mentioning that 60°C is a critical temperature since most biological effects which occur at temperatures higher than that are irreversible. [30]

The most habitually utilized techniques of conversion of photon energy in laser medicine are warming. Warming of illuminated sample occis carried out with all techniques of tissue demolition (cutting, vaporization, coagulation, etc.) Table (1.2) . [31]

Table (1.2) Tissue thermal impacts of laser radiation. **[**31**]**

No.	**Temperature**	**Biological effect**
1.	37°C	Normal
2.	45-50°C	Hyperthermia, Reduction of enzyme activity, Cell immobility
3.	60-80°C	Denaturation of proteins and collagen; Coagulation
4.	100°C	Vaporization, Thermal decomposition(ablation)
5.	>100°C	Carbonization
6.	>300° C	Melting

The spatial extent and location of each thermal impact relies on the locally obtained temperature throughout and after exposure to laser [32] .Figure (1.10).

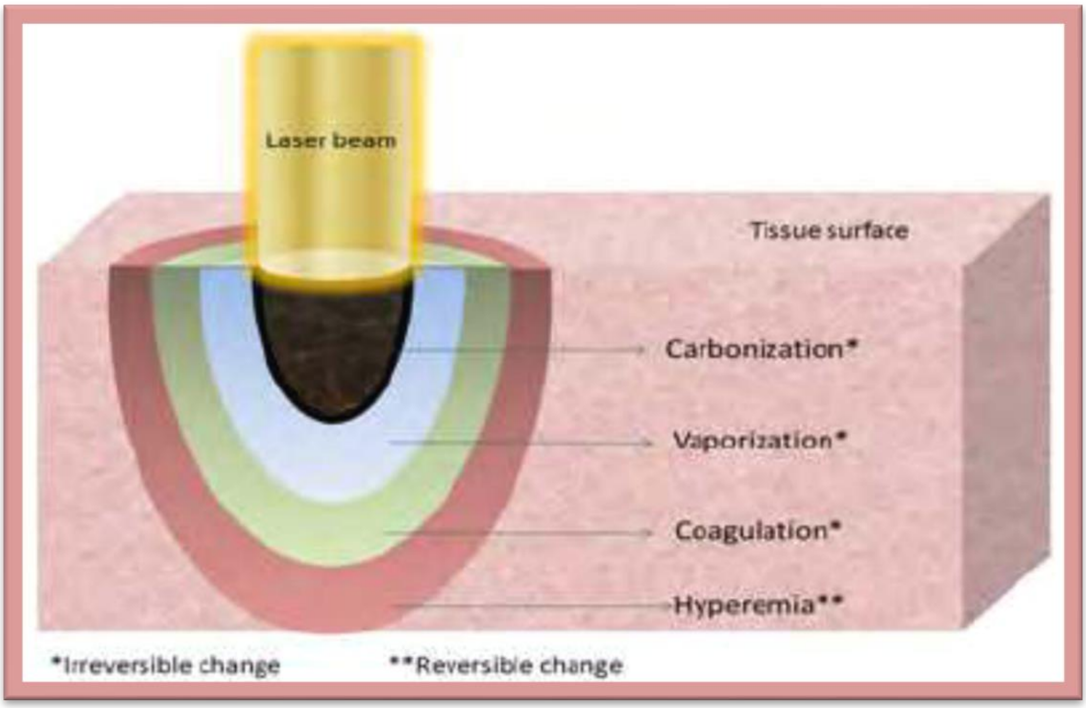


Figure (1.10) Laser thermal effects: Spatial distribution . [32]

1.18.4 Wavelength independent mechanisms

When utilizing power densities outstripping 10^{11} W/cm^2 in fluids and solids or in air 10^{14} W/cm^2, where the duration of the pulse is in the femtosecond or picosecond range, atoms ionization of multiphoton and molecules can occur in a phenomenon called as optical breakdown. The physical impacts connected with optical breakdown are shock wave generation and plasma formation. If a crash occurs in fluids or soft tissues, jet formation and cavitation can take place additionally. By use of plasma-influenced ablation, well defined and very clean tissue removal lacking evidence of mechanical or thermal damage may be attained when selecting proper parameters of laser. Unrestricted, the plasma effect on the surface of tissue may cause damage of tissue ,.[17]

1.19 Types and medical laser

Laser is a photonic gadget which intensifies light and synthesizes a high intensity and highly directional coherent radiation. There are various lasers types accessible for commercial, industrial, medical and research uses. Often lasers are described by the type of lasing medium used. [17]

Various types of lasers are accessible that varies in their applications and wavelengths Table (1.3) . Between the various active media, only some types are having the properties and characteristics which favor broad spread use and are acceptable for medicinal application. The first laser by Maiman in 1960 utilized Ruby as a medium. Nowadays, a broad variety of vapors, liquids, gases or solids are accessible as lasing media .[33]

Table (1.3): The various lasers commonly used in medicine along with the wavelength at which they operate, their absorption chromophores, and their clinical applications .[33]

Laser	**Wavelength**	**Absorption chromophore**	**Mode**	**Application**
Ruby	694nm	Pigment, hemoglobin	Pulsed	Dermatology, tattoo removal
Nd:YAG	1,064nm	Pigment, proteins	CW / Qswitched	Wide applications
Er:YAG	2,940nm	Water	Pulsed	Surgery
Diode	630–980nm	Pigment, water (range)	CW / Pulsed	LLLT, PDT, surgery
Argon	350–514nm	Pigment, hemoglobin	CW / Pulsed	Surgery, PDT, ophthalmology, dermatology
CO2	10,600nm	Water	CW / Pulsed	Surgery
Pumped-dye	504–690nm	Pigment	CW	PDT, dermatology

1.20 Depth of optical penetration

Red light penetrates deeper than blue light .[34] The reason is that skin consists of a range of chromophores which have scattering and absorption coefficients which are highly wavelength dependent. [34,35,36,37,38]. The scattering properties of tissue are due to attenuation properties intrinsic to the chromophore and also to the size of the particles within the tissue, which also governs the type of scattering that occurs, namely Mie or Rayleigh scattering .[39] Scattering leads to light dispersion in the tissue and the eventual reduction in the energy density with increasing depth[40,41] looked at the transmission of laser light through tissues over a range of skin types and for laser wavelengths in the range 532–1064nm and showed that 1064-nm light penetrated deepest into tissue .[41]

Intense pulsed light (IPL) systems emit light in the wavelength range 400–1200 nm .[42] For wavelengths greater than 1000 nm, there is not a great amount of information regarding the penetration depth, and there is also little information regarding the photobiological effects at wavelengths greater than 1000 nm. The wavelength of a therapeutic source therefore has a double importance, namely to ensure absorption of the incident photons in the target chromophores and to be able to do so at the depths at which these chromophores exist. [41]

The waveband in which the wavelength of the incident photons is located determines not only which part of the cell is the target but also the primary photo action. Wavelength is thus probably the single most important consideration in phototherapy, because without absorption, there can be no reaction. For normally incident radiation, this regular reflectance is on the order of 4–7% .[43] The remaining 93–96% of the radiation entering the skin is either scattered or absorbed. The type of scattering is an elastic interaction between a photon and matter in which only the direction of propagation of the photon is altered. Elastic scattering results from inhomogeneity's in the skin's index of refraction corresponding to the physical boundaries of anatomical features, such as collagen fibers, and is characterized by the wavelength dependent scattering coefficient, μ_s (λ) (cm−1). Once absorbed, the radiation is predominantly converted non-radiatively, (*i.e.* without luminescence) into heat by the absorbing chromophore molecules.[42] When there are pigmented tissue structures present that are more strongly absorbing at the laser wavelength than the surrounding tissue, e.g. hair shafts, the photons propagating randomly within the tissue will tend to be absorbed selectively by the pigmented structures. Thus, given enough deposited energy, selective photothermolysis of the pigmented structures will occur. Absorption by the pigmented structures or the surrounding tissue is characterized by their respective wavelength dependent absorption coefficients, μ_a (λ) (cm−1).[43]

Optical characters of the dermis and epidermis are unalike. In pigmented epidermis, absorption of melanin is generally the governing procedure over the optical spectrum majority (200–1000 nm). In the dermis, there is powerful, wavelength-relying scattering by fibers of collagen, which weakens light penetration. This scattering inversely varies with wavelength. Normally, among 280 and 1300 nm, the penetration depth grows with wavelength. Over 1300 nm, there is decrease in penetration because of light absorption by water. The most enormously pungenting wavelengths are 650– 1200 nm, where the slight pungenting wavelengths are among the IR and UV regions. [44]. Figure (1.11).

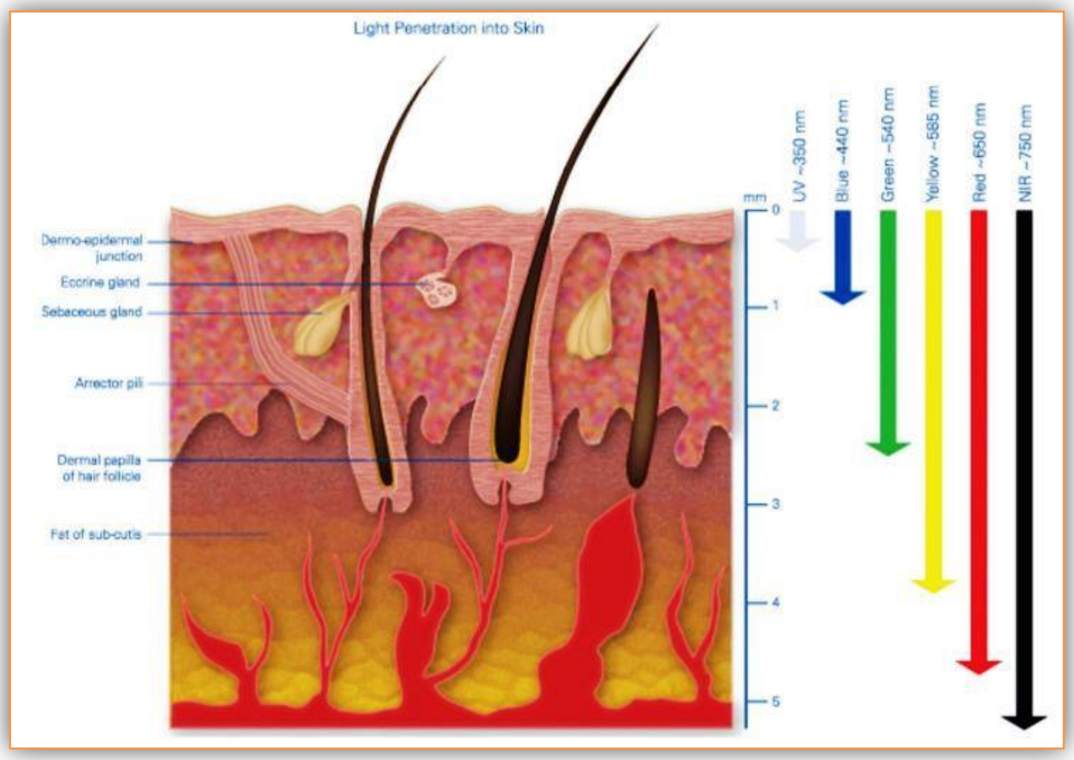


Figure (1.11) Illustration of different lasers depth of penetration in human skin.[44]

Light penetration into skin illustrating the depth to which wavelengths penetrate human skin. Red light is extinguished some 4–5 mm beneath the surface of the skin, where as ultraviolet hardly penetrates at all and blue barely 1 mm into tissue .[40]

1.21 Medical Lasers Types

Medical lasers are medical devices that use precisely focused light sources to treat or remove tissues .The basic difference between ablative and non-ablative treatments is that ablative lasers remove the top layer of skin, while non-ablative lasers work by heating up the underlying skin tissue (without harming the surface) so that the body will produce new collagen. [42] Medical laser types can be divided into three types.

Ablative laser: This is an injure laser which separates the outer thin skin layer (epidermis) and warms the basal skin (dermis), which invigorates the expansion of novel fibers of collagen.[43]

Non-ablative laser: This is a non-injure laser which invigorates the growth of collagen.

Fractional Lasers: Fractional laser treatment is a non-invasive treatment that uses a device to deliver a laser beam divided into thousands of microscopic treatment zones that target a fraction of the skin at a time, analogous to a photographic image being enhanced or altered pixel by pixel. terminate the energy of laser into chiliad of small beams to cure only a skin fragment in the area. The optical penetration depth for CO_2 laser is just around 20µ, but Fractional CO_2 laser may evaporate closely total thickness microchannels via the dermis. [44]

1.22 CO_2 (10600nm) laser

The main biological targets such as blood, melanin and water, absorb light energy very differently and have optimum absorption spectra depending on the wavelength of the incident photon energy. The CO_2 (carbon dioxide) laser discharge light at a 10,600 nm wavelength. Its photo thermal impact on tissue comprises of the alteration of water into vapor, which accompanies total cell vaporization. Nevertheless, as the light of CO_2 only perforates 0.3–1mm toward the target and, the thermic injury to the tissue afar the area of vaporization is minimum.[43] For visible light lasers and some near-infrared lasers, the main target chromophores are hemoglobin (consisting of oxy- and deoxy hemoglobin) and melanin, the former being found in vascular lesions and the latter in melanogesic lesions. For the CO_2 laser at 10,600 nm, the only chromophore is water, as is also the case with the Er: YAG laser. When utilized along a pattern or scanner generator, cosmetic skin resurfacing is achieved easily.[40] The therapy may be totally ablative or fractional [Little, technical director laser training institute]. Evolution in fiber optics formed it feasible to transfer beams of far-infrared laser, enhancing the CO_2 lasers flexibility for endoscopic abscission .[45] The optimum absorption spectra depending on the wavelength of the incident photon energy depicted in the Figure (1.12). This can be thought of as denoting the degree of penetration into tissue: the lower the value on the y-axis, the better the penetration of light at the given wavelength. The absorption spectra are for the laser tissue chromophores comprising the major biological pigments (oxy- and deoxyhemoglobin and melanin) and water. Note the high absorption in water at 10,600 nm, the wavelength of the CO_2 laser

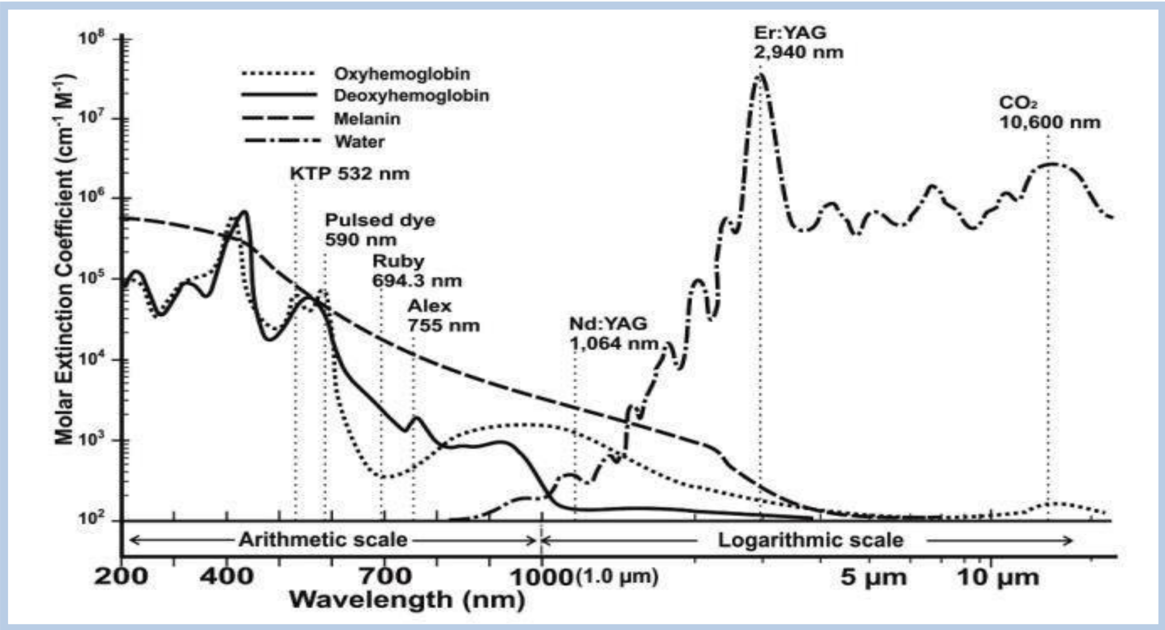


Figure (1.12) Optimum absorption spectra depending on the wavelength of the incident photon energy. Wavelength is shown on the x-axis (200-400 nm, UV; 400 – 700 nm, visible light; 700 – 2000 nm, near infrared; > 2000 nm, mid-infrared) with an arithmetic scale from 200 – 1000 nm (1.0 µm) and a logarithmic scale from 1.0 µm and longer. The y-axis denotes the coefficient of molar extinction in logarithmic units. [45]

1.23 Fractional CO_2 Laser

Fractionated CO_2 lasers are a new treatment modality for skin resurfacing. This laser therapy is based on the theory of fractional photothermolysis introduced by [46] .These lasers have been shown efficacious in treating facial photoaging changes and scars and have an improved safety and recovery profile compared with traditional CO_2 laser resurfacing .[47,48,49] Although, CO_2 laser skin resurfacing is widely hailed as a safe and effective treatment modality, morbidity is widely reported as well. Furthermore, the patient's medical history may affect the decision to use laser resurfacing Figure (1.13).

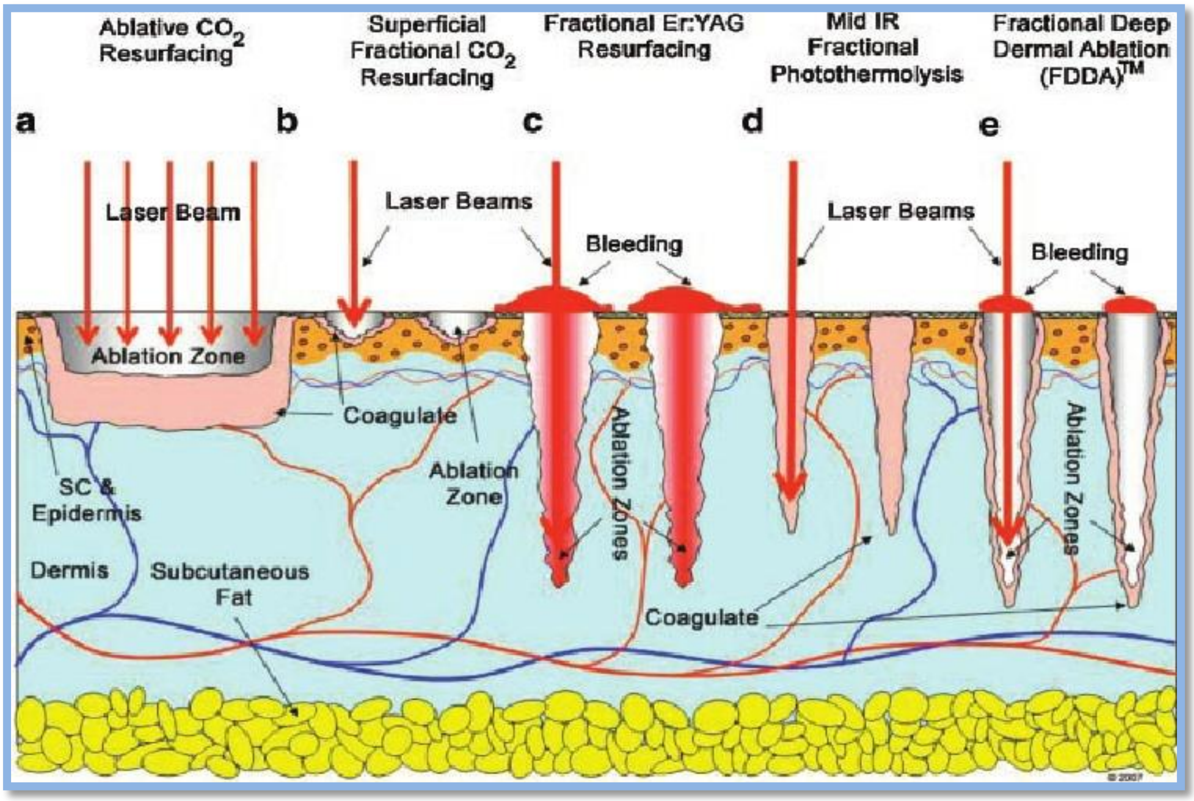


Figure (1.13) Comparison of (a) traditional ablative resurfacing, (b) superficial pseudo-fractional CO_2 resurfacing, (c) fractional Er:YAG resurfacing, with (d) mid-IR fractional photothermolysis and (e) fractional deep dermal ablation (FDDA TM) by a CO_2 laser.[49]

The new conception of fractional photothermolysis was established to the market by Dieter Manstein and Rox Anderson in 2003 year . [32] Unlike traditional non-ablative and ablative lasers, fractional non-ablative and ablative lasers cure only skin's fraction leaving up to a maximal of skin's 95% uninvolved hence the label fractional, relying on the spots number per treatment area.

1.23.1 Physics of fractional lasers

Fractional Lasers break up the laser energy into thousands of tiny beams to treat only a fraction of the skin in the area. This system uses the concept of fractional photothermolysis by creating numerous microscopic thermal injury zones of controlled width, depth and density that are surrounded by normal skin which serves as a reservoir for rapid tissue healing Figure (1.14). [33] The benefits of this system are less downtime or no downtime and less or no side effects. It works on the principle of fractional photothermolysis, that involves creation of pixelated patterns of full thickness columns of skin coagulation, which were termed as microthermal zones (MTZ). following figure shows laser beam delivered by fractional lasers.[32]

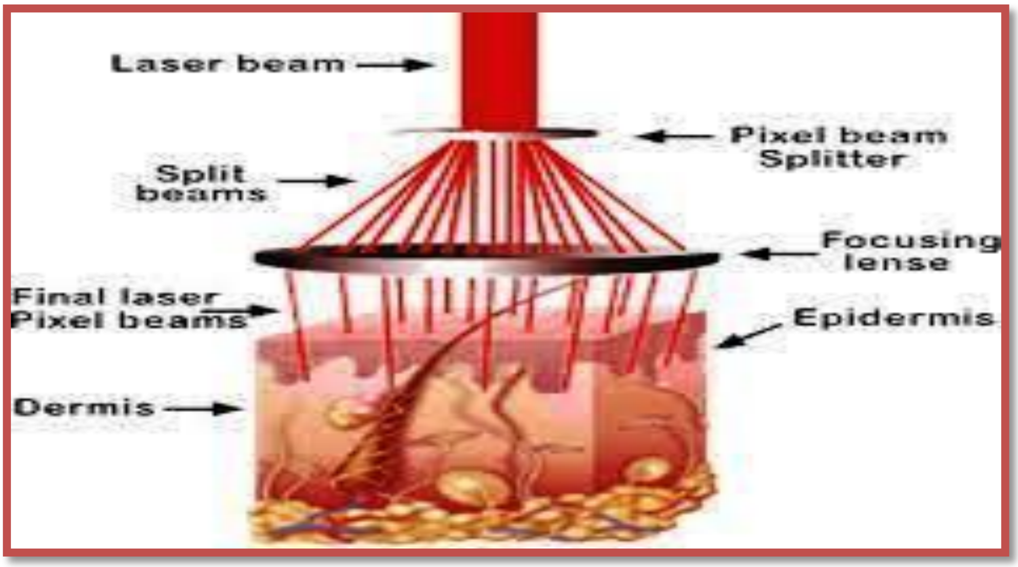


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Figure (1.14) Fractional CO_2 laser components .[33]

1.23.2 Thermal damage zone

It is well documented in the medical literature that a zone of thermal damage to the dermis as a result of ablative CO_2 laser resurfacing increases collagen synthesis and long term skin tightening.[33] Greater thermal injury (up to a certain point) results in greater cosmetic improvement. Also, the thickness (depth) of the thermal damage zone is a function of both the amount of laser beam energy and width of the laser beam pulse (dwell time); the wider the pulse, the greater the thermal injury. Figure (1.15) represents the thermal damage zone as effect of pulse power and pulse duration.[33]

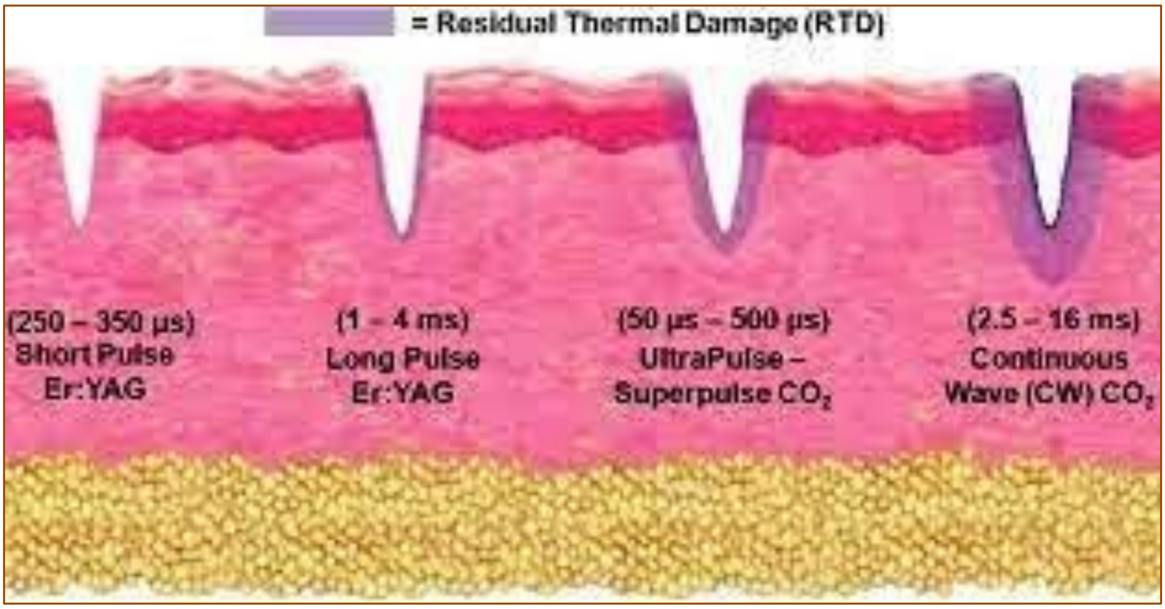

Figure (1.15) Thermal damage zone as effect of pulse power and pulse duration.[32]

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1.24 Aim of the study

Effect of fractional CO_2 laser on perineal changes during puerperium and breast feeding period.

Chapter Two

Material And Methods

2.1 Introduction

It is a case-control study where in 25 women were involved. They were randomly divided (after getting consent) into two groups, *i.e.* treatment group and control group. Fifteen women were enrolled in the treatment group and 10 women were enrolled in the control group for studying postpartum perineal changes during puerperium and breast feeding. In the treatment group, the individuals were treated with fractional CO_2 laser. While, the control group was treated with lubricant (BioGyno vaginal gel).

The study was carried out over five months from September 2021 to January 2022 in private gynaecology clinic in Tikrit city, Iraq.

2.2 Selection of patients

After oral consent, 25 women were enrolled in the study. Each patient was examined for their suitability. Patients symptomatic for any vaginal infection (vaginal discharge, itching and burning) were started on preventive therapy. The patients were recruited based on the inclusion and exclusion criteria.

2.2.1 Inclusion criteria

The inclusion criteria for the study were as follows

1) Female patients $\geq$ 18 years and of reproductive age
2) Women in puerperium or breast feeding with persistent chronic perineal pain and / or deep dyspareunia and / or vaginal atrophy after at least 90 days from delivary.
3) One or more vulvovaginal symptoms and VAS evaluated before and after treatment.
4) Patients without symptomatic genital infection

2.2.2 Exclusion criteria

The exclusion criteria for the study were as follows

1) Pregnancy
2) Haematuria or urine clotting
3) Alcohol-or drug dependent patients
4) Abscess, fistula or any anatomical anomaly that could interfere with treatment
5) Prolapsed stage >2 according to the pelvic organ prolapsed quantification
6) Use of any form of local therapy within the previous 15 days
7) Uncontrolled psychiatric disorders
8) Cancer

2.3 Description of patients

In the present study, 15 patients were included in the treatment group (treated with fractional CO_2 laser) and 10 patients in the control group (treated with lubricant) for studying postpartum perineal changes during puerperium and breast feeding. They were recruited *via* gynaecology clinic advertisements. Every patient was getting prepared for the process after complete discussion and explanation concerning the nature of the procedure, the feasible disadvantages and advantages along with expected complications.

The enrolled patients were given treatment in the three sessions. Every treatment session followed by a 4 weeks gap. Table (2.1) and (2.2) represent the basic study parameters of treatment and control group, respectively.

Table (2.1) Frequency and percent of the treatment group (treated with laser)

Parameters	**Variables**	**Frequency**	**Percent (%)**
Age	From 18-25 year	08	53.3
	From 26-39 year	07	46.7
Parity	Parity (p1)	08	53.3
	multi parity	07	46.7
Mode of delivery	NVD episiotomy	08	46.7
	NVD	02	20.0
	C/S	05	33.3
Time since Last delivery	Less than 3 months	05	33.3
	More than 3 months	10	66.7
Lactating	Breast feeding	13	86.7
	Artificial feeding	2	13.3

Table (2.2) Frequency and percent for the control group (treated with lubricant)

Parameters	**Variables**	**Frequency**	**Percent (%)**
Age	From 18-25 years	04	40
	More than 25 years	06	60
Parity	Parity (p1)	05	50
	Multiparity	05	50
Mode of delivery	NVD episiotomy	06	60
	NVD	02	20
	Cesarean section C/S	02	20
Time since Last delivery	Less than 3 months	03	30
	More than 3 months	07	70
Lactating	Breast feeding	08	80
	Artificial feeding	02	20

2.4 Clinical Assessment

2.4.1 Physical examination and detailed history

Each enrolled patients were undergone for the physical examination. Detailed history regarding the child birth and any discomfort /symptoms were noted.

General history involving following things was taken

1. Gynaecology history and previous obstetrics involving numerous vaginal deliveries, delivery modes, pelvic prolapse symptoms, etc.

2. Common medical conditions which can impact the puerperium and breast feeding.

2.5 Investigations

Following investigations were done for both the groups

1) Complete blood count
2) Hepatitis tests
3) Covid-19 tests (serological test)
4) General urine examination (GUE)
5) Vaginal pH
6) Vaginal swab

2.4.2 Questionnaire format

The questionnaire asked to complete by all enrolled patients. The format of questionnaire is given in the tabular form table (2.3).

Table (2.3) Questionnaire format

-Name : -Age:

-parity : - Lactating: breast feeding - artificial feeding

-Mode of delivry : - time since last delivary day

-Phone numbe:

-Scor number (10) 0-normal 1-3 mild 4-6 moderate 7-10 sever

Base 0	Symptoms	Before first treatment				After first treatment			
		0	1-3	4-6	7-10	0	1-3	4-6	7-10
Dyspareunia									
Perineal pain									
Dryness									
Pruritus									
Burning									
4 Week	Symptoms	Before second treatment				After second treatment			
		0	1-3	4-6	7-10	0	1-3	4-6	7-10
Dyspareunia									
Perineal pain									
Dryness									
Pruritus									
Burning									
8 Week	Symptoms	Before third treatment				After third treatment			
		0	1-3	4-6	7-10	0	1-3	4-6	7-10
Dyspareunia									
Perineal pain									
Dryness									
Pruritus									
Burning									
12 Week	Symptoms	Before first treatment				After last treatment			
		0	1 – 3	4-6	7-10	0	1-3	4-6	7-10
Dyspareunia									
Perineal pain									
Dryness									
Pruritus									
Burning									

2.6 Specifications of CO_2 laser

Figure (2.2) represents the Femi Med Laser Tell CO_2 laser system. The fractional CO_2 laser specifications were as follows

1	Power output	60W
2	Wavelength	10.6 µm
2	Laser type	UltraPulse; CW; Fractional
3	Spot size	0.12 mm & 1.25 mm (adjustable)
4	Scan size	up to 20 x 20mm^2
5	Cooling	Self-contained, Closed Cycle
6	Stand-by Working	Continuously for 18 hours
7	Electrical Requirements	100-240VAC, 20A max., 50/60Hz
8	Dimension	55 x 65 x 130cm
9	Gross Weight	62 kg

Figure (2.1) Femi Med Laser Tell CO_2 laser system.

2.7 Parameters of treatment

The vaginal and vulvar treatment parameters were noted separately. The images of the instrument during vaginal and vulvar treatment are depicted in the Figure(2.2) and (2.3), respectively. In the vaginal treatment, fractional CO_2 laser utilized with the following :

protocol parameters

Power	40W
Pulse duration	1.0 ms
Distance	1mm
Scan rows	8
scan times	3
scan mode	normal

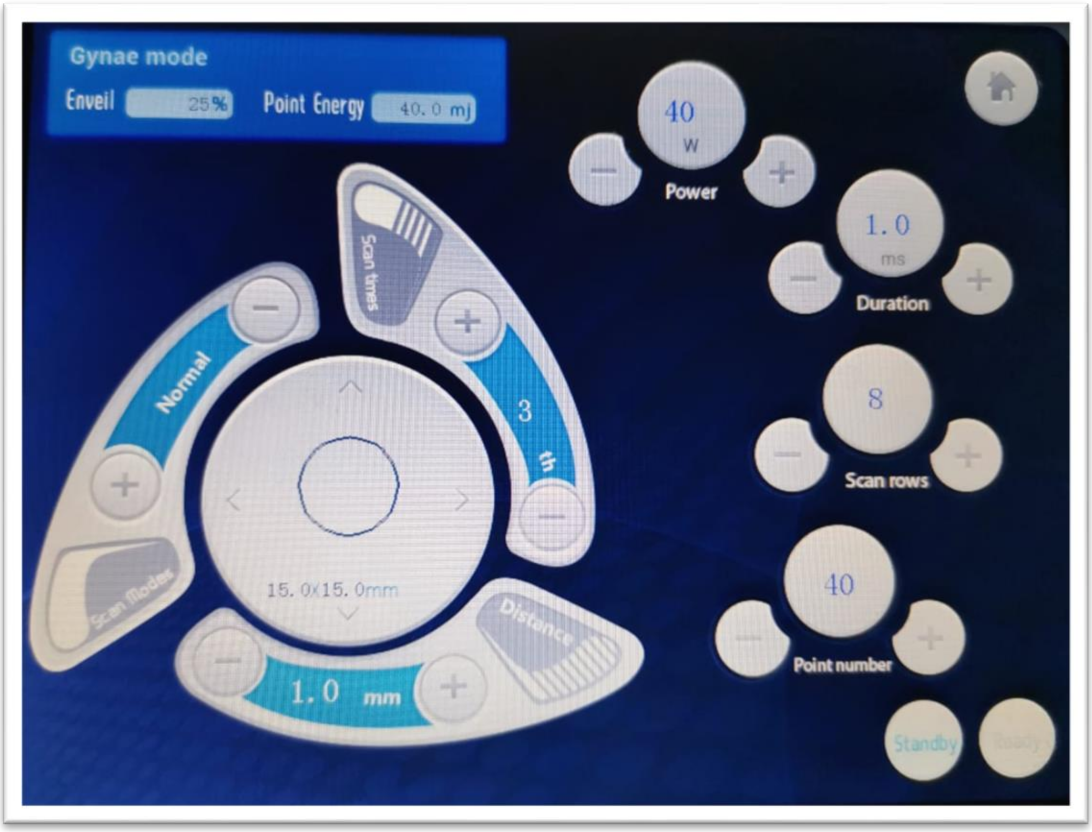


Figure (2.2) Parameters of laser used in the vaginal treatment.

After 15 min of anesthesia vulvar treatment procedure was started. In the vulvar treatment, fractional CO_2 laser utilized with the following protocol parameters

Power	25W
Pulse duration	0.5 ms
Distance	0.5 mm
interval	1.0 ms
scan times	1
Scan mode	Normal

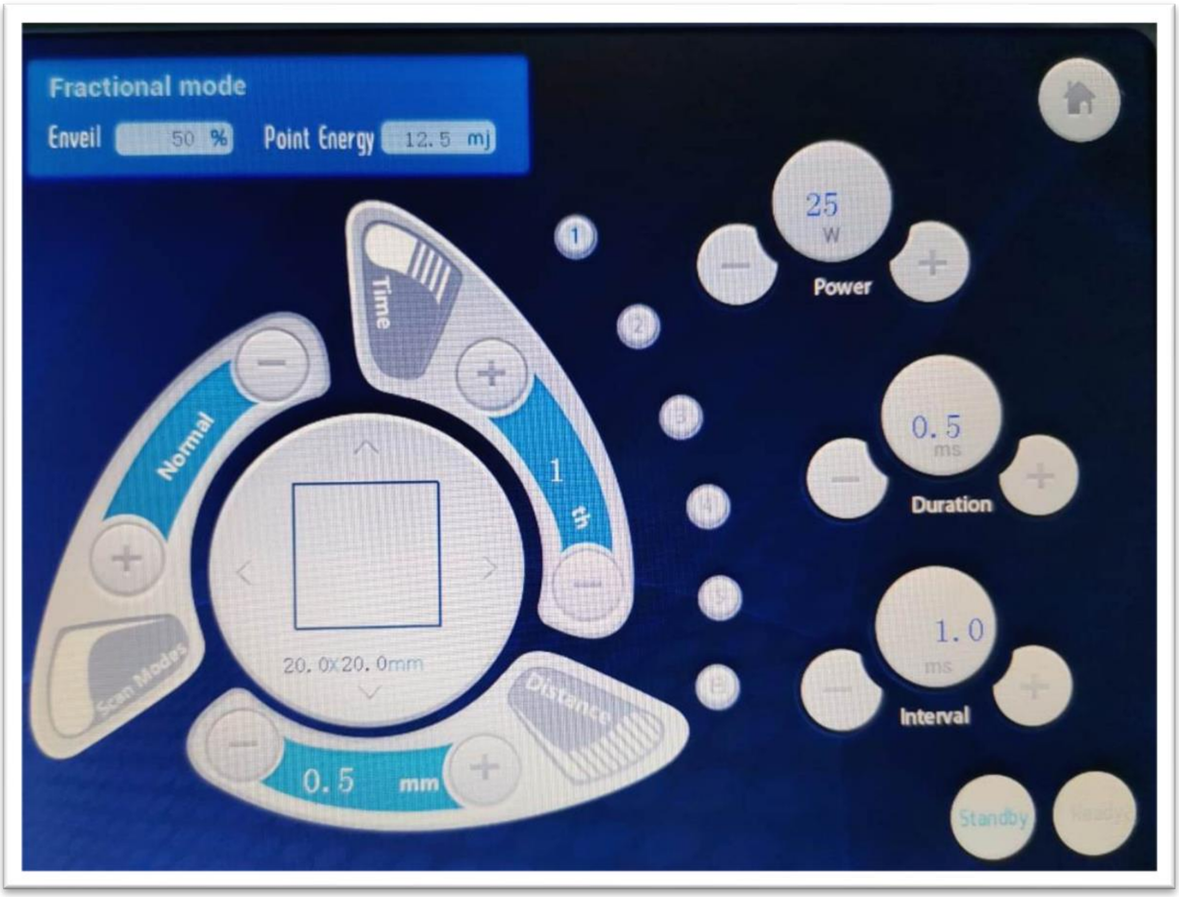


Figure (2.3**)** Parameters of laser used in the vulvar treatment.

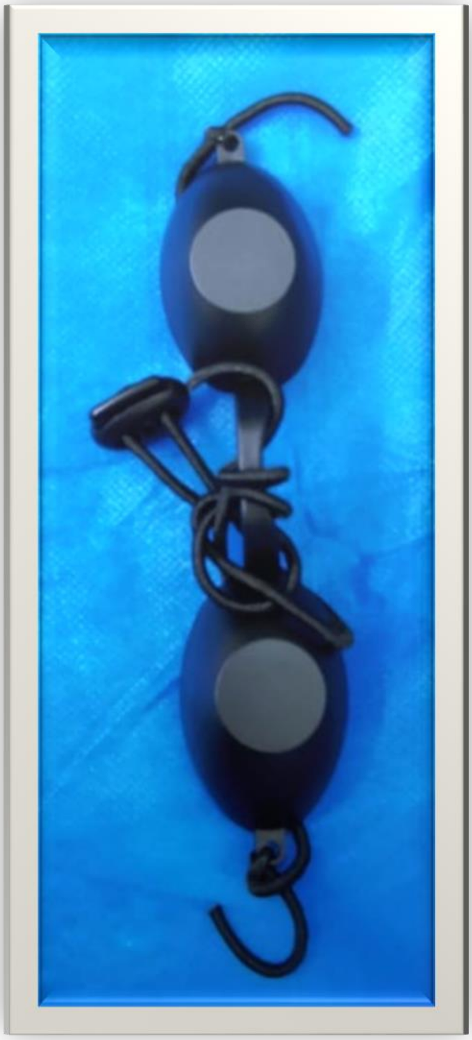
Gynaecological hand piece, speculum cage and lenses are shown in the Figure (2.4).

Figure (2.4) Gynaecological hand piece, speculum cage and lenses.

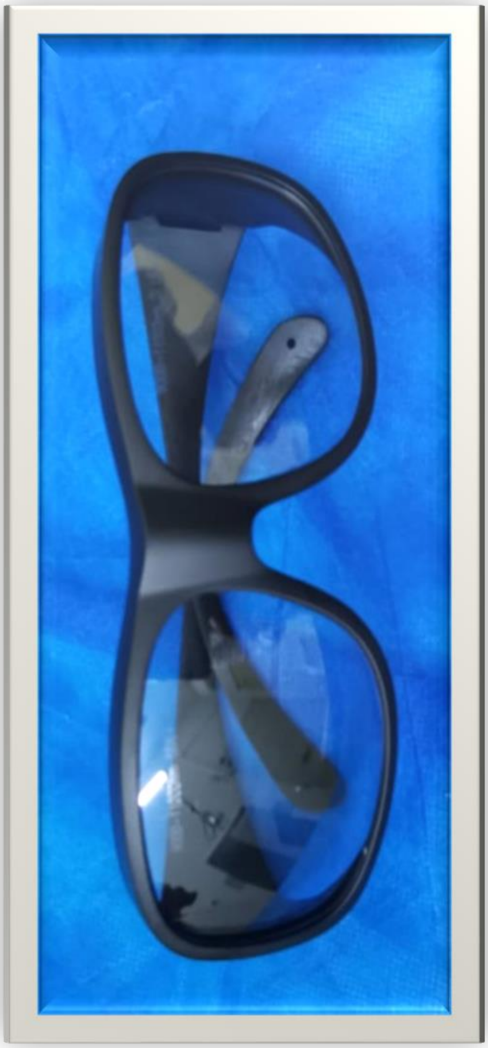
2.8 Measures of safety throughout the procedure

The most proper protective apparatus required to lower potentially hazardous subjection to laser light. Eye protection from laser safety involves full face shields, eye safety filters, goggles and spectacles, etc.

Absorptive materials utilized in the safety eyewear products, construction are made either by absorbing or polycarbonate glass filters, where transmittance of light at a provided wavelength is a material thickness function.



(A) Goggles for the patient.



(B) Eye safety goggles for the doctor.

Figure (2.5) Goggles used in the CO_2 laser treatment.

2.9 Treatment procedure

The instruments used for pH measurement and the swab collection are depicted in the Figure (2.6).

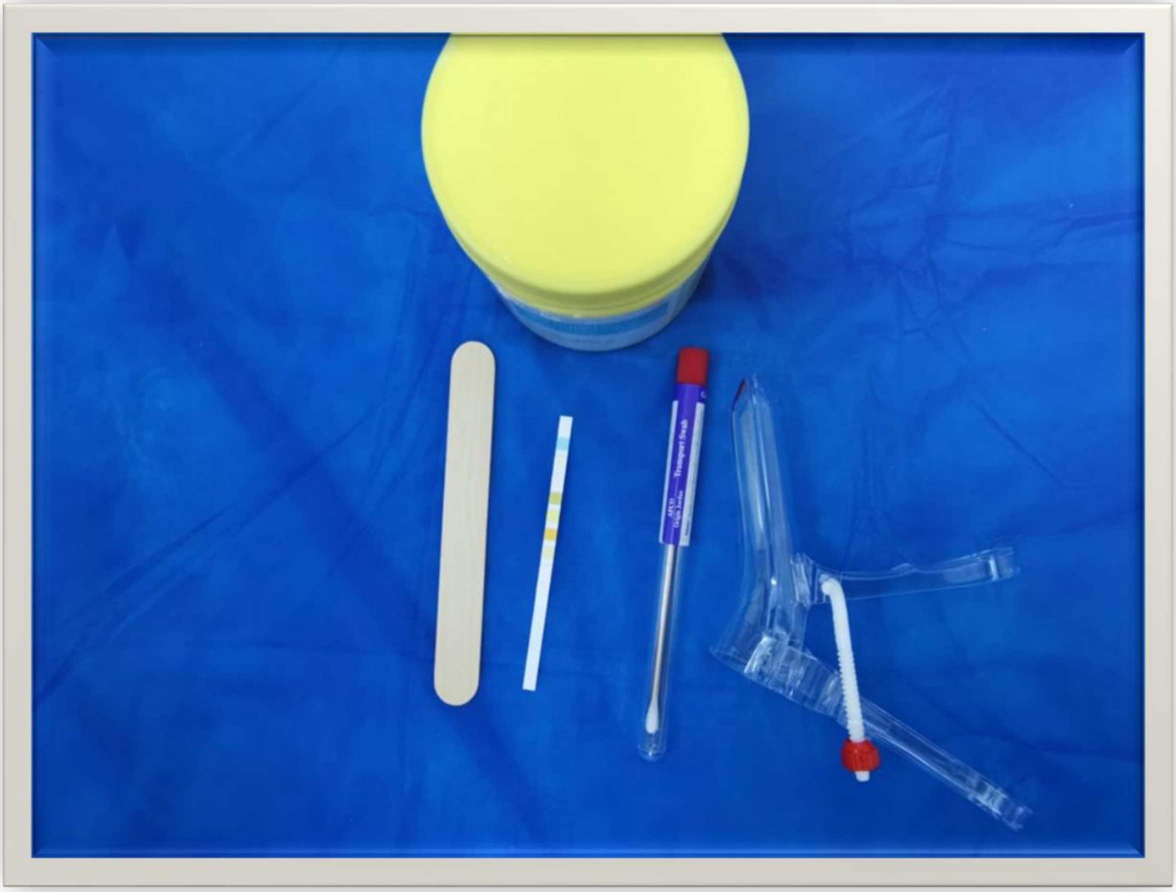


Figure (2.6) Instruments used for pH measurement and the swab collection.

The treatment procedure were as follows

1. After few days of menstruation .
2. The patients were then asked to evacuate her bladder before start the procedure.
3. The patient asked for lay down in lithotomy position.
4. The vagina was cleaned by mobbing with a cotton piece soaked with normal saline. Topical anesthetic cream 5% Emla cream containing lidocaine (2.5%)

and prilocaine (2.5%)] was applied at the level of vaginal orifice. Further, ask the patient to wait 15 minutes for the area to be anaesthetized.

5. Laser proper goggles were wear by physician, patient and if in the room anyone present to protect eyes.

6. The laser beam was emitted from a 360° vaginal probe gently inserted up to the level of the vaginal fundus, to emit multiple laser spots while progressively extracting the probe from the vaginal fundus. Each treatment consists of two passages.

7. For vulvar treatment, the laser pulse beam was applied to the external perineal area, in particular, the scarred skin of the episiotomy or previous lacerations. Just one passage.

8. The operative time taken about 15 minutes to complete.

9. No specific postoperative instructions required only avoiding intercourse for 5 days after treatment and returning for the next session in the scheduled time.

Figure (2.7) depicts the laser treatment procedure .**[**49**]**

2.10 Follow up

After treatment, the patients enrolled in both the groups were monitored for four weeks. After each 4 weeks, the next treatment procedure was followed. Three treatment sessions were done. After each session, the assessment was recorded in the study.

Chapter Three

Results, Dissection,

Conclusion

And Recommendation

3.1 Results

In the present study, postpartum perineal changes during puerperium and breast feeding period were evaluated in the Tikrit city . It is a case-control study (n=25) in which treatment group (n=15) was treated with laser. The results of the study were given in this chapter.

3.1 .1Specification of study groups

All 25 patients (100%) have finished their follow up for 4 weeks after the treatment. The main age with standard deviation (SD) Non-significant difference was observed between control (28 ± 6.75) and treatment group (26.93 ± 6.12). In the mode of delivery, C/S was found to be less (20.00%) in the control group than the treatment group (33.33%). NVD episiotomy and NVD along were maximum in the control group as compared to the treatment group. In the treatment group, maximum number patients showed less than three parities as compared to the control group. The pattern was reversed in the parity for more than three. All the patients enrolled in the treatment group showed more time since last delivery. Correlation among mode of delivery and breast feeding with time is given in the Table (3.1).

Table (3.1) Correlation among the studied parameters

No	**Variants**	**Percent (%)**
1	Less than 3 months / NVD episiotomy	62.5
2	More than 3 / NVD episiotomy	37.5
3	Less than 3 month / breast feeding	23.07
4	More than 3 month / breast feeding	76.92

Table (3.2) Specification of study groups

No.	Parameters	Sub-parameters	Treatment group (n=15)	Control group (n=10)
1	Age		26.93 ± 6.12	28 ± 6.75
2	Mode of delivery	C/S	05 (33.33%)	02 (20%)
		NVD episiotomy	08 (53.33%)	06 (60%)
		NVD	02 (13.33%)	02 (20%)
3	Parity	01	08 (53.33%)	05 (50%)
		02	02 (13.33%)	01 (10%)
		03	02 (13.33%)	01 (10%)
		More than 3	03 (20.00%)	03 (30%)
4	Time since Last delivery	Less than 3 months	05 (33.33%)	03 (30.00%)
		More than 3 months	10 (66.66%)	07 (70.00%)

3.1.2 Data of treatment and control groups

The study parameters before and after treatment of treatment and control groups are depicted in the Table (3.2) and (3.3), respectively.

Table (3.2)Treatment group data (n=15)

NO.	**Dyspareunia**		**Perineal pain**		**Dryness**		**Pruritus**		**Burning**		**PH**	
	B	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**
1	6	2	2	1	4	2	4	1	5	1	8	6.5
2	6	2	5	2	5	2	4	1	5	1	7	6.5
3	4	2	4	1	6	1	7	1	6	1	8	6
4	6	2	6	3	5	2	5	2	6	2	7	6
5	7	3	7	3	2	1	4	1	4	1	7	5
6	8	3	8	2	4	1	5	1	3	1	7	6
7	8	2	7	3	4	1	5	1	4	1	8	6
8	8	3	7	2	5	2	4	1	5	2	7	5
9	6	3	7	2	5	2	4	1	4	1	7	6
10	8	3	7	3	2	1	4	0	4	1	7	5

11	6	2	6	2	4	1	3	1	5	1	7	5
2	6	2	7	2	4	2	3	1	4	2	7	5
13	6	2	5	2	5	2	4	1	4	2	7.5	6
14	7	3	5	2	5	2	4	1	4	1	7	7
15	7	1	6	2	2	2	3	1	5	2	7	6
Sum	99	35	89	32	62	24	63	15	68	20	108.5	87
Mean	6.6	2.33	5.9	2.1	4.1	1.6	4.2	1.0	4.5	1.3	7.23	5.8

A = After

B = Before

Table (3.3) Control group data (n=10)

NO.	Dyspareunia		Perineal pain		Dryness		Pruritus		Burning		PH	
	B	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**
1	6	6	7	6	4	3	6	5	6	4	7	6
2	6	6	6	5	5	4	3	2	5	3	7	7
3	6	5	4	3	5	4	4	2	4	2	8	7
4	6	6	6	5	3	3	3	3	6	4	7	7
5	6	4	5	4	7	7	4	4	5	2	7	6
6	7	7	6	5	5	5	5	4	7	2	8	8
7	7	8	7	6	3	3	4	4	5	4	7	7
8	7	7	5	4	3	3	3	2	5	1	7	7
9	6	6	6	5	4	4	4	4	5	2	7	7
10	7	7	7	6	4	4	5	5	4	1	8	8
Sum	64	62	59	49	43	40	41	35	52	25	73	70
Mean	6.4	6.2	5.9	4.9	4.3	4	4.1	3.5	5.2	2.5	7.3	7

3.1.3 Analysis of symptoms in the control and treatment groups

The study group symptoms before and after treatment is depicted in the Table (3.4). Non-significant difference was observed in the control and treatment groups before treatment for dyspareunia, perineal pain, dryness, pruritus, burning and pH. Significant improvement in the dyspareunia (6.60-2.30) (p.v = 0.001), perineal pain(5.93-2.10) (p.v = 0.003), dryness(4.13-1.60) (p.v = 0.000), pruritus (4.26-1.00) (p .v= 0.000), burning (4.53-1.33) (p.v = 0.000) and pH (7.20-5.86) (p.v = 0.000) were observed after the laser treatment as compared to the control group.

While the control group showed not significant improvement for vaginal atrophy, perianal pain and statistically significant improvement for burning.

Table 3.4 Analysis of various symptoms in the study group

No.	Symptoms	Treatment	Treatment group	Control group
1	Dyspareunia	Before	6.60 ± 0.724	6.4 ± 0.991
		After	2.30 ± 0.211	6.2 ± 0.211
		p value	0.001	0.283
2	Perineal pain	Before	5.93 ± 0.884	5.9 ±0.224
		After	2.10 ± 0.000	4.9 ± 0.771
		p value	0.003	0.961
3	Dryness	Before	4.13 ± 0.632	4.3 ± 0.852
		After	1.60 ± 0.000	4 ± 0.861
		p value	0.000	0.884
4	Pruritus	Before	4.26 ± 0.775	4.1 ± 0.937
		After	1.00 ± 0.000	3.5 ± 0.453
		p value	0.000	0.681
5	Burning	Before	4.53 ± 0.258	5.2 ± 0.719
		After	1.33 ± 0.000	2.5 ± 0.668
		p value	0.000	0.001
5	pH	Before	7.20 ± 0.724	7.3 ± 0.19
		After	5.86 ± 0.258	7 ± 0.934
		p value	0.000	0.492

3.1.4 Visual analog scale score of the studied group

Figure (3.1) represents the study parameters before and after laser treatment in the treatment group. All the parameters showed significantly decrease in the visual analog scale score after laser treatment.

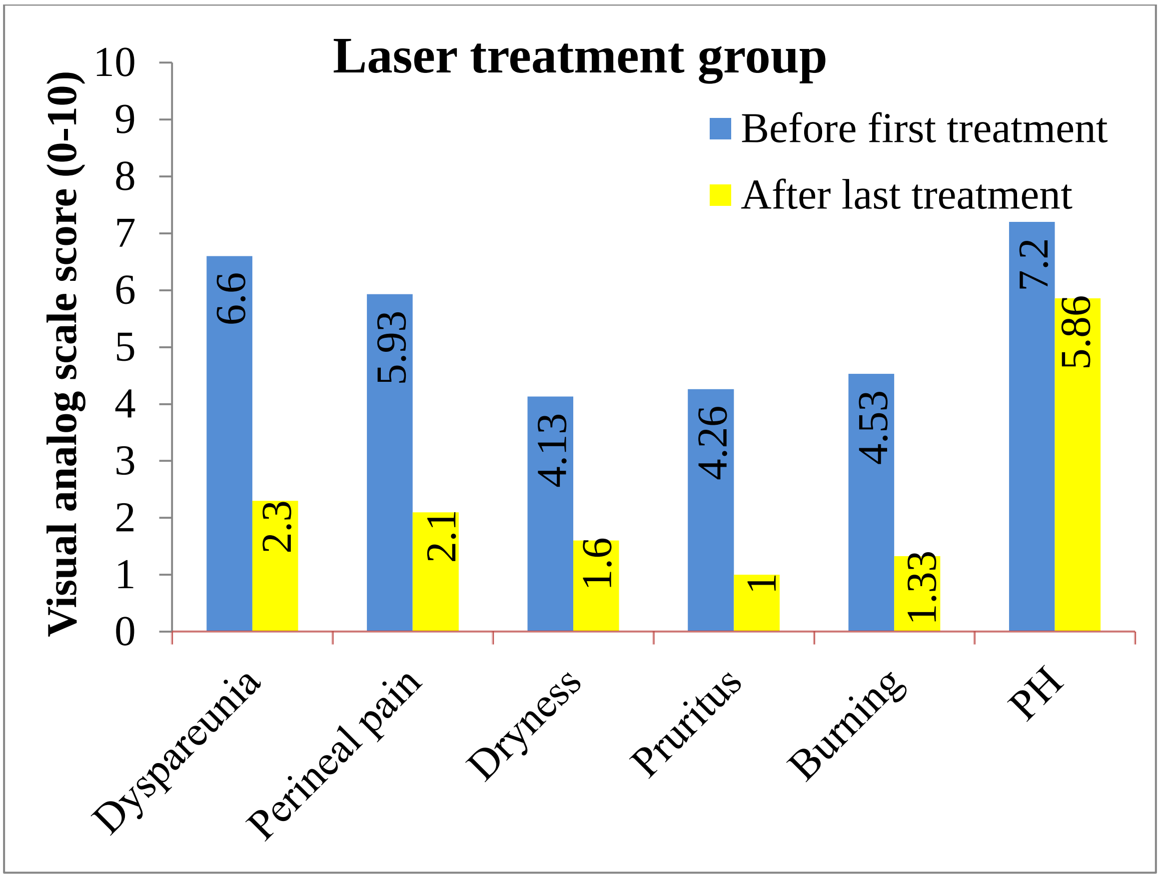


Figure (3.1) Study parameters before and after laser treatment in the treatment group.

Figure (3.2) represents study parameters before and after lubricant treatment in the control group. All the parameters were non-significantly differs in the both before and after treatment in the control group.

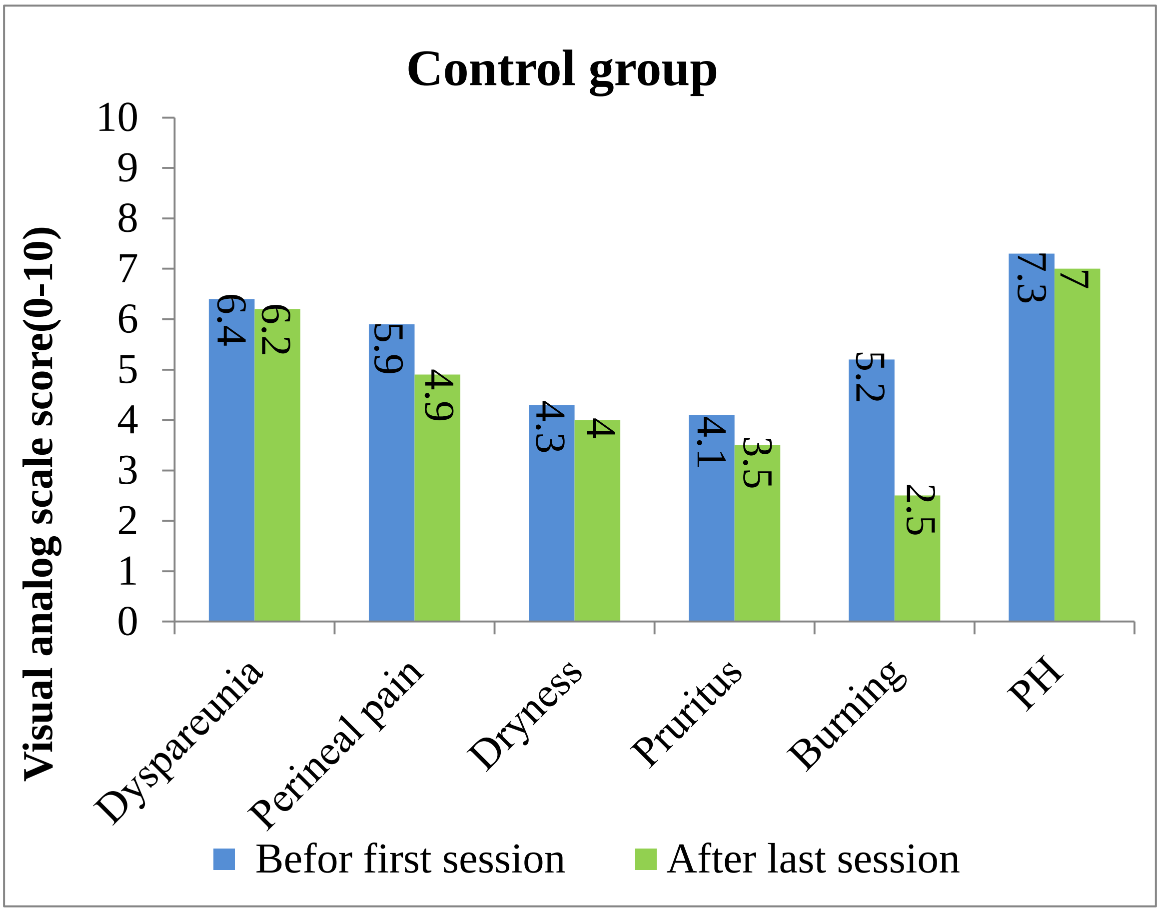


Figure (3.2) Study parameters before and after lubricant treatment in the control group.

Figure (3.3) represents study parameters of control and treatment groups. All the parameters showed decrease visual analog score values in the laser treatment group as compared to control group.

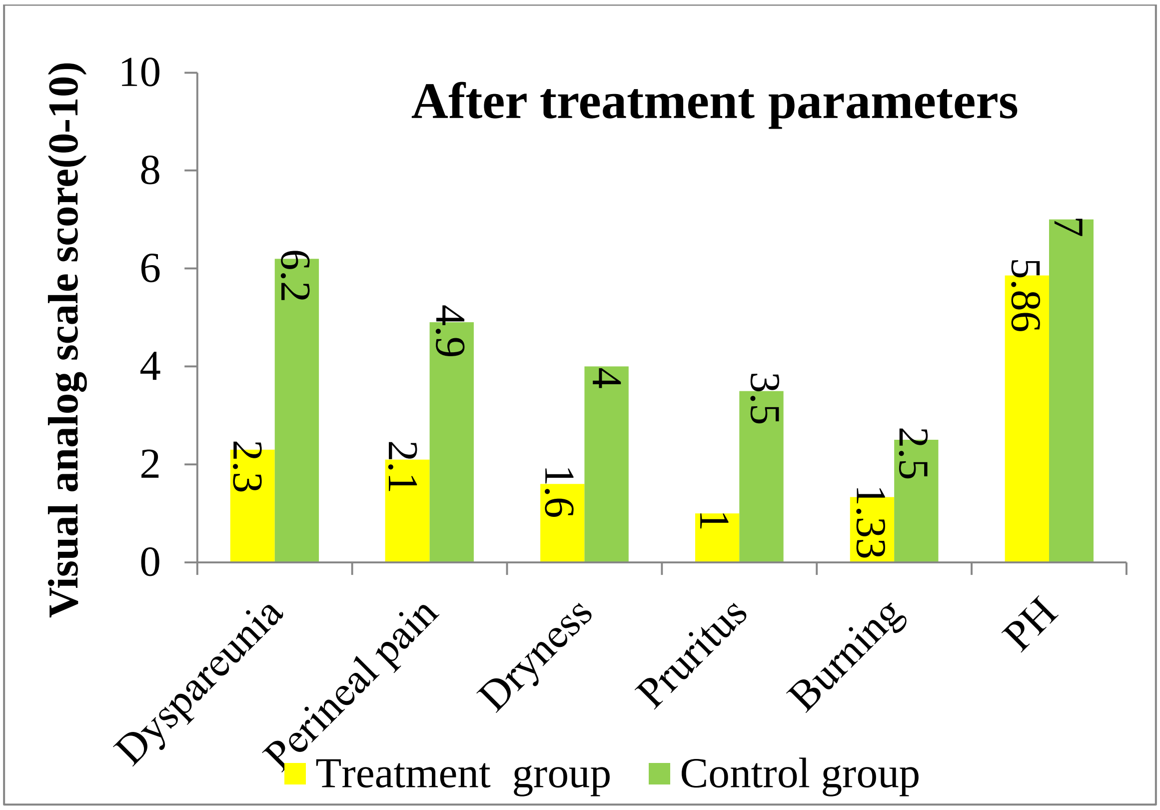


Figure (3.3) Study parameters of both control and treatment groups after treatment.

3.2 Discussion

Laser photo thermal energy can reduce tissue inflammation and the related symptoms by intervening in cellular signaling which responsible for pain transmission.[48]

The efficacy of micro- ablative fractional CO_2 laser stimulate fibroblast, collagen and angiogenic activity, an increase in glycogen, a decrease in vaginal pH ,and a reduction in dryness, so allowing an improvement in quality of life.

The same mechanism neocollagenesis leads to an increase in epithelial thickness, removing the nociceptors from the surface, and a subsequent reduction in the pain chronic syndrome.[49]

Breastfeeding and pregnancy indicates a very difficult period for women because of a number of causes: delivery related mechanical trauma, hormonal changes and psychological changes. In our study 62% of women delivered normally with episiotomy showed correlation with less than 3 months delivery time this mean the symptoms dyspareunia and perineal pain related to the episiotomy, while, around 76.92% of breastfeeding women showed correlation with more than 3 months delivery time this mean the perineal symptoms changes related to the reduction in the hormonal level due to the high level of prolactin, result in physiological transient loss of estrogen.

Since 2015 a growing number studies have been published the use of laser treatment for gynaelogical conditions such as postpartum perineal symptoms.

Farage et al [50] evaluated vaginal pH at 4 anatomic sites, i.e. vaginally and at the introitus, the labia minora, and the labia majora. Differences in pH were small (not reaching statistical significance), however, within each test group, women who claimed sensitive genital skin tended to demonstrate a higher pH vaginally and at the introitus compared to those who did not claim sensitive skin Farage et al., [50] . Vaginal PH in our study is according to this report.

perineal pain and dyspareunia are generally described symptoms in the period of postpartum, chiefly because of vacuum or forceps use at delivery, episiotomy, and postpartum tears and perineal trauma .[51,52,53]

Additionally, the data from literature indicate that breastfeeding women encounter dyspareunia post delivery 6 months more regularly than women who utilize artificial feeding Rowland et al., .[54]

Perineal pain and dyspareunia seem to be generated because of lowering in thickness of mucosa which exposes receptors of pain to the surface, generating nerves hypersensitivity Filippini et al.,[55]. It is reported that CO_2 laser treatment is safe and effective and tolerated well Filippini et al., [55]

Filippini et al.,[55] assessed the efficiency of CO_2 laser in women having perineal postpartum symptoms, gaining significant results in terms of vaginal burning, itching, vaginal dryness, pain at introitus and dyspareunia which are similar with the present study results as got significant results on treatment with CO_2 laser on symptoms like vaginal pH, vaginal burning, pruritus, vaginal dryness, perineal pain and dyspareunia. The most crucial benefit of the treatment is that it is well tolerated and noninvasive. In fact, for the laser light nature, this therapy is painless, since the beam of laser penetrates only a few of hundred microns.

Luvero et al.,[56] got significant results on the use of CO_2 laser treatment in perineal changes throughout the breastfeeding and puerperium which were similar with the present study results. They found similar significant changes in dyspareunia, pain at the vaginal orifice, dryness, itching, heat, burning. The life's quality for women throughout puerperium and breastfeeding is very critical from both prospectives of physical and psychological well being.

3.3 Conclusions and Recommendations

This study has shown the effectiveness of fractional CO_2 laser treatment in postpartum perineal changes when specific protocol and parameters used in the study. However, our results should be considered promising, but preliminary. In the future, the study protocol will need to be tested in a larger cohort of patients to confirm its application in clinical practice.

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وزارة التعليم والبحث العلمي

جامعة بغداد

معهد الليزر للدراسات العليا

التأثير الايجابي للعلاج بليزر ثنائي اوكسيد الكربوني التجزيئي على التغيرات العجانية خلال فترة النفاس والرضاعة الطبيعية

دراسة مقدمة الى معهد الليزر للدراسات العليا / جامعة بغداد كجزء من متطلبات نيل درجة الدبلوم العالي في تطبيقات الليزر في الطب /النسائية والتوليد

من قبل

شذى خليل ياسين

بكالوريوس طب وجراحة عامة /جامعة هولير ١٩٩٠

دبلوم عالي نسائية وتوليد جامعة بغداد ١٩٩٧

بأشراف

الدكتورة منال ابراهيم مزعل

بكالوريوس طب وجراحة عامة

زميلة المجلس العراقي لاختصاص النسائية

زميلة المجلس العربي لاختصاص النسائية

دبلوم عالي في الليزر/النسائية

١٤٤٣ هـ ٢٠٢٢ م

الملخص

الخلفية:- النفاس او فترة ما بعد الولادة هي الفترة التي تلي الولادة وتستمر عادة ستة اسابيع وتستعيد فيها التغيرات الفسيولوجية والتشريحية للحمل الى الحالة الطبيعية قبل الحمل .

الاهداف :- الهدف من هذه الدراسة تقييم فعالية ليزر ثنائي اوكسيد الكربوني التجزيئي في علاج التغيرات العجانية بعد الولادة خلال فترة النفاس والرضاعة الطبيعية.

المواد والطرق :- اجريت هذه الدراسة في عيادة الامراض النسائية الخاصة في مدينة تكريت من شهر ايلول ٢٠٢١ الى كانون الثاني ٢٠٢٢ شملت الدراسة ٢٥ امرأة قسمت الى مجموعتين وكانت المجموعة الاولى ١٥ امرأة في مجموعة العلاج بينما المجموعة الثانية هي المجموعة الضابطة وعددها ١٠ نساء لدراسة التغيرات العجانية بعد الولادة واثناء النفاس والرضاعة الطبيعية تم علاج المجموعة الاولى باستخدام ليزر ثنائي اوكسيد الكربوني التجزيئي بينما عولجت المجموعة الضابطة بمادة تشحيم (بدون معالجة بالليزر) وتم تقييم الاعراض المختلفة مثل عسر الجماع والم العجان والجفاف والحكة والحرق ودرجة الحموضة على مقياس النظير البصري وكانت على ثلاث جلسات في كل جلسة علاج تتبعها فجوة اربعة اسابيع وكانت معلمات ليزر ثنائي اوكسيد الكربوني التجزيئي المستخدمة هي الطول الموجي ١٠٦٠٠ نانومتر بطاقة ٤٠ واط ، المدة ١ملي ثانية والمسافة ١ ملم ،وضع المسح العادي للعلاج المهبلي بينما في علاج الفرج كانت المعلمات بطاقة ٢٥ واط ،ومدة النبض ٠.٥ ملي ثانية والمسافة ٠.٥ ملم .

النتائج:- كانت نتيجة عسر الجماع بنسبة (٦.٦٠-٢.٣٠) والم العجان (٥.٩٣-٢.١٠) والجفاف (٤.١٣-١.٦٠) والحكة (٤.٢٦- ١.٠٠) والحرق (٤.٥٣- ١.٣٣) ودرجة الحموضة (٧.٢٠ -٥.٨٦) حيث وجد تحسن وبشكل ملحوظ في مجموعة العلاج بالليزر مقارنة بالمجموعة الضابطة ، اظهرت الولادة الطبيعية (قص العجان) ارتباط بنسبة ٦٢.٥ % و٣٧.٥ % مع فترة الولادة الاقل من ثلاث اشهر واكثر من ثلاث اشهر على التوالي بينما اظهرت الرضاعة الطبيعية ارتباط بنسبة ٢٣.٧ % و ٧٦.٩٢ % مع فترة الولادة الاقل من ثلا ث اشهر واكثر من ثلاث اشهر على التوالي .

الخلاصة / اظهرت هذه الدراسة العلاج بالليزر ثنائي اوكسيد الكربوني التجزيئي هي طريقة سهلة و فعالة لعلاج التغيرات العجانية بعد الولادة مع تأثير جانبي اقل .