Ministry of Higher Education and Scientific Research
University of Baghdad
Institute of Laser for Postgraduate Studies

Fractional CO_2 Laser for Treatment of Vulvovaginal Atrophy Symptoms and Vaginal Rejuvenation

A dissertation Submitted to the Institute of Laser For Post Graduate Studies - University of Baghdad In Partial Fulfillment of the Requirement for the Degree of Higher Diploma in Laser in Medicine/ GYNECOLOGY

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بسم الله الرحمن الرحيم

تَبَارَكَ الَّذِي بِيَدِهِ الْمُلْكُ وَهُوَ عَلَىٰ كُلِّ شَيْءٍ قَدِيرٌ

صدق اللهُ العظيم

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Certification

I certify that this dissertation (**Fractional CO_2 laser treatment for vulvo-vaginal atrophy symptoms and vaginal rejuvenation**) was prepared under my supervision at the Institute Of Laser For Postgraduate Studies, University Of Baghdad, as a partial fulfillment of the requirements for the degree of Diploma in Laser in Medicine/ Obstetrics and Gynecology Surgery.

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Dedicated to

My family

Nadia

Acknowledgements

Thanks **God** who granted me this chance for giving me power and support to finish this work.

I would like to express my gratitude to to my supervisor Assistant Professor **Dr. Ali Shukur Mahmood, the** Institute of Laser for Postgraduate Studies, University of Baghdad, for his encouragement, help, and his support during the study and research work.

Also I present my great thanks and appreciation to my supervisor **Dr. Shatha Atrah**. Iam very grateful to her help and valuable advices .

I wish to express my deep appreciation to **Dr. Layla M. H. Al. Amery, the** Institute of Laser for Postgraduate Studies, University of Baghdad for her encouragement and support.

Great respect is to **Dr. Mahmood Shakir**, Asst.Dean of the Institute of Laser for Postgraduate Studies, for his help and cooperation.

Iam deeply grateful to Assistant Professor **Dr. Hussein A. Jawad** for his valuable advices and encouragement.

Great thanks to **Dr. Ahmed M. Hasan** for his support and advices.

My thanks extended to Department of Biomedical Laser Application, Laser Institution for Postgraduate Studies for their help and cooperation especially to Assisstant Lecturer **Noor Taha Ismaeel.**

Nadia

ABSTRACT

Background: Vulvovaginal atrophy is a condition that affects menopausal women, although it is mainly associated with the onset of menopause mainly due to hormonal changes vulvovaginal laxity and mucosal atrophy can also affect women at different life stages. This condition negatively influences quality of life. Fractional CO_2 laser (10600nm) is the recent method for treatment of vulvovaginal atrophy symptoms in women.

The Objectives: The purpose of the study was to evaluate the efficacy of fractional CO_2 laser (10600nm) in the treatment of vulvovaginal atrophy symptoms and for vaginal rejuvenation.

Materials & Methods: This study was done in laser medicine research clinics of institute of laser for postgraduate studies from July 2019 to end of September 2019. Twelve females with vulvovaginal atrophy symptoms were enrolled in this study, their ages ranged from 42-56 years old. The laser parameters used were CO_2 laser wavelength 10600 nm, power 30 watt, duration 1.7ms, Point number 28, distance 1.0 mm, scan mode normal, scan times 4^{th} and scan Rows 5.

Results: Most of the twelve women included in the study 75 % (n.9) reported satisfaction with treatment after 2 sessions of CO_2 laser four weeks a part .

Conclusion: fractional CO_2 laser treatment is an effective method with less side effect.

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LIST OF ABBREVIATIONS

Abbreviations	Item
A	Area
Arf laser	Argon fluoride laser
Cm	Centimeter
CO2	Carbon dioxide
CW	Continuous wave
E	Energy
(Er):YAG	Erabium yag
ERs	Estrogen receptors
F	Focal length
Fs	Femtosecond
H	Plank constant 6.626×10^{-34} joule/sec
Hz	Hertz
I	Irradiance
J	Joule
µW	Microwatt
Mm	Millimeter
m W	Miliwatt
Nd:YAG	neodymium: Yttrium-Aluminum-Garnet
Nm	Nanometer
OD	Optical density
P	Power

p g/mL	Pico gram per mill
PDT	Photodynamic therapy
PRP	platelet rich plasma
Ps	Picosecond
RF	Radiofrequency
sec.	Second
SP	Super pulse
T	Time
Uv	Ultraviolet
V̒	Frequency
W	Watt
Λ	Wavelength
VHI	Vaginal health index
VHIS	Vaginal health index score
VMI	Vaginal maturation index
VRS	Vaginal relaxation syndrome
VVA	Vulvo-vaginal atrophy

Chapter One

Introduction and Basic Concepts

1.1 INTRODUCTION

The development of basic sciences in the past century has had a substantial impact on the progress of numerous technologies, which in turn has played an extremely important role in various fields of practical life. Among these technologies are laser radiation and its use in medicine for diagnosis and therapy. [1]

Laser now widely used for medical, scientific, commercial, and industrial applications. Laser beams can be extremely hazardous if not understood and property controlled, in 1964, CO_2 laser was developed at Bell laboratories. [1]

Laser CO_2 which has already gained popularity in dermatologic and esthetic surgery uses a wavelength (10,600 nm) having high water absorption which could ablate and coagulate vaginal and vulvar tissues. This stimulates neocollagenesis, and neovascularization and thus improves vaginal lubrication by revitalizing and restoring the elasticity and hydration of the female lower genital tract mucosa.[2]

1.2 Vulvovaginal atrophy

Vulvovaginal atrophy is a condition that affects women, although it is mainly associated with the onset of menopause mainly due to hormonal changes vulvovaginal laxity and mucosal atrophy can also affect women at different life stages such as after pregnancy or for cancer patients who have undergone chemo or endocrine therapy . This condition negatively influence quality of life, sexual desire, and self-confidence.

In 2014, the International Society for the Study of Women's Sexual Health and the North American Menopause Society agreed that "genitourinary syndrome of menopause" is a more inclusive and accurate term to describe the conglomeration of external genital, urological, and sexual sequelae caused by hypoestrogenism during menopause.[3] ,so its defined as chronic,progressive vulvovaginal, sexual, and lower urinary tract condition characterized by a host of symptoms secondary to a clinical state of hypoestrogenism after onset of menopause. These genitourinary changes are a response to the decreased level of circulating estrogen caused by ageing. [3]

The hypoestrogenic environment leads to significant tissue changes such as loss of collagen, elastin, and smooth muscle in the genital/vaginal tissues resulting in thinning of the vaginal epithelium, diminished blood flow, elasticity, and rogation[4] . Morphological changes lead to atrophic genitalias causing irritation, itching, burning, dyspareunia, and contact bleeding [5].

1.2.1 Anatomy of the vagina

The vagina is a fibromusculomembranous sheath communicating the uterine cavity with the exterior at the vulva.

It constitutes the excretory channel for the uterine secretion and menstrual blood. It is the organ of copulation and forms the birth canal of parturition. The canal is directed upwards and backwards forming an angle of 45° with the horizontal in erect posture. The long axis of the vagina almost lies parallel to the plane of the pelvic inlet and at right angles to that of the uterus as shown in figure 1.1.

The diameter of the canal is about 2.5 cm, being widest in the upper part and narrowest at its introitus. It has got enough power of distensibility as evident during childbirth.[6]

Vagina has got an anterior, a posterior and two lateral walls. The anterior and posterior walls are opposed together but the lateral walls are comparatively stiffer especially at its middle, as such, it looks “H” shaped on transverse section. The length of the anterior wall is about 7 cm and that of the posterior wall is about 9 cm.[7] .

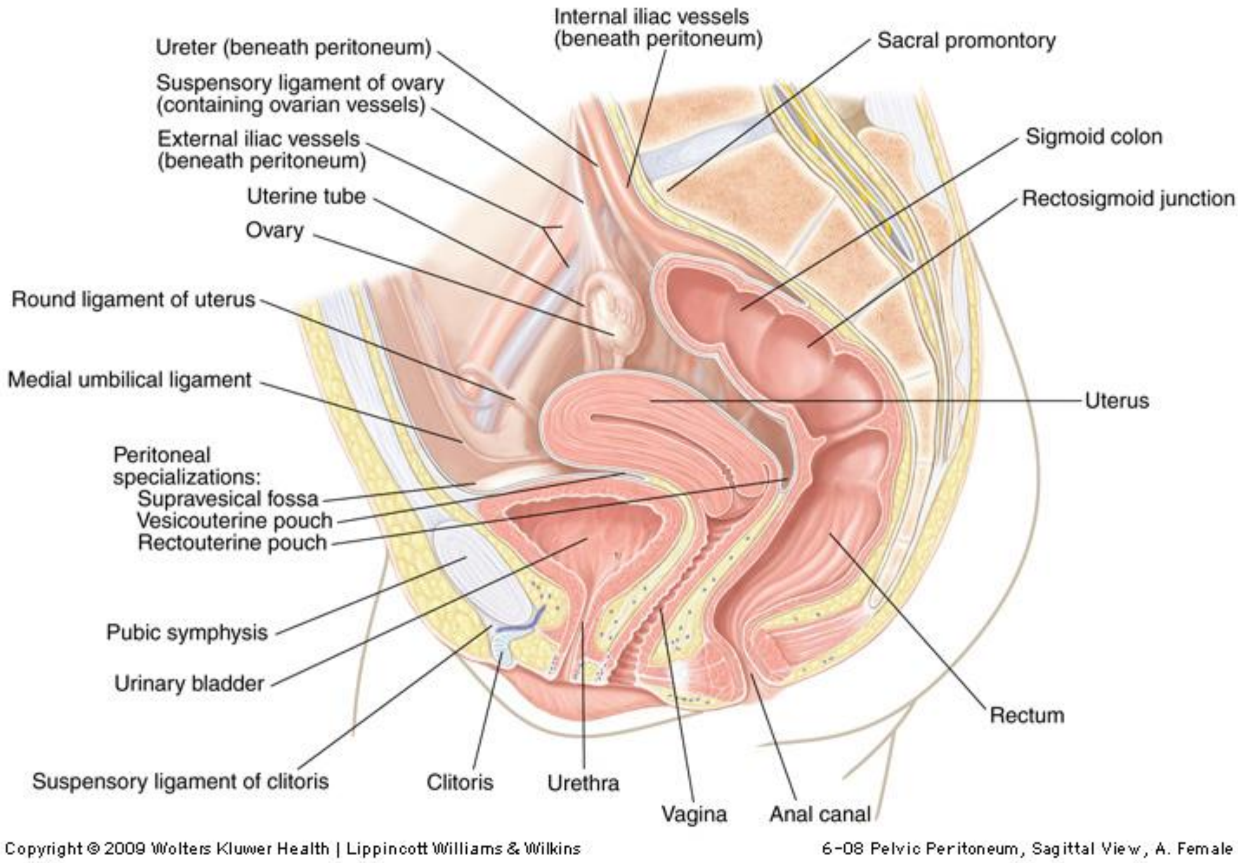


Figure 1.1: Midsagittal section of the female pelvis showing relative position of the pelvic organs [8]

Layers of the vagina from within outwards are mucous coat which is lined by stratified squamous epithelium without any secreting glands. submucous layer of loose areolar vascular tissues.muscular layer consisting of indistinct inner circular and outer longitudinal muscles and the fibrous coat derived from the endopelvic fascia and is highly vascular.[7]

1.2.2 The prevalence of vulvo vaginal atrophy (VVA)

The prevalence of VVA ranged from about 4% in the early premenopausal groups to 47% in the late postmenopausal group.In a cohort of breast cancer survivors, vaginal dryness was present in 23.4% of the premenopausal patients and in 61.5% of the postmenopausal patients. [9,10]

1.2.3 Pathophysiology of vulvo vaginal atrophy

Vulvovaginal atrophy occurs under conditions of hypoestrogenism. In the premenopausal state, estradiol levels fluctuate from 10 to 800 pg/mL depending on when measured during the cycle. In the postmenopausal state, estradiol levels are typically less than 30 pg/mL. After menopause, circulating estradiol derives from estrone, which is peripherally converted in adipose tissue from adrenal androstenedione. The vaginal epithelium is a stratified squamous epithelium, which until menopause is moist and thick with rugae (The formation of rugae aids in expandability, distensibility, and lubrication of the vagina during sexual stimulation).[11]

At menopause, with declining levels of estrogen, the vaginal epithelium thins. Fewer epithelial cells result in less exfoliation of cells into the vagina. As epithelial cells exfoliate and die, they release glycogen, which is hydrolyzed to glucose. Glucose, in turn, is broken down into lactic acid by the action of lactobacillus, a normal vaginal commensal organism. Without this cascade, the pH in the vagina rises, resulting in a loss of lactobacilli and an over growth of other bacteria, including group B streptococcus, staphylococci, coliforms, and diphtheroids (figure 1.2). These bacteria can cause symptomatic vaginal infections and inflammation. After menopause, the elasticity of the vagina is reduced and connective tissue increases. A decline in estrogen level causes a decrease in vaginal blood flow and a decrease in vaginal lubrication(Vaginal lubrication is caused by fluid transudation from blood vessels, and from endocervical and Bartholin glands).These changes can be reversed by the use of estrogens.[11]

Hypoestrogenism has both vulvovaginal and urologic effects; urogenital tissue receptors are dependent on endogenous estrogen levels to maintain normal physiology .[12]

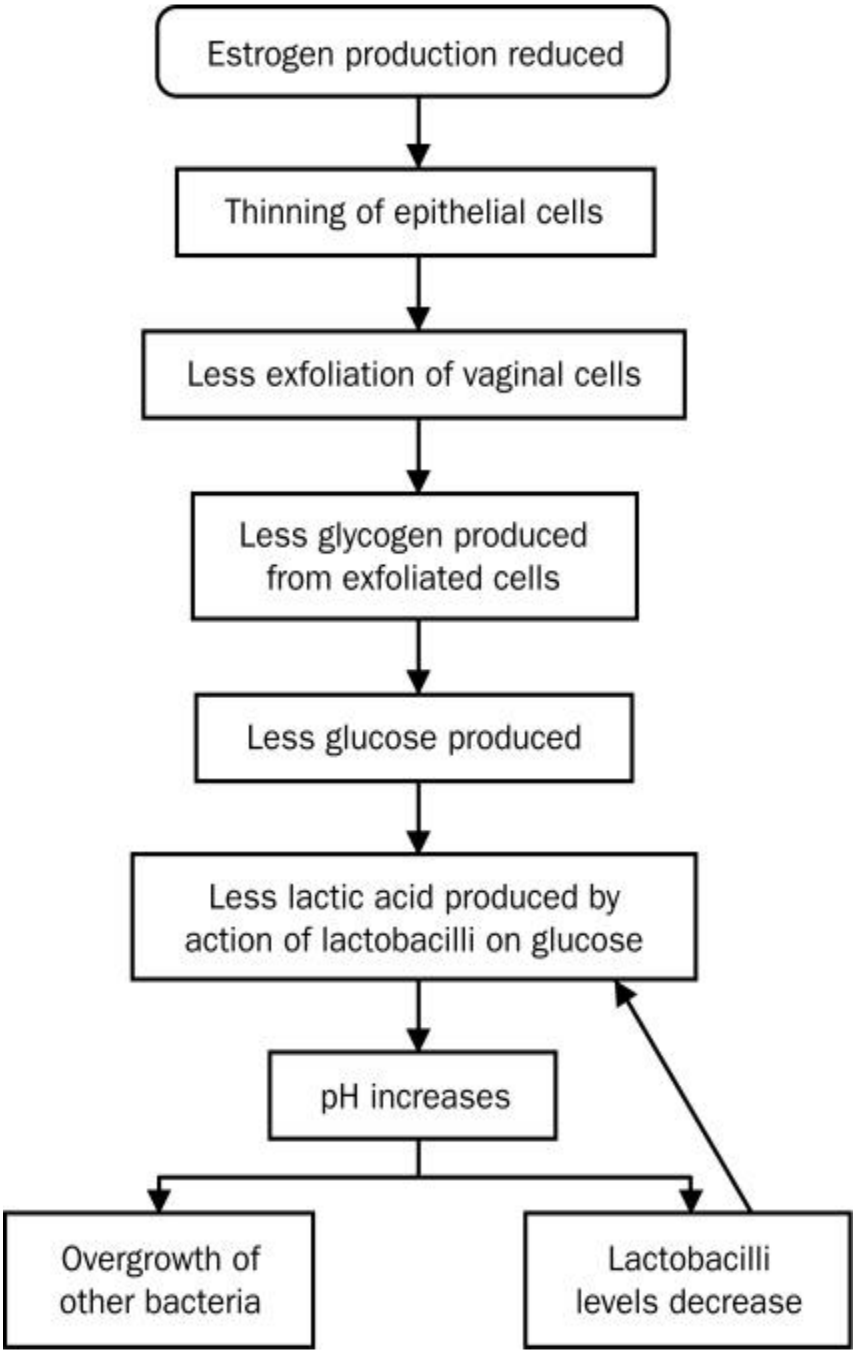


Figure 1.2 Proposed cascade-of-effects mechanism for vulvovaginal atrophy. [11]

The effects of endogenous estrogens on vulvovaginal tissues are mediated through estrogen receptors (ERs) α and β, found at sites throughout the urogenital area, including the vagina, vulva, labia, urethra, and bladder trigone. These sites, in turn, regulate transcription at specific areas on the DNA [12]. Figures (1.3) and (1.4) show the pathophysiology of vaginal atrophy.

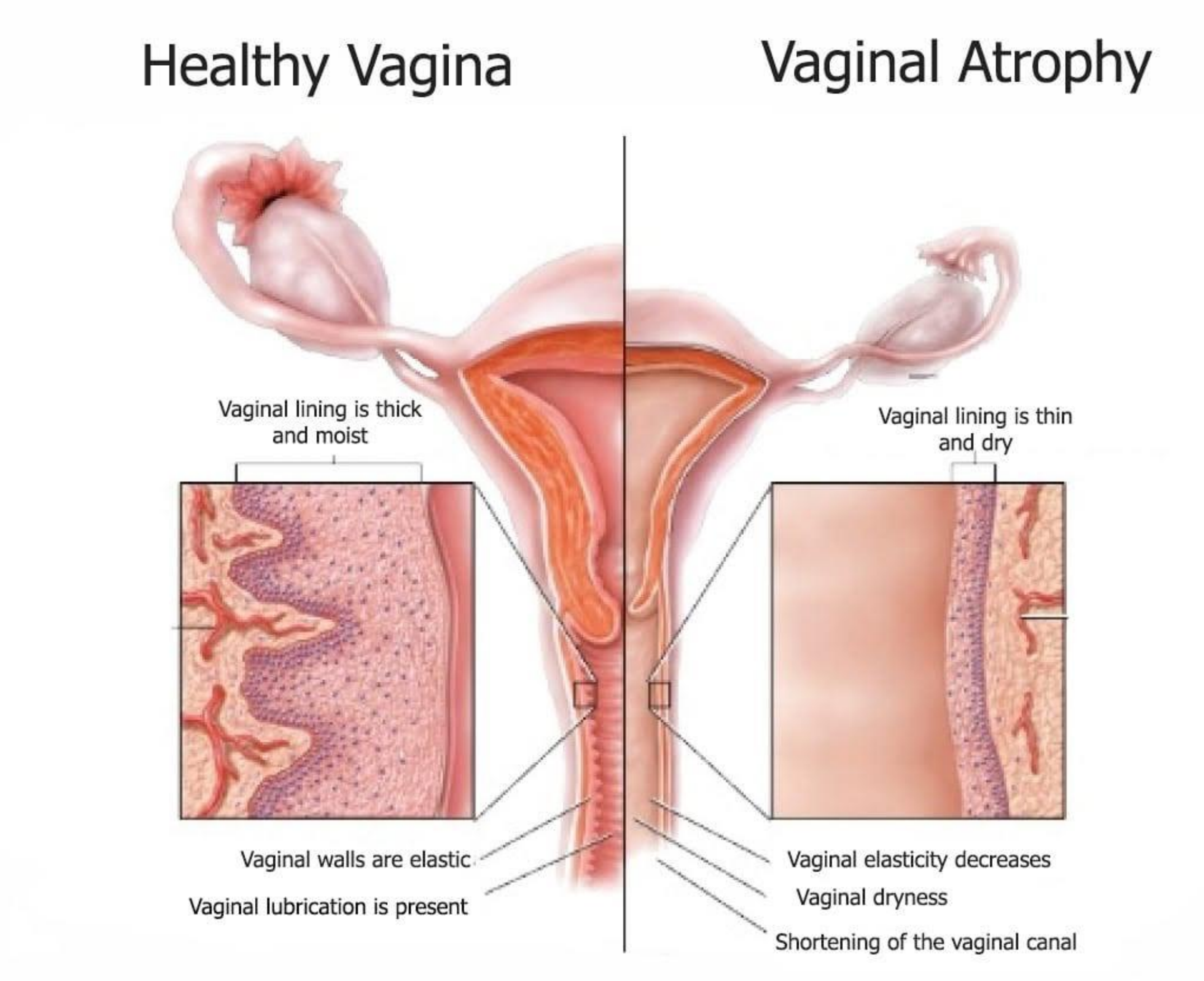


Figure 1.3 show pathophysiology of vulvovaginal atrophy [13]

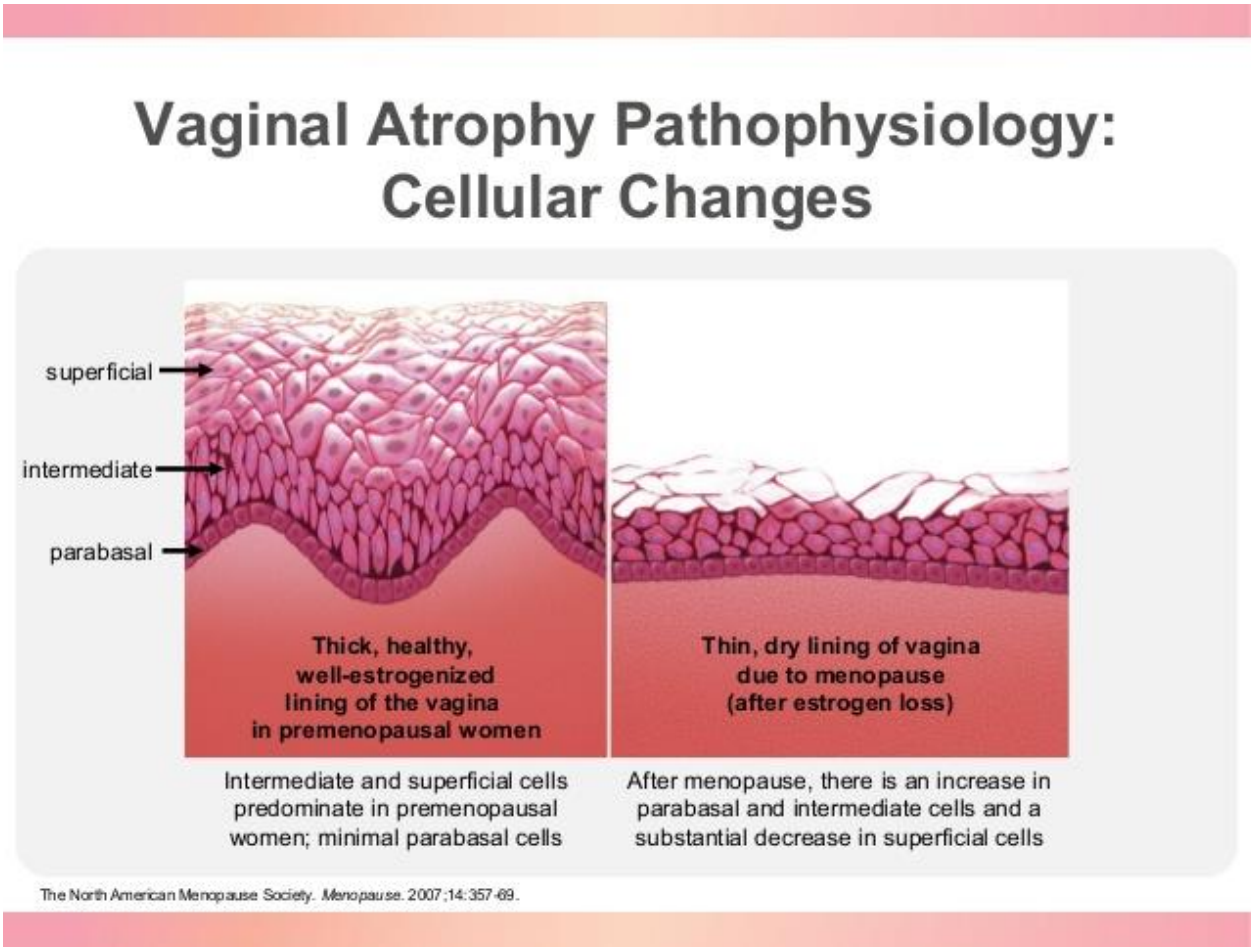


Figure 1.4 vaginal atrophy pathophysiology ,cellular changes[3]

1.2.4 Symptoms of VVA

The initial symptom is often lack of lubrication during intercourse. Eventually, persistent vaginal dryness may occur. Thinning of the epithelial lining may also cause pruritus, soreness, and a stinging pain in the vaginal and vulvar area, which, in turn, may further contribute to dyspareunia. Vaginal spotting, due to small tears in the vaginal epithelium, may also occur. Women with VVA may report a thin yellow or grey watery discharge secondary to the rise in pH that accompanies VVA . [14]

Women with VVA often report symptoms such as urgency, frequency, nocturia, and urge incontinence. Urinalysis may show microscopic hematuria. Recurrent urinary tract infections can also result. Stress incontinence is commonly found in this age group of women, but current evidence suggests it is not directly attributable to VVA. [15]

Women do not always report their symptoms of VVA. They are more likely to report vaginal discharge and urinary urgency but are less likely to report vaginal itching, soreness, or dyspareunia.Women may not report symptoms because they are self-treating, feel the symptoms are not important enough or are embarassed.[16]

1.2.5 Clinical signs and diagnosis

Clinical findings include atrophy of the labia majora and vaginal introitus. The labia minora may recede. Vulvar and vaginal mucosae may appear pale, shiny, and dry; if there is inflammation, they may appear reddened or pale with petechiae. Vaginal rugae disappear, and the cervix may become flush with the vaginal wall. Vaginal shortening and narrowing tend to occur. [17] A thin watery yellow vaginal discharge may be observed. A urethral caruncle, a small, soft, smooth friable red outgrowth along the edge of the urethra, may develop.

The diagnosis of VVA is a clinical one. However, two tests may be used to support the diagnosis: a vaginal pH and a vaginal maturation index (VMI). To assess pH, a piece of litmus paper is placed on the lateral vaginal wall until moistened. A pH of 4.6 or greater indicates VVA, assuming the patient does not have bacterial vaginosis. Premenopausal women without VVA typically have a pH of 4.5 or less. [18]

The VMI is the criterion standard for VVA confirmation but is generally not used or needed in clinical practice. This test assesses the relative proportion of parabasal, intermediate, and superficial vaginal epithelial cell types. In premenopausal women, greater than 15%

superficial cells would be considered normal; however, in postmenopausal women with VVA, the typical proportion would be less than 5%.

1.2.6 TREATMENT

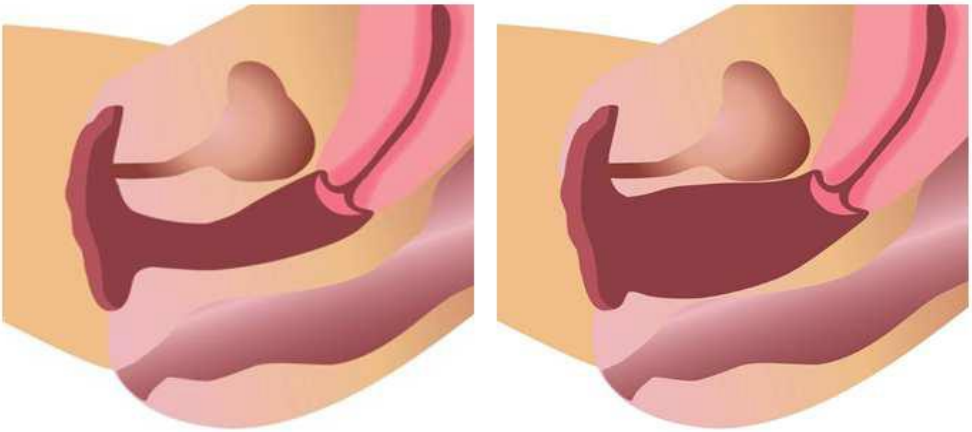
1. Non hormonal treatment: Vaginal moisturizers for VVA symptoms and lubricants for dyspareunia.

2. Hormonal treatment : For symptomatic vaginal atrophy that does not respond to self-care measures, estrogen treatment is the standard of care, typically with vaginally administered local estrogens.The 2006 Cochrane Database of Systematic Reviews concluded that vaginal estrogen is an effective treatment for VVA and that all forms, whether cream, ring, or tablet, appeared to relieve symptoms more effectively than nonhormonal gels. [19]

1.3 Vaginal Relaxation Syndrome (VRS)

A. Definition and predisposing factors

Is a quite common medical condition described as a loss of the optimal vaginal structure and is usually associated with vaginal child delivery and natural aging. Multiple pregnancies and deliveries contribute to a worsening of the VRS condition, as well as the onset of menopause, which causes a decline in hormone levels and vaginal atrophy. Most women (and their husbands or partners) refer to vaginal relaxation syndrome as “loose vagina” [20] complaining of a loss of vaginal tightness, as in (fig.1.5) which is directly related to the reduction of friction during intercourse and thus to a decrease physical sensation during intercourse and this lead to decrease in sexual satisfaction which can affect a women sense of sexual self-esteem and her relationship with her sexual partner. [21]



A B

Figure 1.5 A. Tight vagina B. Lax vagina (20)

By stimulating the production of collagen within the vaginal wall tissues, the vaginal tightening procedure helps produce more collagen and circulates within the vaginal tissues causing the tightening of the tissue walls. The laser rejuvenation can be performed on both the inner and exterior vaginal tissues. Leaving the surrounding tissue intact.

In this study we used the Fractional CO_2 laser that delivers controlled energy to the vaginal tissue. New collagen growth is stimulated as the tissue heats up. Sexual pleasure is improved with this procedure because it can reverse vaginal laxity and vaginal dryness. (21)

B. management (21)

pelvic floor training and Kegel exercises may be recommended to tighten the vaginal muscles there is no evidence that such isometric exercises result in vaginal tightening. pharmacological therapies (hormonal, tightening creams and sprays) those are noninvasive and safe, they have limited efficacy. Various surgical procedures promise a much better final result at the price of higher associated risks. vaginal tightening by laser ,radiofrequency,PRP platelet rich plasma,vaginal fillers. (21)

1.4. Laser Basic Principles

The acronym laser shortly described light amplification by stimulated emission of radiation.

1.4.1. Laser history:

During sixties, a lot of work had been carried out on the basic development of almost all the major lasers including high power gas dynamic and chemical lasers. [22] [23]

Table (1.1) A Brief history of laser development. [22] [23]

Year, Contributors	Events
1917: Einstein, A.	Concept and theory of stimulated light emission
1951: Charles H Townes, Alexander Prokhorov, Nikolai G Basov, Joseph Weber	The invention of the MASER (Microwave Amplification of Stimulated Emission of Radiation) at Columbia University, Lebedev Laboratories, Moscow and University of Maryland
1956: Bloembergen, N.	Solid-state maser- [Proposal for a new type of solid state maser] at Harvard University.
1958: Schawlow, A.L. and Townes, C.H.	Proposed the realization of masers for light and infrared at Columbia University.
1960: Maiman, T.H.	Realization of first working LASER based on Ruby at Hughes Research Laboratories.

1961: Javan, A., Bennet, W.R. and Herriot, D.R. -	First gas laser: Helium- Neon (He-Ne laser) at Bell Laboratories.
1961: Fox, A.G., Li, T.	Theory of optical resonators at Bell Laboratories
1962: Hall,R.	First Semiconductor laser (Gallium-Arsenide laser) at General Electric Labs.
1962: McClung,F.J and Hellwarth, R.W.	Giant pulse generation / Q-Switching.
1962: Johnson, L.F., Boyd, G.D., Nassau, K and Sodden, R.R.	Continuous wave solid-state laser.
1964: Geusic, J.E., Markos, H.M., Van Uiteit, L.G.	Development of first working Nd:YAG LASER at Bell Labs.
1964: Patel, C.K.N.	Development of CO_2 LASER at Bell Labs
1964: Bridges, W.	Development of Argon Ion LASER a Hughes Labs.
1965: Pimentel, G. and Kasper, J. V. V.	First chemical LASER at University of California, Berkley.
1965: Bloembergen, N.	Wave propagation in nonlinear media.
1966: Silfvast, W., Fowles, G. and Hopkins	First metal vapor LASER - Zn/Cd - at University of Utah
1966: Walter, W.T., Solomon, N., Piltch, M and Gould, G	Metal vapor laser.
1966: Sorokin, P. and Lankard, J.	Demonstration of first Dye Laser action at IBM Labs
1966: AVCO Research Laboratory, USA.	First Gas Dynamic Laser based on CO_2

1970: Nikolai Basov's Group.	First Excimer LASER at Lebedev Labs, Moscow based on Xenon (Xe) only.
1974: Ewing, J.J. and Brau, C.	First rare gas halide excimer at Avco Everet Labs.
1977: John M J Madey's Group	First free electron laser at Stanford University
1977: McDermott, W.E., Pehelkin, N.R,. Benard, D.J and Bousek, R.R.	Chemical Oxygen Iodine Laser (COIL).
1980: Geoffrey Pert's Group	First report of X-ray lasing action, Hull University, UK.
1984: Dennis Matthew's Group	First reported demonstration of a "laboratory" X-ray laser from Lawrence Livermore Labs.
1999: Herbelin,J.M., Henshaw, T.L., Rafferty, B.D., Anderson, B.T., Tate, R.F., Madden, T.J., Mankey II, G.C and Hager, G.D.	All Gas-Phase Chemical Iodine Laser (AGIL).
2001: Lawrence Livermore National Laboratory	Solid State Heat Capacity Laser (SSHCL).

1.4.2 Laser components

1. Active medium.

The active medium is a collection of atoms, molecules or ions that absorb energy from an outside source and generate laser light by stimulated emission, the active medium can consist of a solid, liquid, gas or a semi-conductor material. [22]

- Solid state as Nd: YAG laser.
- Liquid as dye laser.
- Gas, as CO_2 gas laser.
- Semiconductor, diode laser.

2. Excitation mechanism

Excitation mechanisms pump energy into the active medium by one or more of three basic methods; optical, electrical or chemical to create a population inversion.

For a laser to create a "population inversion" where most or all of the particles are in the excited state, this is achieved by adding energy to the laser medium (usually from an electrical discharge or an optical source such as another laser or a flash lamp); this process is called pumping most common optical pumping by flash lamp, electrical pumping by electrical current, chemical reaction pumping, or the use of another laser light source. [23.24]

3. Optical Resonator

Reflect the laser beam through the active medium for amplification. It is consisting of High Reflectance Mirror: A mirror which reflects 100% of the laser light and Partially Transmissive Mirror: A mirror which reflects less than 100% of the laser light and transmits the remainder.

The resonant cavity thus accounts for the directionality of the beam since only those photons that bounce back and forth between the mirrors lead to amplification of the stimulated emission. Once the beam escapes through the front mirror it continues as a well-directed laser beam. However, as the beam exits the laser it undergoes diffraction and does have some degree of spreading. Even more, the resonant cavity also accounts for the amplification of the light since the path through the laser medium is elongated by repeated passes back and forth.

Typically this amplification grows exponentially. If the direction is parallel to the optical axis, the emitted photons travel back and forth in the optical cavity through the lasing material between the totally reflecting mirror and the partially reflecting mirror. The light energy is amplified in this manner until sufficient energy is built up for a burst of laser light to be transmitted through the partially reflecting mirror.(24)

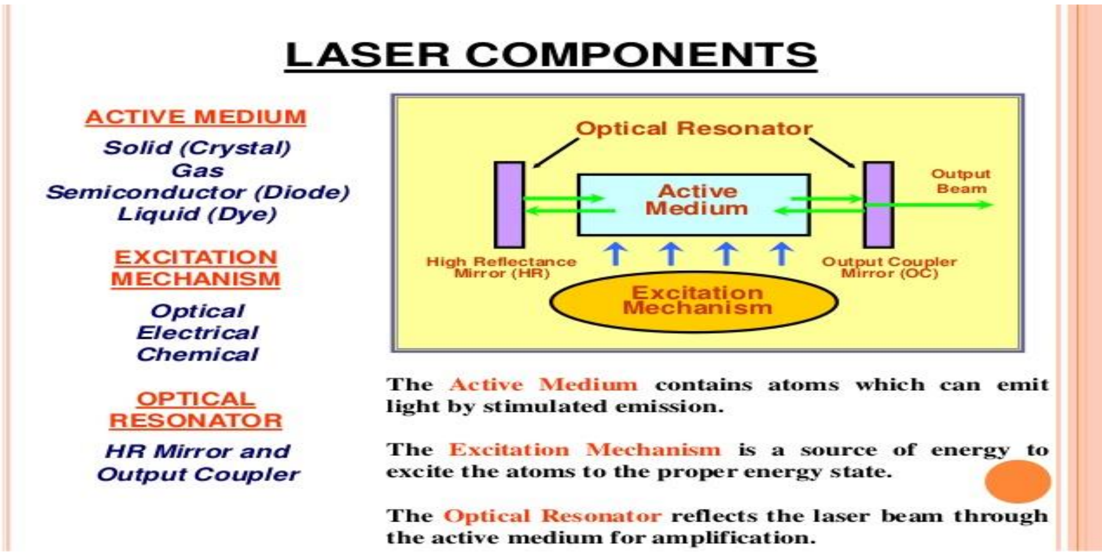


Figure (1.6) Laser Components

1.4.3. Properties of Laser Light

Unlike ordinary light, laser light is coherent, collimated, monochromatic, directionality, and brightness. [25]

1-Coherent: refers to synchronized phase of light waves, where all individual waves are in step or 'in –phase,' with one another at every point. So "coherence" is the term used to describe the in – phase property of light waves within a beam (Figure 1-7)

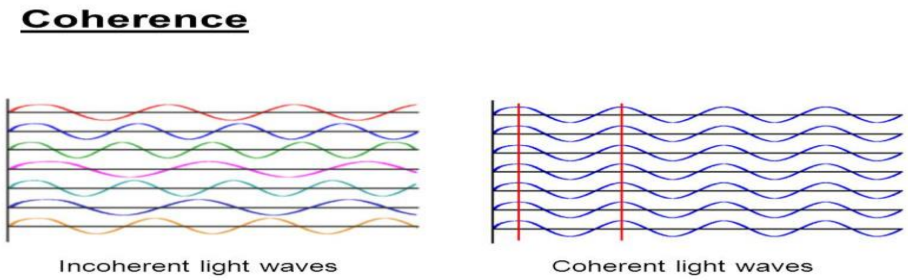


Figure (1.7) Incoherent Light and Coherent Light

2- Monochromatic: refers to single wavelength (color) of a laser beam. Ordinary white light is a mixture of colors, as can be demonstrated by passing ordinary light through a prism, will be dispersed into its components wavelengths (colors) .

3- Collimated: refers to the parallel nature of the laser beam, it is emitted in a very thin beam, with all light rays parallel. By focusing and defocusing this beam, a surgeon can vary its effects on tissue.

4-Directionality: divergence of beam is very small as shown in (Figure1.8).

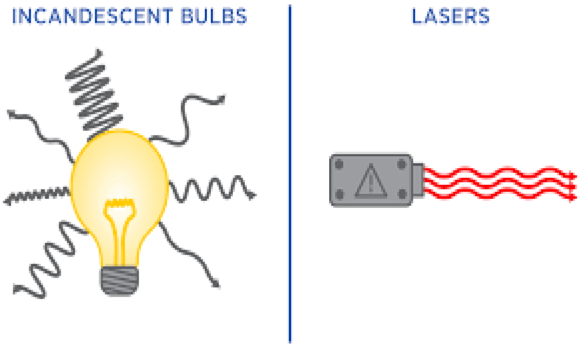


Figure (1.8) Difference between Light Bulb & Laser and its Directionality.

5- Brightness: refers to the wave that contains a lot of energy. These properties allow a laser of a given power to be immensely more powerful than ordinary light of the same power.

These unique characteristics make the laser useful for thousands of applications including medical applications.

1.4.4. Laser Beam Modalities:

1. Continuous wave (CW) laser.

2. Pulsed laser.

3.Chopped laser.

A CW laser is one whose power output undergoes little or no fluctuation with time. It exhibits a steady flow of coherent energy. Helium neon and argon gas lasers are typical examples, and are measured as power in watts. A larger group of lasers has output beams that undergo marked fluctuations i.e. beam power changes with time and said to operate in the "Pulsed mode".Nd: YAG solid crystal lasers and CO_2 gas lasers often, but not always, is operated in pulsed mode.[26]

1.4.5. Laser parameters

- Wavelength (nm) is an important laser parameter. It determines how deep laser radiation penetrates into tissue, i.e. how effectively it is absorbed and scattered. [27]
- Power(W): The rate at which the energy is delivered (W) [28]
- Exposure time(S):The duration of exposure to laser(s). primarily characterizes the type of interaction with biological tissue. [27]
- Energy(J)= P x t,(j) [28]
- Spot size (cm). [28]
- Power Density (Irradiance)=P/A (W/cm²). [27]
- Energy density (Fluency)= E/A(J/cm²) , its value only serves as a necessary condition for the occurrence of a certain effect and then determines its extent. all medically relevant effects are achieved at energy densities between 1 J/ cm² and 1000 J/ cm² [27]
- PRR is the pulse repetition rate, which represent number of pulses per second[28].

1.4.6. Laser Tissue Interactions

THE EFFECT OF THE TISSUE ON THE LASER LIGHT

*Reflection: is defined as the returning of the electromagnetic radiation upon which it is incident. There are two types of reflections; the specular reflection, seen in smooth surfaces (mirrors) where the surface irregularity is small compared to the wave length of radiation. The other is the diffuse reflection where the roughness of the reflecting surface is comparable or even larger than the wavelength of the radiation. [27]

*Scattering: is the basic origin of dispersion, her there is absorption and re-emission. If the frequency of the wave is not corresponding to the natural frequency of the particles, scattering occurs. The resulting oscillation is determined by forced vibration. If the frequency of the wave equals the natural frequency of free vibration of a particle, resonance frequency occurs being accompanied by a considerable amount of absorption. [27]

*Absorption: is defined as the attenuation of the intensity of light when it passes through a medium. Factors affecting absorption are: (1) The electronic constitution of the medium. (2) The wave length of the radiation. (3) The thickness of the absorbing layer. (4) Internal parameters; the temperature and the concentration of the absorbing agents. [27]

*Transmition: light which pass through the tissue without any interactions between the photons of laser radiation and the tissue [this part constitute the basic principle of optical diagnostics]. The previous mentioned effects are shown in figure (1.9) .

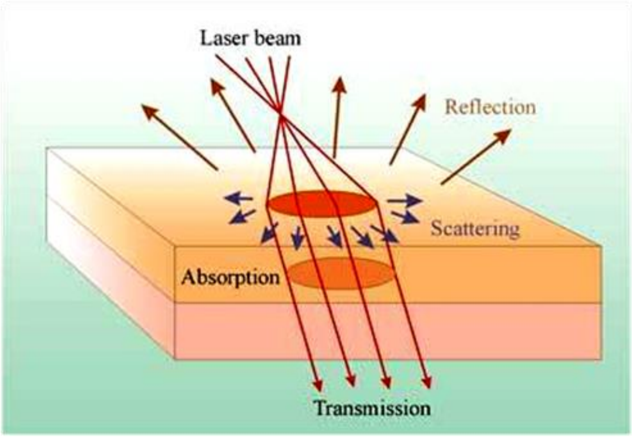


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Figure (1.9) Pathway of light when it passes from one media to another

THE EFFECT OF THE LASER ON THE TISSUE

Five categories of interaction types are classified today. These are photochemical interactions, thermal interactions, photoablation, plasma-induced ablation, and photodisruption. In particular, the physical principles governing these interactions are reviewed. Emphasis is placed on microscopic mechanisms controlling various processes of laser energy conversion. Each type of interaction will be introduced by common macroscopic observations including typical experimental data and/or histology of tissue samples after laser exposure. [27] The previous mentioned effects are shown in figure (1.10) .

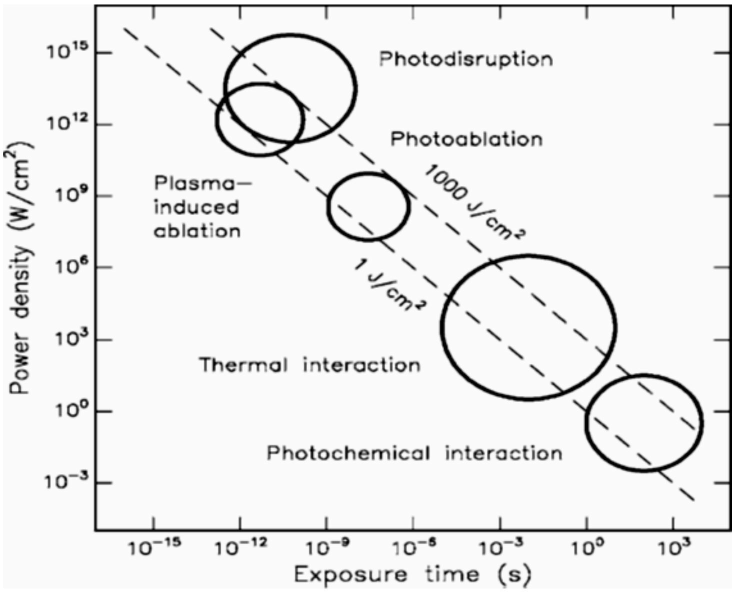


Figure (1.10) five interaction mechanisms depend on the duration of the light exposure and the irradiance, i.e. the power per unit area, in W/cm²

Laser tissue interaction can be either:

1. Wavelength dependent mechanisms.

2-Wavelength independent mechanisms.

1.4.6.1. Wavelength—Dependent Mechanisms

Wavelength-dependent interactions of radiant energy depend largely on the laser wavelength that has impacted the tissue. Because the wavelength is a very important parameter that determines the index of refraction (governs the overall reflectivity of the target) as well as the absorption and scattering coefficients. [27] These mechanisms are shown in figure 1.11.

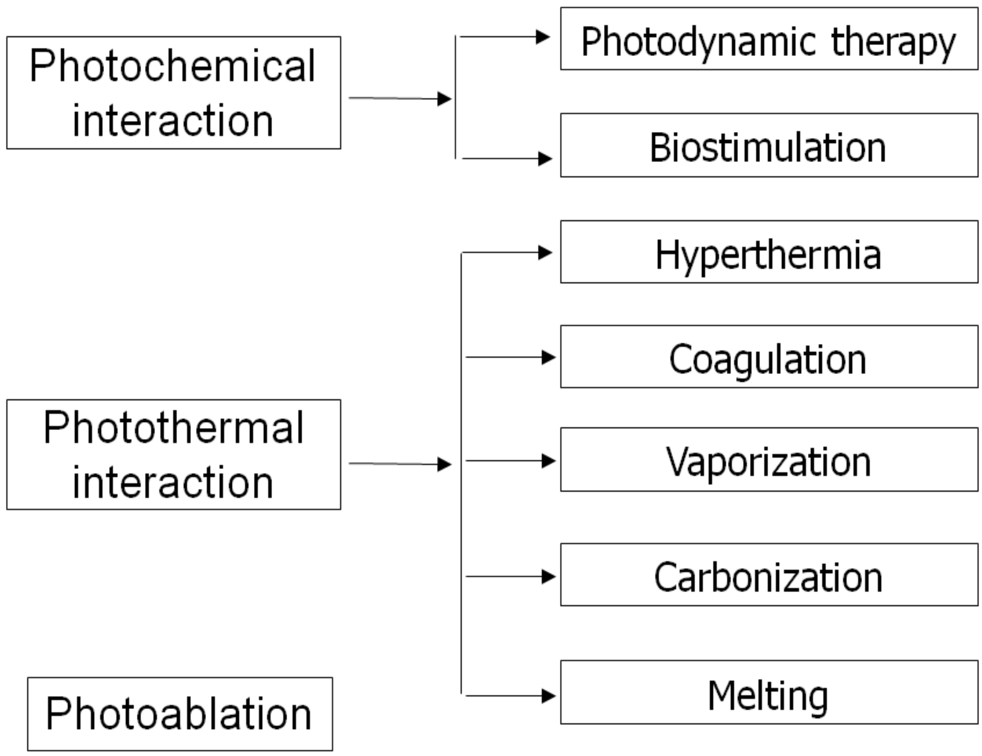


Figure (1-11) Wavelength dependent mechanism

1. Photochemical reactions:

In this type of interactions the light can induce chemical effects and reactions within macromolecules or tissues. In the photochemical interaction mechanisms play a significant role during photodynamic therapy (PDT). Frequently, bio stimulation is also attributed to photochemical interactions, Photochemical interactions take place at very low power densities (typically 1W/cm2) and long exposure times ranging from seconds to continuous wave[(27).]. Photochemical reactions occur with endogenous or exogenous photosensitizers, such as those used in photodynamic therapy, where light absorbing chromophores are introduced into the tissue and then elicit selective photochemical reactions by light absorption [(29).] This photosensitizing drug absorb light, forming reactive oxygen species which is used to cause necrosis (cell death) and apoptosis (programmed' cell death), photodynamic therapy is increasingly widely used in oncology to destroy cancerous tumors [(29).]

The generation of cytotoxic ROS in PDT requires the presence of oxygen, e.g. if the tissue is clamped to prevent blood from deoxygenating the tissue so the tissue becomes hypoxic (lack of oxygen) then photodynamic therapy does not work [29].

2. **Photothermal interactions**

The term thermal interaction stands for a large group of interaction types, where the increase in local temperature is the significant parameter change. Thermal effects can be induced by either CW or pulsed laser radiation. However, depending on the duration and peak value of the tissue temperature achieved, different effects like coagulation, vaporization, carbonization and melting may be distinguished.

Table (1.2) Thermal effects of laser

Temperature	Biological effect
37^0 C	Normal
45^0 C	Hyperthermia
50^0 C	reduction in enzyme activity, cell immobility
60^0 C	denaturation of proteins and collagen, coagulation
80^0 C	increased permeability of membrane
100^0C	water vaporization, thermal decomposition (ablation)
>150 ^{0}C	Carbonization
>300 ^{0}C	Melting

A temperature increase in the tissue at temperatures above 100°C, the intracellular water exceeds the boiling point and vaporization occurs, which can be seen clinically as ablation of the tissue [27].

The location and spatial extent of each thermal effect depend on the locally achieved temperature during and after laser exposure.[27]

(Figure1-12).

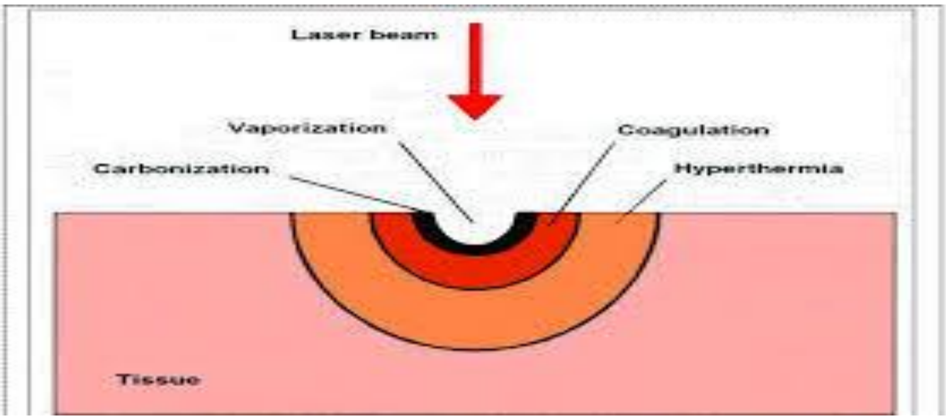


Figure (1.12) Location of thermal effects inside biological tissue

3. **Ablative Photodecomposition (Photoablation)**

It is of high-energy, ultraviolet (UV) photon (from an excimer laser, e.g. ArF laser) is absorbed by electrons, causing virtually immediate dissociation of the molecules. This naturally leads to a rapid expansion of the irradiated volume and ejection of the tissue from the surface and there are no thermal effects associated with this process and it is therefore sometimes known as cold ablation [29] . Typical threshold values of this type of interaction are 10^7–10^8 W/cm2 at laser pulse durations in the nanosecond range [27]. Today, because photo ablation causes no thermal damage, and the very accurate etching that can be achieved, so it is one of the most successful techniques for refractive corneal surgery.[27,29]

1.4.6.2. Wavelength—Independent Mechanisms.

1. Plasma-induced ablation

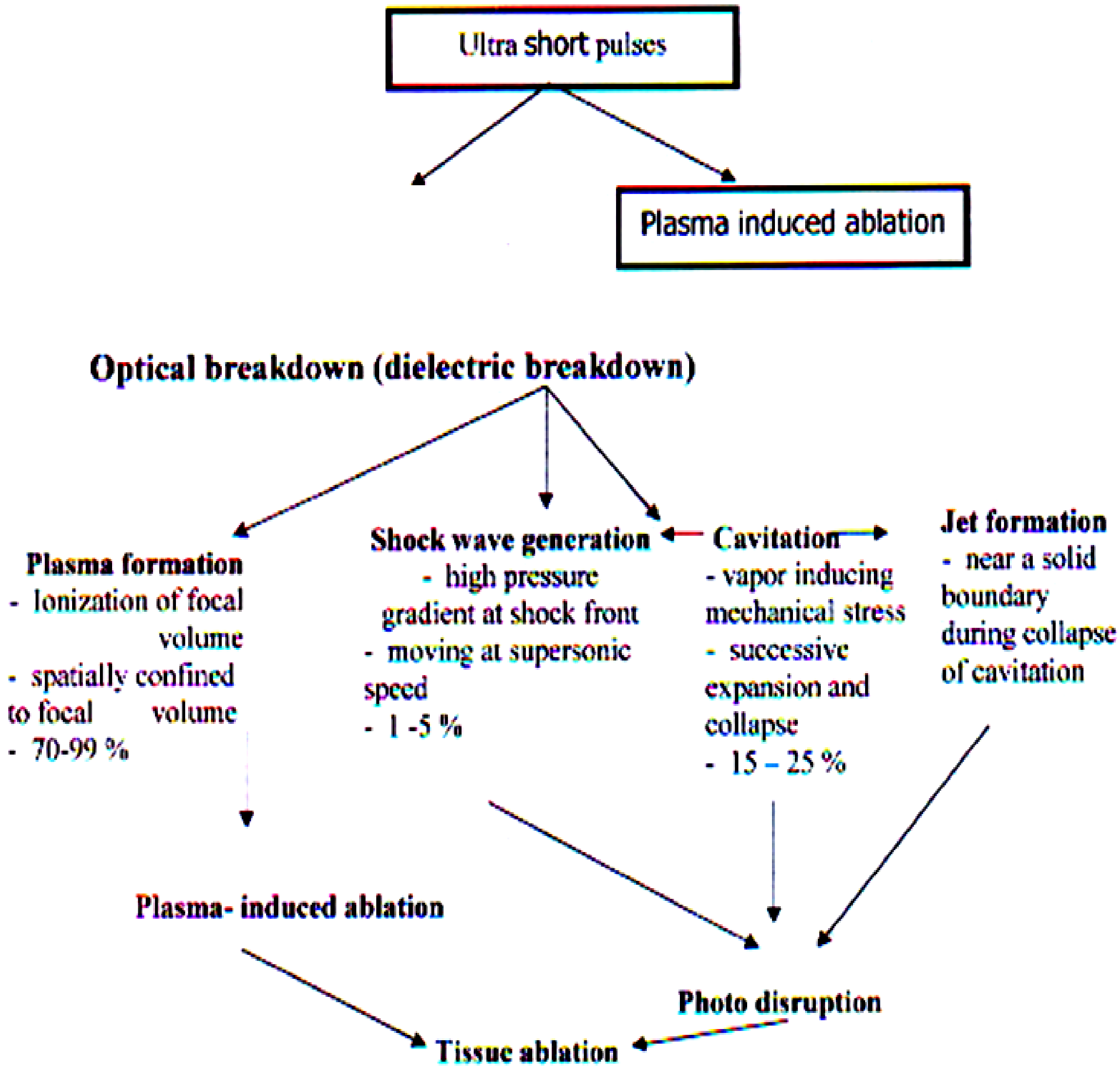
Plasma is a `soup' of ions and free electrons formed when sufficient energy is transferred to free a bound electron, and a chain reaction of similar collisions is initiated [29].

By means of plasma-induced ablation, very clean and well-defined removal of tissue without evidence of thermal or mechanical damage can be achieved when choosing appropriate laser parameters [27]. One application of this is in lens capsulotomy to treat secondary cataracts [27]. The principal advantages of plasma-induced ablation, sometimes called plasma-mediated ablation or laser-induced breakdown, are that: [29]

- The thermal damage is minimal (as with photo ablation).
- It is possible to ablate transparent tissue.
- When using fs and ps pulses the damage is well-confined.
- It is good for cutting close to tissue that must not be damaged, as the high absorption of the plasma has a shielding effect.

2. Photodisruption

It is the mechanical effects that can accompany plasma generation, such as bubble formation, cavitation, jetting and shockwaves [29]. The physical effects associated with optical breakdown are plasma formation and shock wave generation, if breakdown occurs inside soft tissues or fluids, cavitation and jet formation may additionally take place [27] . These can be used in lithotripsy [29]. (Figure 1.13)



Figure(1.13) Scheme of the physical processes associated with optical breakdown.

Percentages given are rough estimates of the approximate energy transferred to each effect (incident pulse energy: 100%). Cavitation occurs in sof tissues and fluids only. In fluids, part of the cavitation energy might be converted to jet formation.

1.4.7. Medical laser systems [30]

Table (1.3) Types of lasers mostly applied in surgery

Laser type	Wavelength	Power range	Mode	Delivery system
Co_2	10600nm	0.1 -100 W	CW / Pulsed	Articulated arm
Nd: YAG	1060nm	5 – 120 W	CW/Qswitched	Fiber optic
Ruby	694nm	> 30j	Pulsed	Coupled to microscope
Doubled Nd:YAG	532nm	> 3j	Pulsed	Coupled to microscope
Argon ion	488–514nm	0.001–25W	CW/Pulsed	Fiber optic
Dye	400–700 nm	0.001 – 6W	CW	Fiber optic
He:Ne	632.8nm	10^{-3} – 10^{-2}W	CW	Fiber optic
Diode laser	630-1000nm	15-61W	CW / pulsed	Fiber optic

Carbon dioxide (CO_2)

The carbon dioxide (CO_2) laser emits light at a wavelength of 10 600 nm. Its photo thermal effect on tissue consists of the transformation of water into vapor, which leads to complete cell vaporization .However, as the CO_2 light only penetrates 0.3–1mm into the target and, the thermal damage to the tissue beyond the vaporization area is minimal.

In practical terms, the CO_2 laser is applied in a non- contact technique in CW and about 15W.As the laser light is in the far-infrared band, visual control can be achieved by the addition of visible guiding beam, such as a helium-neon or diode laser to mark the aimed focal spot. (27) It is often used in the super-pulsed wave mode, which produces power peaks that are about ten times higher than the CW mode. This allows application with more precision and less thermal injury as the surrounding tissue can cool down between the power intervals. The CO_2 laser cannot be used for sealing vessels of more than 0.5 mm in diameter, The CO_2 laser is mainly a surgical tool. It can cut or vaporize tissue with fairly little bleeding as the light energy changes to heat. This type of laser is used to remove thin layers from the surface of the skin without going into the deeper layers. A carbon-dioxide laser kills tissues by destroying cells. When touched by this type of laser, tissues that are composed of 80 percent to 90 percent water are destroyed by the steam formation in the cells. The area that is vaporized by the laser is both localized and also does not present any combustion because the intracellular temperatures never go beyond 100 degrees Celsius. Moreover, there is also very little damage to the surrounding areas, CO_2 laser is the standard laser in surgery. Depending on the type of treatment, CO_2 lasers can be operated in three different modes – CW radiation, chopped pulse, and super pulse. (27)

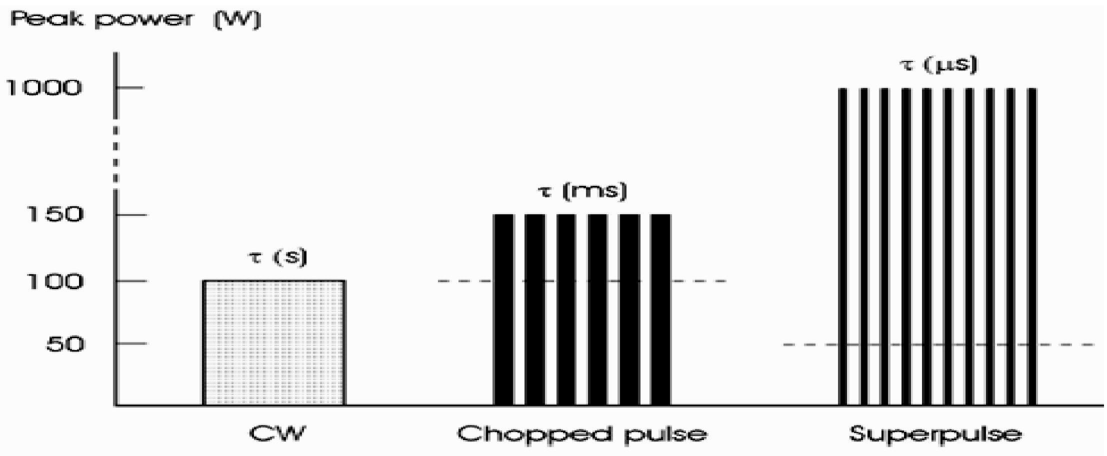


Figure (1.14) CW, Chopped pulses, and super pulses mode of a CO2 laser. Dash line denote mean power

As shown in Figure.(1.14) Chopped pulses with durations in the millisecond range are obtained from CW lasers when using rotating apertures, Superpulses are achieved by modulation of the high voltage discharge, Thereby, pulse durations less than 1 ms can be generated. The peak power is inversely related to the pulse duration. The mean powers of CW radiation and chopped pulses are nearly the same, whereas it decreases in the case of superpulses. Shorter pulse durations are associated with a reduction of thermal effects. Hence, by choosing an appropriate mode of the laser, the best surgical result can be obtained. (27) Besides selecting the temporal mode, the surgeon has to decide whether he applies a focused or defocused mode as shown in Fig. (1.15). Only in tightly focused mode are deep excisions achieved. In partially focused mode, less depth but a larger surface is vaporized. In defocused mode, the power density decreases below the threshold of vaporization, and tissue is coagulated only (27).

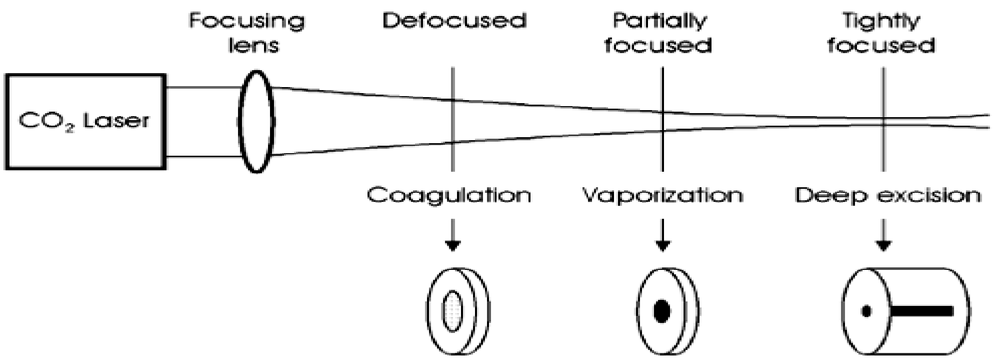


Figure (1.15) Coagulation, vaporization, and excision modes of a CO2 laser. Depending on defocused ,partially focused, or tightly focused beam.

Because of its very long and Far-IR wavelength, the CO_2 beam has a very shallow absorption depth and a great affinity for water and almost everything including glass and fiber optics. Though the beam must be delivered via mirrors mounted in an articulated arm, the CO_2 makes a great surgical "light" scalpel and ablator. When used with a scanner or pattern generator, cosmetic skin resurfacing is easily achieved. The treatment can be fractional or totally ablative (31). Developments in fiber optics made it possible to transmit far-infrared laser beams, increasing the flexibility of CO_2 lasers for endoscopic surgery [32].

In 1996, the erbium (Er):YAG laser with a very short wavelength of 2,940 nm allowed a more superficial vaporization of tissue and was used together with CO_2 lasers for skin resurfacing [32]. Very recently, the new technical concept of fractional photothermolysis was introduced. It received FDA approval in 2004 for skin resurfacing and in 2005 for the treatment of melisma [33].

Fractional CO_2 laser

The novel concept of fractional photothermolysis was introduced to the market by Dieter Manstein and Rox Anderson in the year 2003 [27]. Unlike conventional ablative and non-ablative lasers, fractional ablative and non-ablative lasers treat only a fraction of the skin, leaving up to a maximum of 95% of the skin uninvolved thus the name „fractional‟, depending on the number of spots per area of treatment. This is achieved by inducing microscopic small three dimensional zones of thermal damage or ablation, surrounded by undamaged tissue allowing for rapid epidermal repair [34]. Fractional lasers will act on the water chromophore, whose absorption rate varies in accordance with the wavelength used [35]. Based on the wavelength‟s affinity for water, fractional technologies can be divided into two main categories. Those with wavelengths that are highly absorbed by water are termed „ablative‟, while those wavelengths that are less avidly absorbed by water are termed non- ablative [34]. Therefore, in every laser shot we will treat a certain percentage of the area of the skin, leaving, between every spot, unharmed zones, and these uninjured zones help the skin heal quickly. [35]

The lesions damaged by CO_2 laser ablation is first filled with kerationocyte within 48 hours and replaced by dermis through the remodeling process, a process that can be continued even after three months [36]. Fractional lasers have a structure similar to that of non-fractional lasers, i.e., a power supply unit, a tube that generates the laser emission and a hand piece or scanner that breaks the emission into fractions. By means of a lens a pixel-like area is produced, transforming the emission from the tube in multiple laser spots of varying diameter and number. These spots are applied on the skin in each shot. These micro spots are evenly distributed on the area selected by the hand piece of the device. (Fig. 1.16) [35] From the point of view of the interaction Laser-Tissue, the biological effect produced on the tissue will basically depend on the Energy Density applied on that tissue, and on the energy this tissue absorbs [35].

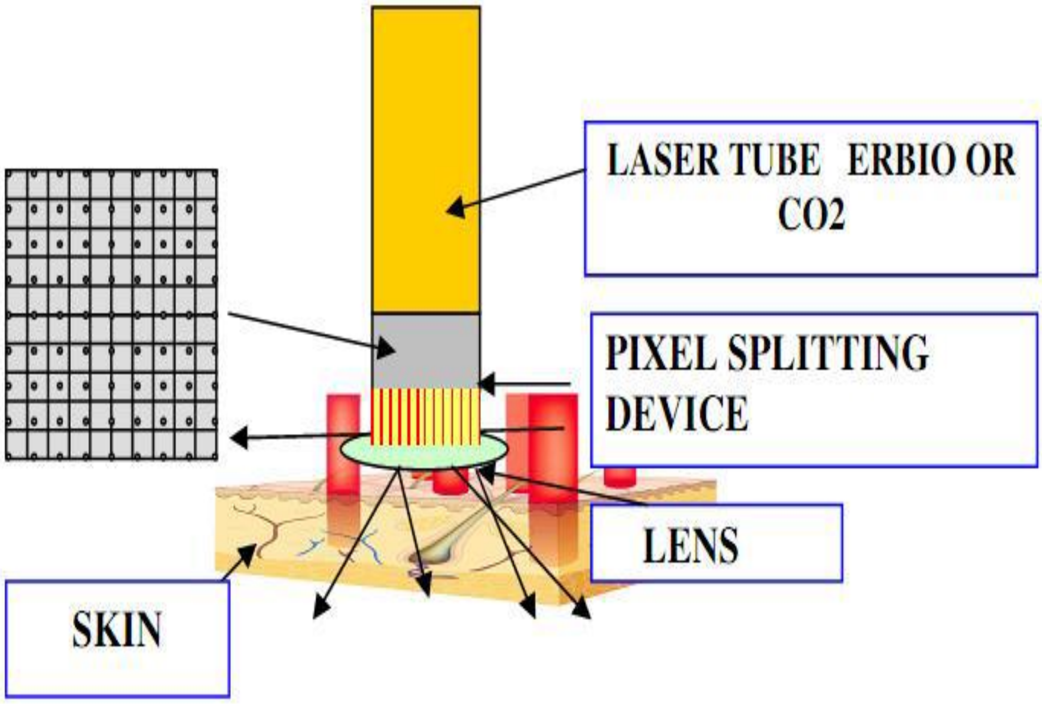


Figure.1.16 Operation Diagram of the fractional píxel laser.

The beam is delivered from the laser tube and when it goes through the splitting device it is transformed into multiple spots which, once filtered by a lens, are applied on the skin.

1.4.8.1 Laser radiation hazards and damage mechanism

Hazards from the laser include direct and indirect (reflected) beam exposure; fire hazards; smoke produced by vaporization (containing pathogen and chemical toxins. Table 1.4 summarizes laser hazards:

Table 1.4 : Laser hazards[38]

Laser radiation hazards	Eye	Corneal or retinal burn(depending on wavelength) Cataract Retinal injury
	Skin	Skin burn from acute exposure(direct or reflected beam) Skin carcinogenesis(depending on wavelength)
Chemical hazards		Eximer,dye,chemical lasers contain toxic substance Smoke produced from vaporization or laser induced reactions
Electrical hazards		Danger from high power voltage supplies.
Secondary hazards		Cryogenic coolant hazards Excessive noise X-radiation (from high voltage power supplies). Fire hazards(from beam exposure to flammable substances).

Laser radiation predominantly causes injury via thermal effects. potential damage to the eye can be categorized with respect to the laser wavelength and the eye structures affected with the most significant injuries being to the retina and caused by radiation in the visible and and near infrared spectral region. Damage to the cornea caused by radiation in the far UV and infrared.[38] The skin is usually much less sensitive to laser light than the eye, but excessive exposure to ultraviolet light from any source (laser or non-laser) can cause short- and long-term effects similar to sunburn, while visible and infrared wavelengths are mainly harmful due to thermal damage. [39]The Table (1-5) below summarizes the various medical conditions to the eyes and the skin caused by lasers at different wavelengths. [40,41]

Table (1.5) Bio-effects of the eye and skin

SPECTRUM	EYE EFFECT		SKIN EFFECT
	Location	Effect	
UV-C (200-280 nm)	Cornea	Photo keratitis	Erythema, cancer, accelerated aging
UV-B (280-315 nm)	Cornea	Photo keratitis	Erythema, increased pigmentation, cancer, accelerated aging
UV-A (315-400 nm)	Lens	Cataract	Erythema, increased pigmentation, skin burn
Visible (400-780 nm)	Retina	Retinal injury*	Photosensitive reactions, skin burn
IR-A (780-1400 nm)	Retina, Lens	Retinal burn, cataract	Skin burn
IR-B (1400-3000 nm)	Cornea, Lens	Corneal burn, cataract	Skin burn
IR-C (3000-1000000 nm)	Cornea	Corneal burn	Skin burn

* Retinal injury can be thermal, acoustic or photochemical.

1.4.8.2. Classification of laser hazards [42]

Table 1.6

Class	Basis for classification
Class 1 Safe Visible and nonvisible	Laser that are safe under reasonable condition of operation, generally a product that contains a higher-class laser system but access to the beam is controlled by engineering means.
Class 2 Laser power Visible only	For CW laser, protection of the eyes is normally provided by the natural aversion response, including the blink reflex, which takes approximately 0.25 sec (these lasers are not intrinsically safe) AEL=1mW for a CW laser.
Class 1M safe without viewing aids 302.5 to 4300nm	Safe under reasonable condition of operation. Beam are either highly divergent or collimated but with a large diameter. May be hazardous if user employs optics within the beam
Class 2M safe without viewing aids Visible only	Protection of the eyes is normally provided by the natural aversion response, including the blink reflex, which takes approximately 0.25 sec. beams are either highly divergent on collimated but with a large diameter . May be hazardous if user employs optics within the beam.
Class 3R Low and medium power 302.5nm to 1mm	Risk of injury is greater than for lower class but not as high as for class 3B. Up to five times that AEL for class one or class two.
Class 3B Medium and high power Visible and nonvisible	Direct intrabeam viewing of these devices is always hazardous. Viewing diffuse reflections is normally safe provided the eye is no closer than 13 cm from the diffusing surface and the exposure duration is less than 10 sec. AEL =500Mw for a CW laser.
Class 4 high power Visible and nonvisible	Direct intrabeam viewing is hazardous. Specular and diffuse reflections are hazardous. Eye, skin and fire hazard. Treat class 4 laser with caution.

1.4.9 Safety measures [43]

Safety guides of eye protection

1.Natural eye protection or defence : When the light strike the eye, it stimulate the optical protective mechanism of the eye or what is called reflexes.

2.Artificial or external eye protection : By using protective eyewear that designed for that specific wavelength and optical density. The selection of eyewear must be proper ,fit, comfort and visual performance. [40]

Fig.(1.17) laser goggles

1.5 Litreture review

Vulvovaginal atrophy is a condition that affects women, although it is mainly associated with the onset of menopause mainly due to hormonal changes vulvovaginal laxity and mucosal atrophy can also affect women at different life stages such as after pregnancy or for cancer patients who have undergone chemo or endocrine therapy. This condition negatively influence quality of life, sexual desire, and self-confidence. So we can use fractional CO_2 laser (10600nm) as an effective and efficient method with less side effect for treatment of vulvovaginal atrophy symptoms and vaginal rejuvenation for perimenopause and postmenopausal women .

The concept behind laser procedures to treat vulvovaginal conditions is to use a wavelength having high water absorption, such as the carbon dioxide (CO_2) laser (10,600 nm), to ablate and coagulate vaginal and vulvar tissues.[(44)] A wound response is initiated due to the heating and results in tissue remodeling with neo formation of collagen and elastic fibers in atrophic skin.[(44,45)] The muscle tone of the vagina is then restored by tightening the supportive structures of the vulvovaginal complex . [(46)]

CO_2 laser treatment has previously demonstrated significant improvement in GSM symptoms in postmenopausal women, [(47,48)].

Fractional CO_2 laser application has also been shown to restore the vaginal mucosa structure in postmenopausal, non-estrogenized women.[(49)] In the published trials to date, only postmenopausal women have been studied[(44)] primarily with short-term follow-up of 12 weeks after treatment. As symptoms of VVA can occur at any time in a woman's life cycle, this study investigated the effects of fractional CO_2 laser in women treated by resurfacing and coagulation of the vaginal canal tissues . Clinical outcome was evaluated at 4 weeks after the final treatment .

So we can use fractional CO_2 laser (10600nm) as an effective and efficient method with less side effect for treatment of vulvovaginal atrophy symptoms and vaginal rejuvenation for perimenopausal and postmenopausal women

1.6 Aim of the study:

To evaluate the efficacy of fractional CO_2 laser (10600nm) in the treatment of vulvovaginal atrophy and vaginal rejuvenation

Chapter Two

Material and Method

2.1 Introduction

This study was done in the laser medicine research clinics of Institute of laser for postgraduate studies beginning from July 2019 to the end of September 2019. In this study Twelve women complained from vulvovaginal atrophy and vaginal laxity treated with fractional CO_2 laser two times four weeks a part.

2.2 Inclusion and Exclusion Criteria

All patients were examined to determine their suitability according to the inclusion and exclusion criteria.

Inclusion criteria

All Patients with symptomatic vulvovaginal atrophy and suffering from vaginal relaxation syndrome or had otherwise acquired “loose vagina”, diminished sexual gratification, and expressed their desire to improve their vaginal tightness included in this study.

Exclusion criteria:

- Pregnancy
- On menstruation
- previous vaginal reconstructive surgery or treatment for vaginal tightening within the past 12 months
- acute or recurrent urinary tract infections
- active genital infections
- undiagnosed vaginal bleeding
- suffering from any serious disease or chronic condition that could interfere with study compliance
- Severe prolapse.

2.3 Patients Description: Patients were aged between 42 and 59 years old (mean 46.5 years old). A total of 75%(n.9) were perimenopause and 25% (n.3) were postmenopausal. The patients' description in table (2.1). Each patient was getting ready for the procedure after full explanation and discussion regarding the nature of the procedure, the possible advantages, disadvantages and complications expected. At the end of discussion each patient was asked to sign an "informed consent" indicating his agreement.

Table 2.1: Patients' description

Age	(40-49) years old	75% (n.9)
	(50-59) years old	25% (n.3)
Menopausal state	Perimenopause	75% (n.9)
	Post-menopausal	25% (n.3)
Parous status	(2-3) children	33.3% (n.4)
	(4-5)children	41.6% (n.5)
	(6-9) children	25% (n.3)
Delivery type	Vaginal delivery	75% (n.9)
	Mixed(Vaginal and Caesarean	25% (n.3) *
Episiotomies	Previous episiotomy	91.6% (n.11)
	Patients with no episiotomy	8.33% (n.1)
Previous vaginal construction surgery	Nil	

* history of previous one caesarean section

2.4 Clinical assessment

1.Data concerning patient's history included:

Age, parity, history of vaginal deliveries ,and any history of obstructed deliveries history of delivering big babies, menstrual cycle and its regularity ,time of menopause, contraceptive method, symptoms (pain, backache and abnormal vaginal discharge ,feeling of bulging or swelling at the vaginal opening),any history of urine leakage ,history of incomplete bladder emptying, sexual life history(frequency of sex ,dyspareunia, feeling of loose vagina or dryness with sexual intercourse), previous vaginal construction surgery and previous vulvar surgery (including episiotomy).

Case sheet Description

A case sheet was prepared to record all the necessary information. Medical and surgical histories were taken from the patients with clinical examination for each patient as displayed in the figure (2.1).

Ministry of Higher Education & Scientific Research

University of Baghdad

Institute of laser for Postgraduate Studies

Patient Case Sheet

Case No. (   )

Following is a list of questions about your bladder, vaginal health and sex life. All information is strictly confidential. The answers will be used to compare symptoms before and after your treatment. When answering the questions, please consider your symptoms over the past 3 months.

1.Name: ……….………2. Age………...…………

3.Address………………………………………4. Phone:…………………

5.parity………6.LMP…….

7.C/C:………………………………………………………………………………………..
.

8.History of obstructed delivery yes ….NO… number if present………
9. How often do you leak urine?
□ never □ 2-3 times per week □ several times per day
□ once a week or less □ once per day □ constantly
10. How much urine do you leak at a time?
□ none □ a moderate amount
□ a small amount □ a large amount

11. When does urine leakage happen? (tick all that apply)
□ never, urine does not leak □ when I am asleep
□ when I am physically active □ after I empty my bladder
□ before I can get to the toilet □ I leak all the time
□ when I cough or sneeze □ for no obvious reason
12. Do you experience bulging or pressure at the opening of the vagina?
□Never □Seldom □Sometimes □Usually □Always

13.. Do you have incomplete emptying of your bladder?
□Never □Seldom □Sometimes □Usually □Always
14. Do you have difficulty completing your bowel movements?
□Never □Seldom □Sometimes □Usually □Always
15. Do you avoid sexual activity because of incontinence or bulging in the vagina?
□Never □Seldom □Sometimes □Usually □Always
16. Do you feel pain during sexual intercourse?
□Never □Seldom □Sometimes □Usually □Always
17. Do you feel experience vaginal dryness with sexual intercourse?
□Never □Seldom □Sometimes □Usually □Always
18. Does your vagina feel loose or is there less sensation than before?
□Never □Seldom □Sometimes □Usually □Always
19.Previous surgical history
20.previous vaginal construction surgery and previous vulvar surgery (including episiotomy.
Finding
Procedure
Any adverse event after the procedure
Follow up Visits
Four weeks after the second session assess the improvement in symptoms (Dryness, Dyspareunia, Incontinence, swelling. lax vagina and Overall satisfaction)
…………

The improvement depends on the patient satisfaction which was graded as follows: (evaluation criteria)
Overall satisfaction
Grade 0= not satisfied.
Grade 1= partially satisfied.
Grade 2= fully satisfied

Figure (2-1) a case sheet for the patients

Depending on history, patient's complaints as in the table (2.2).

Table 2.2: patient's complaints

Dyspareunia	Y	83.3% (n.10)
	N	16.6% (n.2)
Dryness with sex	Y	75% (n.9)
	N	25% (n.3)
Lax vagina		100% (n.12)
Swelling or bulging inside the vagina	Y	58% (n.7)
	N	41.6% (n.5)
Sexual desire	Y	50% (n.6)
	N	50% (n.6)
Drippling urine during stress	Y	11 (91.6%)
	N	1 (8.33)

Y =yes , N=no

2.Gynecological examination:

1-Inspection of external genitalia to exclude any tear, bleeding and infection

2-Vaginal exam to exclude any bleeding or any other abnormality and to demonstrate laxity of pelvic support, presence of any degree of prolapse.

3. A disposable vaginal speculum was introducing to examine the cervix in order to exclude any abnormality or lesion.

4.per vaginal examination(pv) procedure to assess the vaginal diameter.

5.Stress test in supine and standing positions to demonstrates SUI.

6.Investigations: complete blood picture, and viral screen.

2.5 Safety measures : In the present work, the laser employed is class IV laser. These types of laser can cause damage to eye and skin with direct intra beam exposure and from specular or diffuse reflections.

All personals were asked to wear protective goggles appropriate to CO_2 to eliminate the risk of eye damage. These glasses are designed with special wavelength and optical density for CO_2 laser. Doctor goggles in figure(2.2).

Figure (2.2) goggles for CO_2 laser

The eyes of the patient were covered with wet mops of cotton or gauze plus eye blinder which is completely shielded, taking into consideration the elimination of any reflecting materials, metals and polished plastic in the laser room.

The smoke and vapor plume were carefully extracted using a vacuum system. This is necessary to minimize the hazards to the patient and staff as many types of infections can be present in the vapor of CO_2 laser.

2.6 CO_2 Laser specifications

The laser machine used in this study is EX Matrix CO_2 Laser Therapy System manufactured in China. Its clinical data is the following, as shown in the catalogue:

Laser Type	RF-excited CO_2 laser
Wavelength	10.600 nm
Laser average power	CW:0-40W
Headpieces	Surgical Hand pieces (f 50mm, f 100mm)
	Scan Hand pieces (f 50mm, f 100mm)
	Gynecology Headpieces (f 127mm)
Spot Size	more than 0.1mm
Scan Size	up to 20mmx20mm
LCD screen	12.1 inch
Aiming beam	635nm, <5mw
Electrical	100-240 VAC,50-60 Hz, 800VA
Dimensions (LxWxH)	460mmx430mmx1170mm not including articulated arm
Net Weight	40 Kg

Figure (2.3) CO_2 Laser system

2.7 Treatment parameter

The laser parameters used in this study were Fractional CO_2 laser, wavelength 10600 nm, power 30 watt, duration 1.7ms, point number 28, distance 1.0 mm, scan mode normal, scan times 4 and scan Rows 5.

Figure (2.4) Laser parameters used

2.8 Methods

2.8.1: Procedure

Include the following:

1.Preperation of the patients: two days after menstruation for the patients who still menstruated.

2.Few minutes before starting, asked patient to empty bladder.

3.Insert topical anaesthesia Amla cream 5% (2.5 % lidocaine and 2.5 % prilocaine) at the introits then ask the patient to wait 10 minutes to anaesthetized area.

4. Proper eye protection for patient, physician and anyone else in the room is essential when using this laser.

5. a specially designed laser speculum (The speculum cage) as shown in figure (2.5) was introduced into the patient's vagina to serve as a guide for the laser beam delivery system. When the laser speculum is properly positioned into the patient's vagina, the laser beam delivery system (figure 2.6) is introduced into the laser speculum figure (2.7). A simple step-by-step withdrawal of the laser hand piece outwards from the laser speculum. The hand piece was positioned with contact to the vaginal wall and pulses were applied at each 1 cm marking and then retracted, the hand piece was reinserted two times. producing a non-ablative precisely controlled, thermal-only effect on the vaginal wall that causes immediate tissue shrinkage and initiates collagen remodeling and new collagen synthesis in the vaginal mucosa. The safety and tolerability of the procedure was assessed by observation and documentation of potential adverse effects during and after the procedure. The operative time taken about 15±5 minutes to complete.

Figure (2.5) The speculum cage

Figure (2.6) Gynecological hand piece

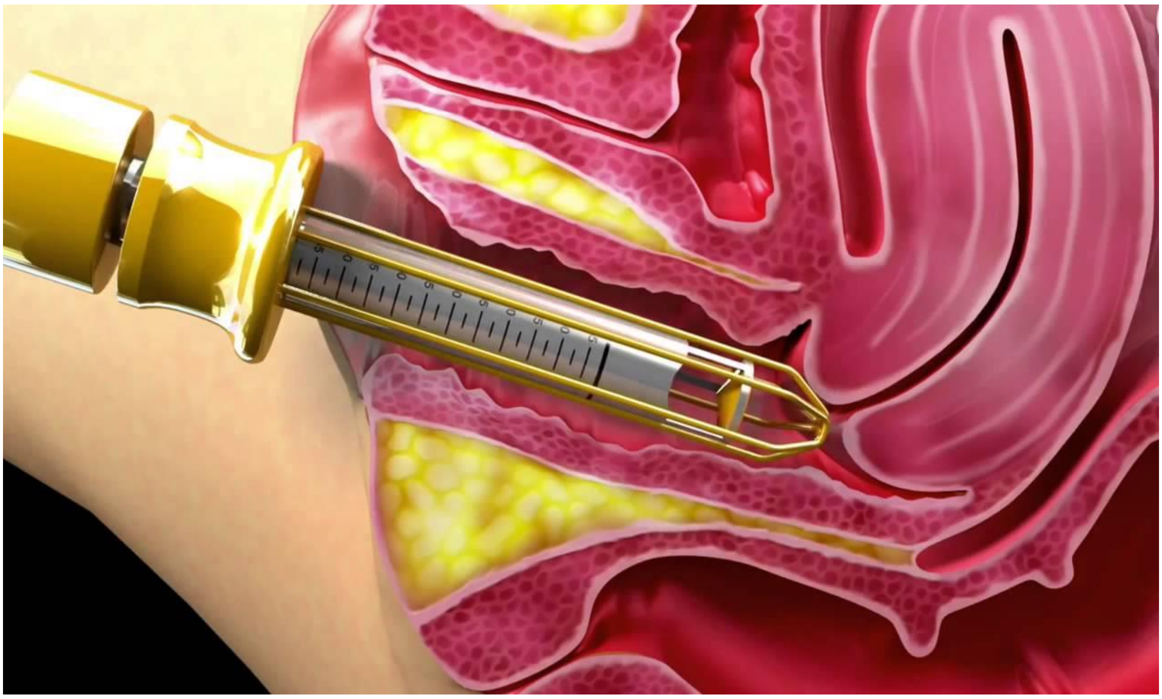


Figure (2.7) Laser procedure

2.8.2 Postoperative Instructions

After laser session all the patients were given instructions that including

1. Commitment to follow up appointments in the exact date.
2. No post-op therapy was needed.
3. Patients were only requested to restrain from sexual activities for a period of 7 days after each of the treatment sessions.

2.8.3 Follows- up

1.After each session patients were assessed about post treatment events .

2.. All patients were assessed at 4 wk. from the second session (final treatment) by subjective assessment (table 2.3) to assess if there is improvement in dyspareunia, dryness during sex, feeling of swelling or bulging, urine incontinence, sexual satisfaction, overall satisfaction and self-assess the efficacy of the laser vaginal tightening treatment.

Table 2.3 Subjective assessment of symptoms improvement

<table>
<tr><th>Four weeks
After 2nd session</th><th colspan="2">dyspareunia</th><th colspan="2">Dryness
with sex</th><th>Urine Incontinence</th><th>bulging or swelling</th><th>lax vagina</th><th>Sexual satisfaction</th></tr>
<tr><td>Not improved</td><td colspan="2"></td><td colspan="2"></td><td>.</td><td></td><td></td><td></td></tr>
<tr><td>Improved</td><td colspan="2"></td><td colspan="2"></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Overall satisfaction</td><td>0</td><td colspan="2">1</td><td>2</td><td></td><td></td><td></td><td></td></tr>
</table>

The improvement depends on the patient satisfaction which was graded as follows: (evaluation criteria)

Overall satisfaction

Grade 0= not satisfied.

Grade 1= partially satisfied.

Grade 2= fully satisfied

Chapter Three

Results and Discussion

Results & discussions

3.1 Introduction

This chapter presents the results, the discussion to explain these results , conclusion and suggestion about this study.

3.2. Results : The result of this study depends mainly on the patients symptoms and follow-up.

- All patients were discharged home immediately after treatment.
- 83% of the patients (n.10) showed improvement in dyspareunia .
- only two patients from 9 did not show dryness improvement
- 91.6% (n.11) reported improvement in stress urine incontinence
- No more feel mass or bulging in the vagina
- 75% (n.9) reported an improvement or increased vaginal tightening.

As shown in figure (3.1)

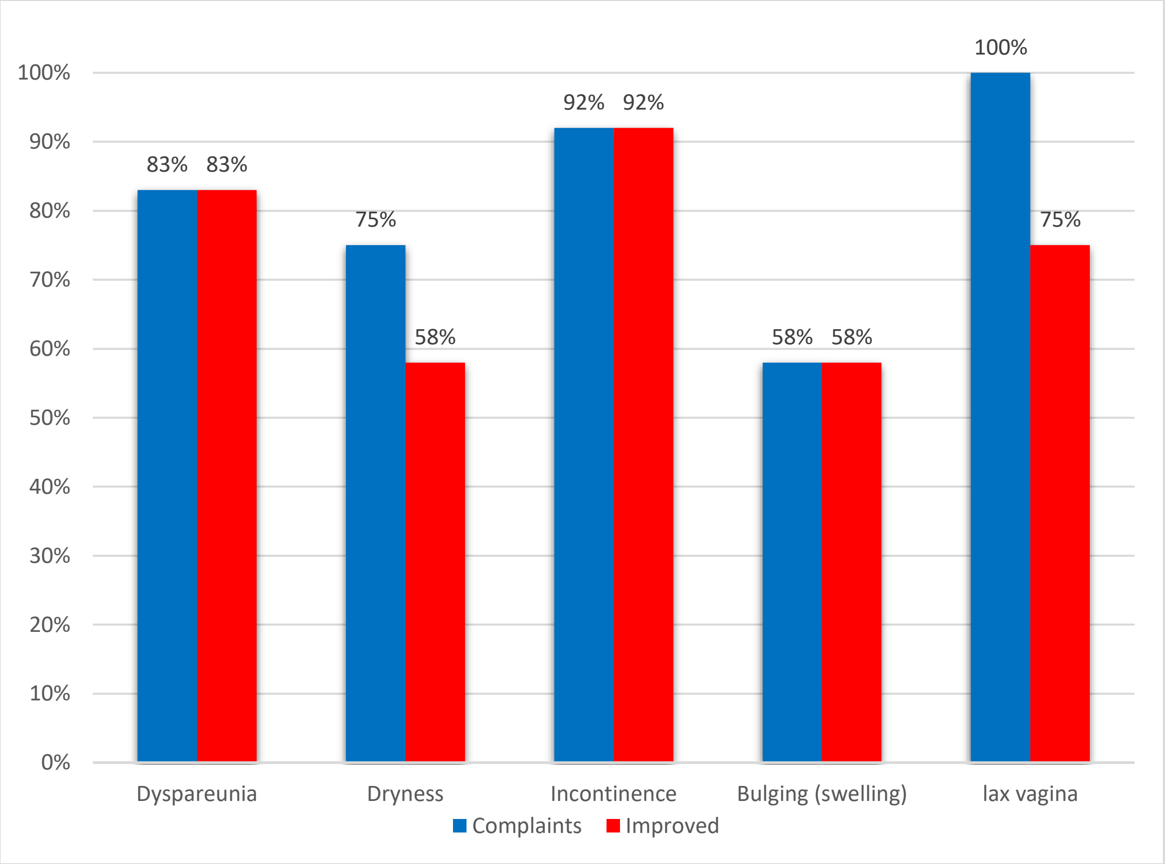


Figure (3.1) patient's improvement

Most of the patient 75 % (n.9) reported sexual satisfaction, all subjects except one (92 %) reported satisfaction with treatment figure (3.2).

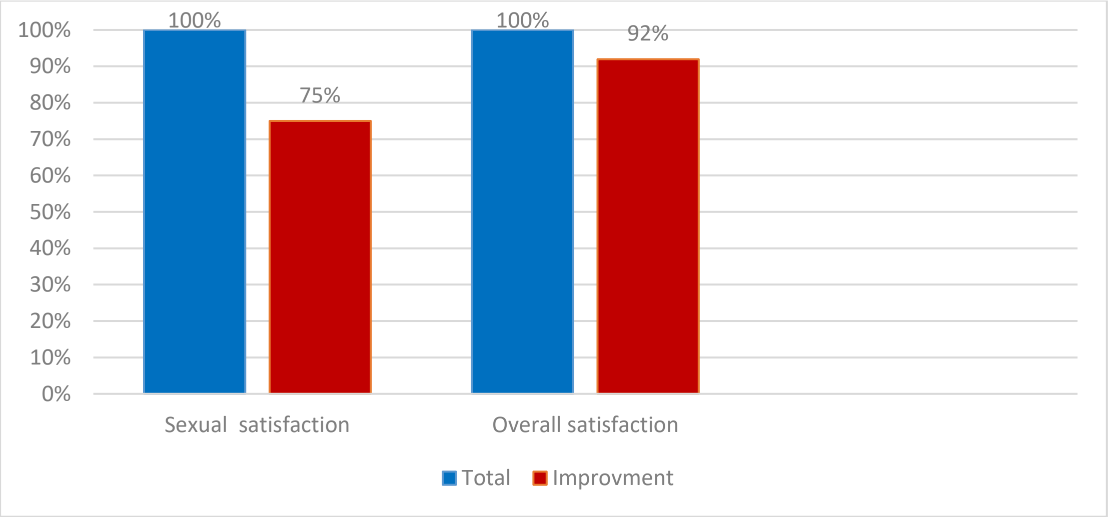


Figure (3.2) Satisfaction with treatment

3.3 Adverse reaction

Most patients (97%) reported that treatment was accompanied with none to mild pain. Immediate treatment responses were mild and transient, resolving within 3-5 days and included two case of swelling (16.6%), one case of twinging sensation (8.3%), one case of numbness (8.3%), two cases of mild bleeding (16.6%), two cases of watery discharge (16.6%) These events occurred following the first treatment only and were reported at the 1-week follow up after the first treatment. The patient did not experience any other adverse symptoms following the additional treatment .No one had more than one adverse event ,all the events were mild ,transient and resolve within few days.

3.4 DISCUSSION

Photo thermal interaction with tissue is the basic concept of CO_2 laser. In this process, radiant light is absorbed by the tissue and transformed to heat energy changing tissue structure. The term thermal interaction stands for a large group of interaction types, where the increase in local temperature is the significant parameter change. Thermal effects can be induced by either CW or pulsed laser radiation. [(27)]

CO_2 lasers have long been considered as a precise and predictable treatment modality to rejuvenate photo aged skin by ablation of abnormal tissues with subsequent regeneration and remodeling of collagen and through heat-induced collagen contraction. [(50)]

The CO_2 energy is delivered in a fractional manner which generates controlled and precise tissue damage. It maintains healthy tissue surrounding each micro ablation zone enabling rapid and complete epithelial repair. Fractional scanner aids in deploying the exact amount of energy, rapidly and the depth of penetration is controllable to address the desired tissue and obtain optimal clinical effect. The energy delivered helps in effective tissue remodeling while ensuring safety of the fibromuscular layer by creating small controlled small ablation coagulation zones within the lamina propria using various energy levels.[(44)] The heat generated with the CO_2 laser induces a transient heat shock response and produces heat shock proteins (HSP). HSP 70 is over-expressed following laser ablation and plays a key role in the production of transforming growth factor-ß (TGF-ß). TGF-ß is a key element in the inflammatory response and the fibrogenic process. This in turn helps in collagenization and production of extracellular matrix. [(51)]

Heat-induced thermal remodeling with new collagen deposition improves the tissue quality of the vaginal canal. Symptoms of dryness and itching, dysuria, and recurrent infections can be alleviated by increasing the glycogen that rebalances lactobacilli, which inhibit the growth and virulence of pathogenic bacteria. [49]

Current therapeutic approaches to relieve vulvovaginal atrophy and vaginal laxity include topical treatments and hormones. They have to be used regularly for long-term to achieve desirable effects.[52] Hormone replacement therapies are also tried which has poor patient compliance and many of the times not that effective.

Surgeries are performed by gynecologists and plastic surgeons on to the pelvic floor but not every patient may be suitable considering post-operative complications. [53] Hence the choice as it is mainly based on the severity of symptoms, safety and ultimately, patient preference. [52]

The recent innovation of treatment modalities is fractional carbon dioxide (CO_2) laser has gathered a lot of attention due to its far superior ability to demonstrate significant improvement in vulvovaginal atrophy (VVA) patients. It has the advantage of being non-invasive with minimal or no down time, painless and has a better outcome. [54]

Data from our study indicated an improvement in vulvovaginal atrophy symptoms in perimenopausal women and postmenopausal women who underwent two sessions of fractional CO_2 laser vaginal treatment, with the majority of patients reporting improvement in sexual gratification and tightening effects (vaginal rejuvenation).

In this study the use of fractional CO_2 laser for vaginal tightening it really reduces the operating time, maximum operating time was 15 +5minutes it is very fast and easy comparing with surgical technique .Also it was very effective in improving and reducing symptoms of vulvo-vaginal atrophy.

In study by Gaspar A, Addamo G,et al. [55] on the use of CO_2 lasers in VRS comprising 51 women in total showed patient improvements in sexual experience after laser treatment but follow-up was short term.

Salvatore S, Nappi RE,et al.showed the Vaginal Health Index Score (VHIS) improved significantly after each laser application compared with baseline. Each VVA symptom (vaginal dryness, vaginal burning, vaginal itching, dyspareunia and dysuria) significantly improved at the 12-week follow-up compared with baseline. In addition, no adverse events related to the fractional CO_2 laser were recorded throughout the study period. [56]

The same study group further investigated the effects of vaginal CO_2 lasers on sexual function and overall satisfaction with sexual life in 77 post-menopausal women with VVA treated with three laser sessions at 30-day intervals. The Female Sexual Function Index (FSFI) and SF-12 were used at baseline and at 12-week follow-up. There was a significant increase in total scores and each individual domain of the FSFI at the 12-week follow-up compared with baseline. In addition of the 20 women who were not sexually active because of VVA, 85% regained normal sexual activity at the 12-week follow-up [55] A replication of the above study was conducted by Perino et al. [44] in post-menopausal women with VVA symptoms. Forty-eight patients were enrolled and treated with fractional CO_2 laser via a vaginal probe. All patients underwent a complete cycle of three treatment sessions spaced over 30 days. At baseline and 30 days post last treatment, the vaginal status of the women was evaluated using the Vaginal Health Index Score (VHIS) and subjective intensity of VVA was evaluated using a VAS. This study again demonstrated significant improvement in the VHIS after laser treatment and 91.7% of patients were satisfied or very satisfied with the treatment. No adverse events due the CO_2 laser were reported.

In a lot of studies that were seeking to find a measurable scale for evolution and assess the improvement in patient's complaint suffering from VVA and relaxation .

Most of these studies try to prove the significance cure through subjective questionnaire and constructed a score to determine the baseline and the significance of changes or improvement in patient's complaint after laser sessions because of the difficulty in measuring the changes in vagina after laser session which is a distensible organ.

In our study we determine in our pre session interview with participants, the baseline of their complaints and then after two sessions of laser we review their previous complaints with post treatment interview to evaluate the difference in their subjective complaints.

Pitsouni et al. performed an observational study looking at the use of CO_2 lasers in vaginal pathophysiology and the symptoms of GSM. The effect on lower urinary tract symptoms has been described above; however, the primary outcomes of this observational study were the vaginal maturation value and VHIS . Secondary outcomes included symptoms of GSM and the female sexual function index (FSFI). Participants received vaginal CO_2 laser therapy once a month for 3 months and questionnaires were completed at baseline and 4 weeks after the last laser treatment (at 12-week follow-up). Fifty-three women (postmenopausal with 1 or more symptoms of GSM with moderate to severe intensity and clinical signs of GSM) were enrolled in the study. The VHIS significantly improved at 12-week follow-up compared with baseline. In addition, the severity of GSM significantly decreased while sexual function increased significantly.

Among our participant no one of them have any harmful effect that may indicate CO_2 laser was a safe tool in management. This goes in agreement with study of Sokoi etal.

Sokol et al. [47] carried out the first US study looking at the use of the CO_2 laser for the treatment of VVA, evaluating the safety and efficacy. Women presenting with GSM were enrolled and assessments performed at baseline and 3 months after the final treatment. Women received three vaginal laser treatments, 6 weeks apart. Visual analogue scales were used to assess pain, burning, vaginal itching, vaginal dryness, dyspareunia and dysuria; VHIS, FSFI and SF-12 questionnaires were also completed. Of the 30 women recruited, 27 completed the study. For all six symptoms of VVA there was a statistically significant improvement in symptoms at follow-up compared with baseline. There was also a statistically significant improvement in mean VHIS scores, FSFI scores and at follow-up compared with baseline scores. There was a non-significant improvement in SF 12 scores assessing physical and mental health at baseline and at 12-week follow-up. Adverse events included mild to moderate pain lasting 2–3 days in two women and two women reported minor bleeding lasting < 1 day; however, none of these women discontinued treatment. Twenty-three women were followed up at 1-year post-treatment.[57] All VVA symptoms continued to be significantly better compared with baseline except dysuria. VHIS and FSFI scores also showed statistically significant improvement at 1 year compared with baseline. Ninety-two per cent of women were satisfied or extremely satisfied at 1-year post-treatment. Although encouraging results, the small numbers and lack of placebo group mean these findings need cautious interpretation.

3.5 CONCLUSION

In this study all the patient had significant improvement in most parameters analyzed. fractional CO_2 laser treatment was associated with improvement and amelioration of symptoms of VVA, resulting in improved satisfaction with sexual intimacy in women. Treatment time was quick, and there was minimal discomfort associated with treatment concluded the benefits from laser vaginal rejuvenation are non-surgical procedure that takes under an hour, minimally-invasive, little to no down time, lessens vaginal dryness and irritation, improves vaginal laxity by tightening vaginal tissue, diminishes urinary stress incontinence and restores sexual function.

3.6 Suggestion for future work

1.Increase the numbers of patients in the study.

2.Make a comparative study between Fractional CO_2 laser and other lasers like Erbium laser including the effectiveness, safety and side effects.

3.Extension of Follow up period for 12 months after complete all sessions.

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الخلاصه

الخلفية: ضمور المهبل هو حالة تؤثر على النساء ، على الرغم من أنها ترتبط بشكل رئيسي مع بداية انقطاع الطمث ويرجع ذلك أساسا إلى التغيرات الهرمونية ويمكن أن تؤثر أيضا على النساء في مراحل مختلفة من الحياة, هذه الحالة تؤثر سلبا على نوعية الحياة. ليزر ثاني أكسيد الكربون التجزيئي (10600 نانومتر) هو الطريقة الحديثة لعلاج أعراض ضمور المهبل لدى النساء.

الأهداف: كان الغرض من هذه الدراسة هو تقييم فعالية ليزرثنائي اوكسيد الكاربون التجزيئي في علاج أعراض ضمور المهبل وتجديد خلايا المهبل.

المواد والطرق: أجريت هذه الدراسة في عيادات أبحاث الطب بالليزر بمعهد الليزر للدراسات العليا من يوليو 2019 إلى نهاية سبتمبر 2019. شملت الدراسه اثني عشرنسوة يعانين من أعراض ضمور المهبل في هذه الدراسة ، وتراوحت أعمارهم بين 42-56 سنة. كانت معلمات الليزر المستخدمة هي الطول الموجي لليزر 10600 نانومتر ثاني اوكسيد الكاربون التجزيئي ، الطاقة 30 وات ، المدة 1.7 مللي ثانية ، النقطة رقم 28 ، المسافة 1.0 ملم ، وضع المسح العادي ، أوقات المسح الصفوف الرابع والمسح الضوئي 5.

النتائج: أبديت معظم النساء الاثني عشر المشمولات في الدراسة(75 ٪) عن رضاهم عن العلاج بعد جلستين من ليزر ثاني أكسيد الكربون التجزيئي (10600 نانومتر) .

الخلاصة: يعتبر العلاج بالليزر ثاني اوكسيد الكاربون التجزيئي طريقة فعالة وآمنة مع تأثير جانبي أقل .

وزارة التعليم العالي والبحث العلمي

جامعة بغداد

معهد الليزر للدراسات العليا

إستخدام ليزر ثنائي اوكسيد الكاربوني التجزيئي لعلاج اعراض ضمور المهبل وتجديد أنسجه المهبل

دراسة مقدمة إلى معهدِ الليزر للدراسات العليا/ جامعة بغداد كجزء من متطلبات نيل الدرجة الدبلوم العالي في تطبيقات الليزر في الطب/ النسائيه والتوليد

من قبل

ناديه محمد سعيد

بكالوريوس طب وجراحه عامه

بورد نسائيه وتوليد

بإشراف

الاستاذ المساعد الدكتور علي شكر **المدرس الدكتور شذى عطره**

١٤٤١هـ **٢٠١٩م**