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Fractional CO2 Laser for Treatment of Female Stress Urinary Incontinence

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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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

﴿ اقْرَأْ بِاسْمِ رَبِّكَ الَّذِي خَلَقَ * خَلَقَ الْإِنْسَانَ مِنْ عَلَقٍ * اقْرَأْ وَرَبُّكَ الْأَكْرَمُ * الَّذِي عَلَّمَ بِالْقَلَمِ * عَلَّمَ الْإِنْسَانَ مَا لَمْ يَعْلَمْ ﴾

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DEDICATED TO

MY

PARENTS

AND

MY WONDERFUL

FAMILY

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ABSTRACT

Background:. Urinary incontinence (UI) is a common disorder that affects women of various ages and impacts all aspects of life. This condition negatively influences quality of life. Fractional CO2 laser (10600nm) is the recent method for treatment of stress urinary incontinence in women.

The Objectives: The purpose of the study was to evaluate the efficacy and safety of fractional CO2 laser (10600nm) in the treatment of female stress urinary incontinence.

Materials & Methods: This study was done from July 2020 to February 2021 in private gynecology clinic. Twenty women clinically diagnosed with SUI preferring non-surgical treatment were recruited to the study, their mean ages 43.6 $\pm$ 13.9 years. Response to treatment was assessed at baseline and at one month follow up after the third session using a pelvic Floor Questionnaire (PFQ-UI).

The laser parameters used were CO2 laser wavelength 10600 nm, power 35 watt, duration 1.0 ms, distance 1.0 mm, scan mode normal, scan times 4 and scan Rows 4,Interval 0.5s.

Results: Most of the twenty women included in the study 80 % reported satisfaction and 20% not satisfied with treatment after 3 sessions of CO2 laser four weeks a part .

Conclusion: Fractional CO2 laser treatment is an easy to use, minimally invasive and effective option for treatment of SUI.

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List of abbreviations

Abbreviation	Item
ANSI	American National Standard Institute
BMI	Body mass index
CA	Carcinoma
cm	centimeter
CO2	Carbon dioxide
CW	Continuous wave
GSM	Genitourinary syndrome
GUE	General urine examination
He: Ne	Helium Neon
Hz	Hertz
ICI	International consultation incontinence
ICIQ	International consultation on incontinence modular questionnaire
ICIQ-UI SF	International consultation on incontinence modular questionnaire-Urinary incontinence- Short form
IR	Infrared
ISD	Intrinsic sphincter deficiency
ISI	Incontinence Severity Index
J	Joule
Kg	Kilogram
LSO	Laser Safety Officer
M	Meter
min	Minute
μm	Micrometer
mm	Millimeter
μs	Microsecond
MTZ	Microscopic Thermal Zone
MUI	Mixed urinary incontinence

nm	Nanometer
NVD	Normal vaginal delivery
PFQ	Pelvic Floor Questionnaire
POP	pelvic organ prolapse
PPE	Personal Protective Equipment
PVR	Post voiding remnant
RF	Radiofrequency
SD	Standard Deviation
Sec	second
SOP	Standard Operating Procedures
SUI	Stress Urinary Incontinence
UV	Ultraviolet
W	Watt

CHAPTER ONE

INTRODUCTION

AND

BASIC CONCEPTS

1.1 INTRODUCTION:

Urinary incontinence is an inability to hold urine in the bladder due to loss of voluntary control over the urinary sphincters resulting in the involuntary passage of urine. The International Continence Society Standardization Committee defines urinary incontinence as an involuntary loss of urine that causes social and hygienic problem. Urinary incontinence symptoms are highly prevalent among women, have a substantial effect on health-related quality of life and are associated with considerable personal and societal expenditure.[1]

1.2 SUI :

Stress Urinary Incontinence (SUI), defined as the complaint of involuntary urine leakage on effort or exertion, or on sneezing or coughing due to insufficient strength of the closure of the bladder when urine leaks out with sudden pressure on the bladder and urethra, causing the urethral sphincter muscles to open briefly. In mild SUI leaking may occur from any sudden forceful activities, like exercise, coughing, laughing or sneezing, more severe SUI, urine may leaks with less forceful activities like standing up, bending over or walking . Urinary leakage can range from a few drops of urine to enough to soak through clothes.[2]

1.2.1 Epidemiology of SUI:

Stress urinary incontinence affects 15.7% of adult women; 77.5% of women report the symptoms to be bothersome and 28.8% report the symptoms to be moderate to severe.[3] Prevalence of stress urinary incontinence will increase with age particularly with menopause. Up to 77% of elderly females in nursing homes will have urinary incontinence.[4]

1.2.2 Anatomy:

The bladder, urethra and urinary sphincters work in concert to store urine at low pressure and to void voluntarily at socially convenient or appropriate times. Anatomically the genitourinary system, or urogenital system, are the organs of the reproductive system and the urinary system. These are grouped together because of their proximity to each other and their common embryological origin

The bladder is a pyramidal shaped organ, the main function of the bladder is to store urine, and under the appropriate signals, release it into a tube which carries the urine out of the body. Normally, the bladder can hold up to 500mls of urine.

Urethra is about 4-6cm long and 6mm wide, the urethra is a tube which runs from the bladder neck to open into an external hole which is located at the top of the vaginal opening.[5]

The anterior vaginal wall plays an important role in continence mechanisms by supporting the urethra and bladder base. Excessive relaxation of the wall may result in urethral hypermobility and bladder descent .[6]

The anatomic feature of stress incontinence as shown in Figure 1.1 .

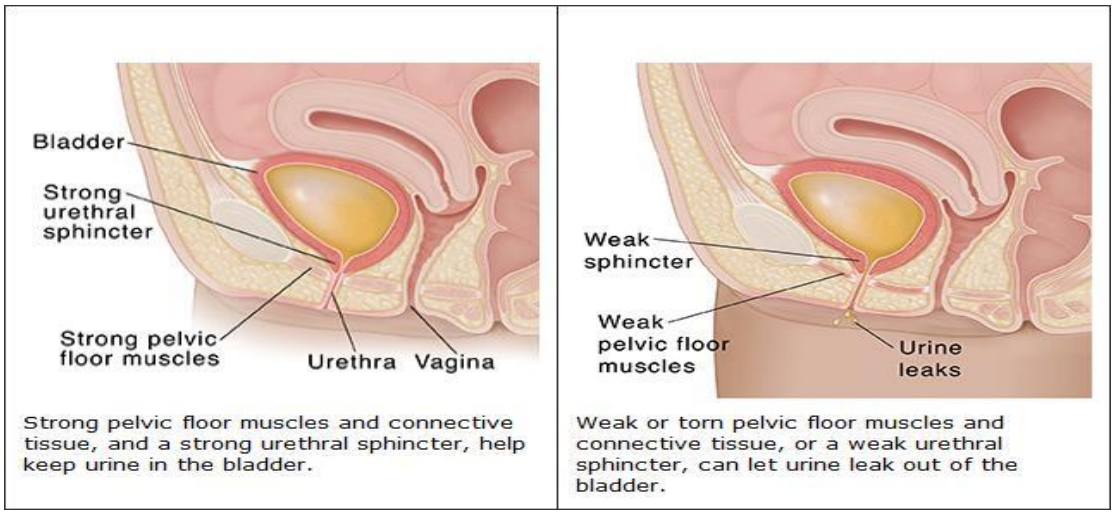


Figure 1.1 The anatomic feature of stress incontinence . [6]

1.2.3 pathophysiology

An understanding of the pathophysiologic mechanisms that are postulated to cause SUI is essential to accurate classification. Broadly two mechanisms are proposed: weakness in the supporting tissues of the urethra resulting in ‘‘urethral hypermobility’’ or a defective urethral sphincter mechanism termed intrinsic sphincter deficiency (ISD), with many patients having features of both.[7]

In 1923, Victor Bonney introduced the concept that SUI results as a consequence of loss in urethral support based on his observation of abnormal downward displacement of the anterior vaginal wall in women with SUI.[8] Urethrocele which is dislocation of urethra and it is the cause of incontinence (Mann’s American System of Gynecology 19 cent.).

Following the work of others, Enho¨rning in 1961 introduced the pressure transmission theory, postulating that stress causes descent of the urethra out of the pelvis due inadequate proximal urethral support leading to a lack of transmission of intra -abdominal pressure to the urethra and thus causing urine leakage.[9]

The concept of ISD, a defective urethral sphincter mechanism as a distinct cause of SUI, was introduced by Edward McGuire in the 1970s and represented a major refinement in thought. McGuire based his theory on video urodynamic findings in women who had persistent SUI despite retropubic suspension procedures.[10] These women had a low proximal urethral closing pressure at rest with minimal or no urethral descent during stress.

1.2.4 Risk factors for SUI:

The peak incidence of SUI occurs between 45 and 49 years of age. Risk factors cited for the development of SUI included: advanced age; obesity; vaginal deliveries, in

which, damage may occur to local musculature and innervation as the fetus passes; traumatic deliveries involving forceps and/or episiotomies; multiparity and pregnancy at an advanced age; estrogen deficiency, conditions associated with increased intraabdominal pressure; smoking; diabetes; collagen diseases; neuropathies; and history of hysterectomy.[11]

Bump and Norton.[12] have constructed an excellent model that places these risk factors in context as Shawn in figure 1.2.

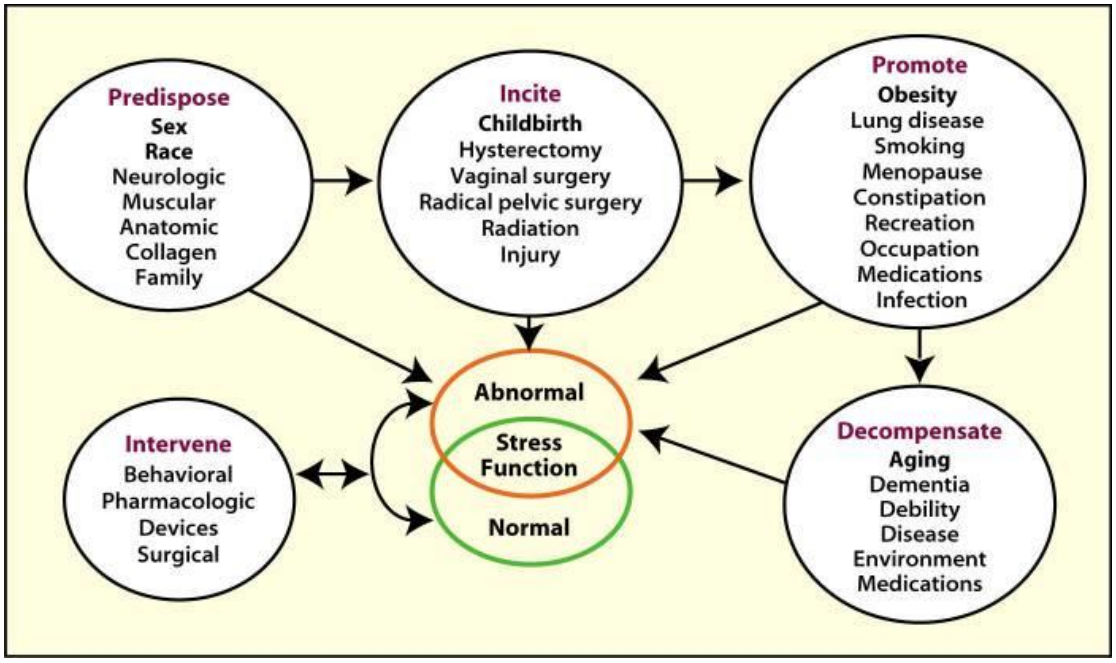


Figure 1.2 Risk factors for stress urinary incontinence. Adapted from Bump RC, Norton PA. Obstet Gynecol Clin North Am. 1998;25:723–746 .[12]

1.2.5 Diagnostic evaluation of SUI:

The severity of stress incontinence is classified by Stamey:

- Grade 1: loss of urine with sudden increases of abdominal pressure: e.g. coughing, sneezing or laughing.
- Grade 2: loss of urine with lesser degrees of stress: e.g. walking or standing up.
- Grade 3: loss of urine without any relation to physical activity or position, e.g. while lying in bed. [13]

1.2.6 Clinical assessment:

Aim of the assessment of a woman presenting with SUI is to confirm the diagnosis, assess symptom severity, and attempt to understand the underlying pathophysiologic mechanism, as to identify treatment options and risks. History and physical examination of the patient with incontinence should focus on both the general medical conditions that may affect the lower urinary tract as well as the problems related to urinary incontinence.

The International Modular Questionnaire (ICIQ) was developed to meet the need of a universally acceptable standard guide for the selection of questionnaires to be used in clinical practice and research.[14]

- Investigations for SUI:

1-stress (cough) test:

A positive cough stress test (whereby observed urethral leakage is provoked by a series of forceful coughs in the supine or standing position with a comfortably full (~300 ml) bladder volume) has a high sensitivity and specificity for diagnosing stress urinary incontinence. [15]

2- Bladder(voiding)diary:

The voiding diary is an essential adjunct to history taking, providing an objective measure of frequency and volume of leakage episodes

A micturition diary with documentation drinking habits, incontinence episodes and voided volumes may help to quantify the severity and bother of stress urinary incontinence. A time period of 24–48 hours is usually sufficient. [16]

3-Pad test for quantification of SUI:

Pad testing is a non-invasive method of detecting and quantifying severity of urine leakage. A 24-hr test is more reproducible then a 1-hr test, but longer testing requires more preparation and a greater commitment on the part of the patient.[17]

4-Q-tip test:

It is an objective method to measure urethral hypermobility in women with stress urinary incontinence

The test is performed by inserting a rigid cotton-tip swab into the urethra to the level of urethrovesical junction, as in fig.1.3 A. Many providers do not feel comfortable performing the test due to the perception of invasiveness or may find the test difficult depending on their level of training and background. There is also a theoretical risk of urinary tract infection.[18]

5-vaginal swab test:

As the urethral supporting structures are interconnected with the vagina, the rotation of the anterior vaginal wall theoretically represents the degree a simpler and less invasive alternative method compared to the urethral Q-tip test.[18] As in fig.1.3 B

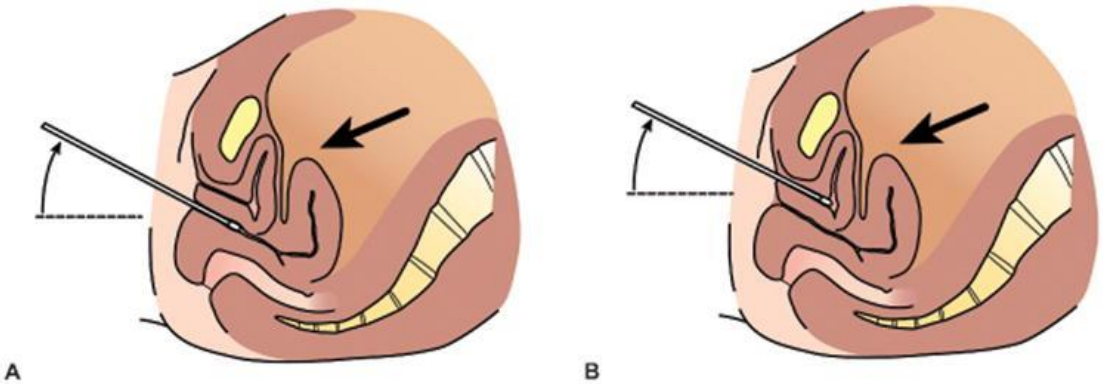


Figure 1.3 Midline female pelvis demonstrating a cotton-tipped swab rotation *(*curved arrow*)* with valsalva (downward abdominal force on the pelvis, straight arrow*)* from the horizontal plane *(*dashed line*)*. Cotton-tipped swab in the vagina, the vaginal swab test (**A**) and in the urethra, the standard urethral Q-tip test (**B**). [18]

6-Ultrasound Imaging:

Abdominal sonography: determination of residual urine

A volume < 50 mL is normal; < 100 mL is usually acceptable in patients > 65 but abnormal in younger patients.[19]

7-Urodynamic Examination:

the 2nd International Consultation on Incontinence (ICI) were published. Among the many outstanding chapters was a review by a consensus panel of experts of the performance, indications, and utility of urodynamic investigations in a variety of clinical settings. The panel recommended urodynamics for the investigation of incontinence symptoms in women in the following cases only:

1) voiding difficulty or neuropathy is suspected,

2) the patient has failed nonsurgical or surgical therapy.

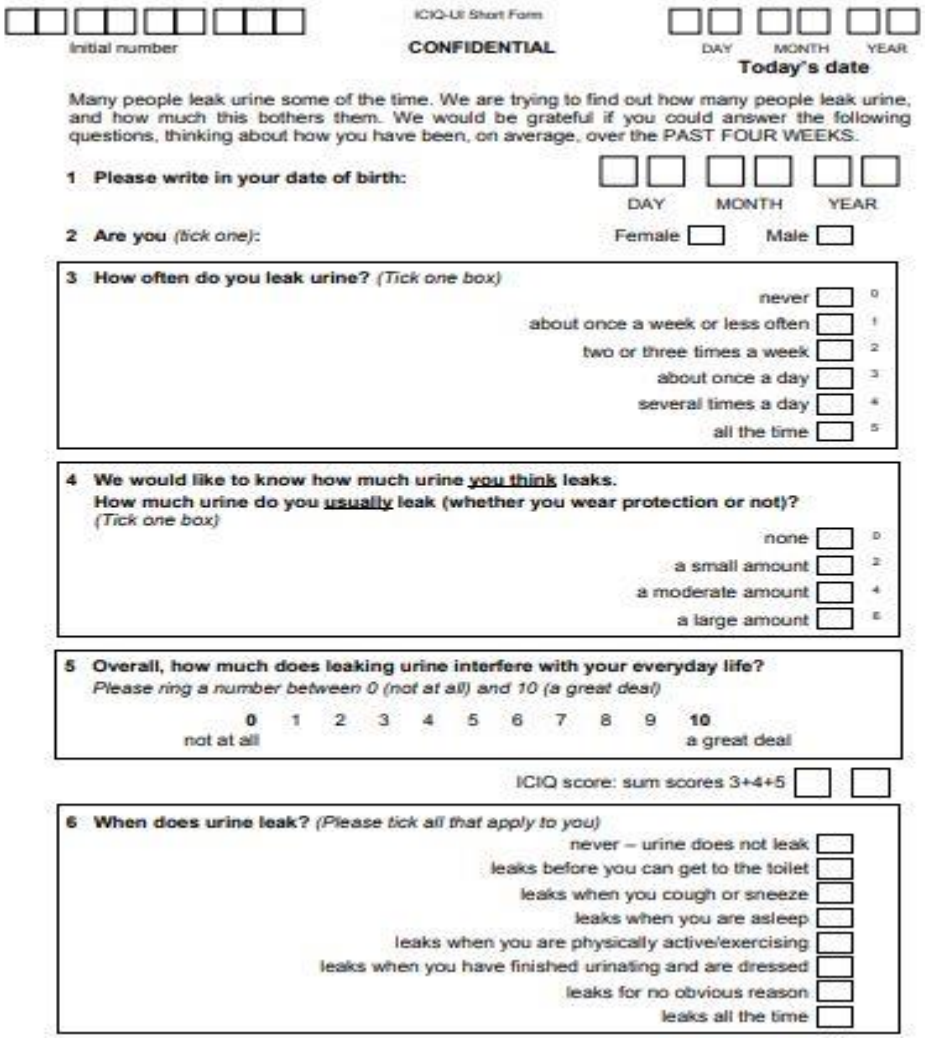
3) invasive or surgical treatments are being considered. [20]

8-Cystoscopy:

Cystoscopy is indicated for the differential diagnosis of incontinence.

1.2.7 SUI severity assessment:

The International Consultation of Incontinence (ICIQ) has developed a series of international questionnaire to investigate lower urinary tract dysfunction. The degree of incontinence and its impact on the quality of life was assessed with the International Consultation on Incontinence Questionnaire UI Short Form (ICIQ-UI SF).[21] Fig.1.4. The questionnaire allows the assessment of the prevalence, frequency and its impact on everyday life.[22] The results of the ICIQ-UI SF may be divided into the following four severity categories: mild (1–5), moderate (6–12), severe (13–18) and very severe (19–21).[23]



ICIQ-UI Short Form

Initial number

CONFIDENTIAL

DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 **Please write in your date of birth:** DAY MONTH YEAR

2 **Are you** *(tick one)*: Female ☐ Male ☐

3 **How often do you leak urine?** *(Tick one box)*

never ☐ 0
about once a week or less often ☐ 1
two or three times a week ☐ 2
about once a day ☐ 3
several times a day ☐ 4
all the time ☐ 5

4 **We would like to know how much urine you think leaks.**
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

none ☐ 0
a small amount ☐ 2
a moderate amount ☐ 4
a large amount ☐ 6

5 **Overall, how much does leaking urine interfere with your everyday life?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all — a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 **When does urine leak?** *(Please tick all that apply to you)*

never – urine does not leak ☐
leaks before you can get to the toilet ☐
leaks when you cough or sneeze ☐
leaks when you are asleep ☐
leaks when you are physically active/exercising ☐
leaks when you have finished urinating and are dressed ☐
leaks for no obvious reason ☐
leaks all the time ☐

Fig. 1.4 ICIQ-UI SF.

1.2.8 SUI treatment:

For most patients, the initial management of uncomplicated SUI involves a variety of noninvasive interventions. If conservative measures fail then surgical treatments are considered. Although surgical treatments are widely used for SUI, many women prefer a self-managed conservative option to avoid long-term recurrence or possible devastating complications of surgical interventions. Conservative measures includes:

1-Behavioral modification: Include patient education regarding the function of the lower urinary tract. 2-Pelvic floor muscle training.

3-Electrical Stimulation.

4-Vaginal Cones.

5-Occlusive Devices.

6-Intravaginal Supportive Devices (Pessaries).[24]

7- Laser treatment.

1.2.9 Roll of CO_2 laser in treatment of SUI:

The common mechanism of UI is pelvic floor dysfunction due to loss of its supportive function. The mechanical stability of the urethra and bladder neck is largely provided by intact pelvic muscles and connective tissue of the pelvis. Thus, the majority of therapeutical approaches aim at strengthening the support of the pelvic floor, either conservatively or surgically. Although, there are reports on the beneficial effects of conservative treatment , patients have to be very compliant and the final outcome remains questionable. On the other hand, none of the existing surgical approaches is optimal as they are often associated with complications .

Laser therapy has a therapeutic role in various medical conditions and most recently has gained interest as a promising treatment for UI, particularly SUI, the most prevalent type of UI.[25] Laser photothermal energy can improve collagen structure and initiate neocollagenesis in the skin and pelvic floor with nearby tissue [26]. Elevation in temperature up to 63°C increases the contraction of collagen fibers in vaginal epithelium and provokes neocollagenesis, elastogenesis, neoangiogenesis, and increased fibroblast. In addition, histopathology showed an increase in the volume density of blood capillaries and the thickness of the epithelial layer that lead to restoration of most vaginal functions and also an increase in muscle tone that seems to be related to a clinical improvement in UI.[27]

1.3 Laser physics:

LASER is an acronym for Light Amplification by Stimulated Emission of Radiation.

1.3.1 Laser history:

The term Laser reflects the crucial role of the process of stimulated emission for the quantum generators and amplifiers of coherent light. Therefore, the history of laser development should be traced as far back as 1917 when Albert Einstein showed that the process of stimulated emission must exist.[28] This was the first step towards the laser. In 1953, a group at Columbia University headed by Charles H.Townes operated a microwave device that amplifier radiation by stimulated emission process, it was termed MASER, an acronym for Microwave Amplification by Stimulated Emission of Radiation.[29] Over next year's Schawlow and Townes made important contributions that help to extend these ideas from the microwaves to the optical wavelength region. These efforts culminated in July 1960 when T.H. Mainian announced the generation of a pulse coherent red light by means of a ruby crystal-the first laser. After that laser started to be used by engineering sciences and industry. An example of its use in computer science such as information security, thus making it possible to secure transmission of information from the patient to data stored in the hospital or from a hospital to another. Also in the field of electronic engineering and medical engineering which made it possible to develop laser devices to be used in medicine and medical applications. There is no universal laser device or set of laser light Parameters for effective treatment of all medical diseases just as there is no universal drug for all human disorders. Therefore, greater acceptance of lasers for medical treatment will come with better understanding of the proper choice of laser light energy value needed to perform a specific treatment, when this knowledge is identified from careful scientific studies in the research laboratory a safety packaged laser device and delivery system operated within appropriate range of conditions will greatly increase the acceptance of laser for clinical applications.[30]

1.3.2 Basic Components of Laser:

In order to operate most laser devices, three basic conditions must be satisfied:

1-Active medium: This is a collection of atoms, molecules, or ions that can be solid, liquid, gas, or plasma states. The composition of the lasing medium determines the wavelength output and name of a particular laser.[30]

2-Pumping source: The source of energy to pump the laser medium. When the laser medium in the optical cavity is pumped, a laser beam is generated that leaves the cavity through the partially transmitive mirror by which the population inversion is created inside the active medium .

3-Optical resonator: This consists of two mirrors. The laser medium is placed in the optical cavity and its axis is made to coincide with the common axis of the mirrors. One mirror is generally fully reflective for the wavelength of operation of the laser and the other is partially transmitive, by which the selection of some photon states and the suppression of other states can be realized.[29] As shown in Figure 1-5.

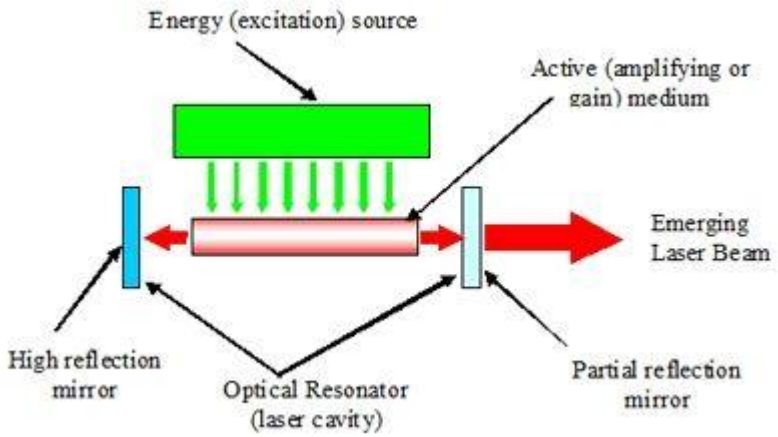


Figure 1-5 Basic components of laser.

1.3.3 Properties of Laser Light:

Monochromaticity: Monochrome means that all the photons have the same wavelength.

Coherence: Coherence means that the electromagnetic waves of light rays are in phase with each other in both space and time.

Directionality: There is little divergence of the laser beam as it exits the laser device and the beam can travel a considerable distance with very little movement away from parallelism.

Brightness or intensity: This property arises from the parallelism or collimation of the laser light as it moves through space maintaining its concentration and thus, the characteristic brightness.

Laser light versus ordinary light. [31]As shown in figure 1-6.

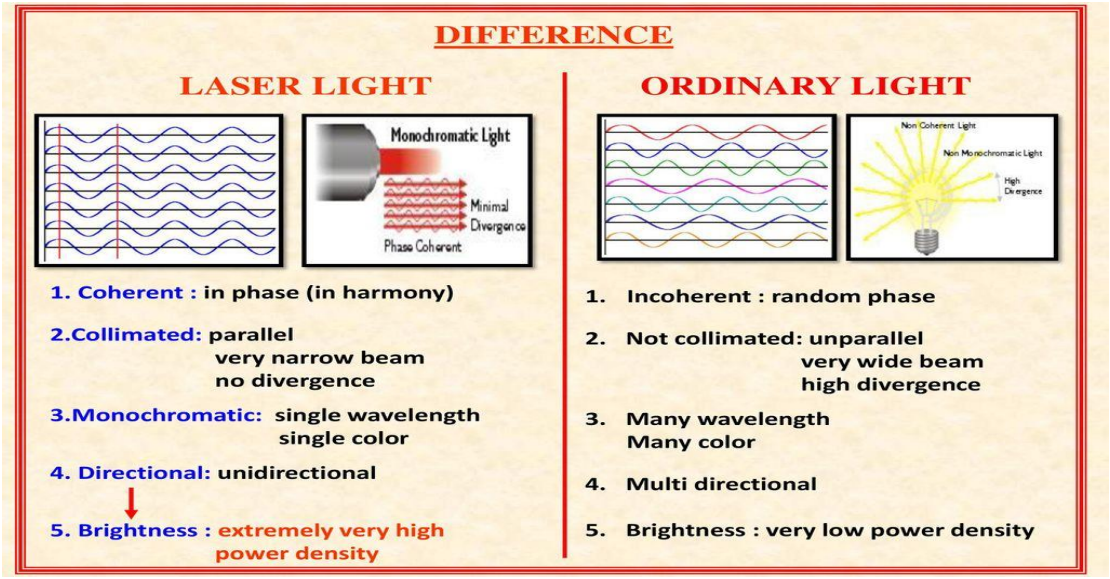


Figure 1-6 Laser light properties vs. ordinary light.

1.3.4 LASER MODES:

Types of laser operation: Lasers can operate in the following modes:

- CW or continuous mode: is generated by continuously pumping energy into active medium to achieve equilibrium between the number of atoms raised to the excited state and the number of photons emitted .At such equilibrium continuous laser output results . The duration of which ranges from fractions of a second to hours .(Figure 1-7)
- Chopped mode: A shutter interrupt The output of a CW laser that chops the beam into trains of short pulses. The maximum power level of each pulse is the same as that obtained in the CW mode.(Figure 1-7)
- Pulsed: Gas lasers such as the CO_2 laser can be gated or pulsed. Electronically the gating permits the duration of the pulses to be compressed; producing a corresponding increase in peak power that is much higher than it is commonly available in the CW
  mode .(Figure 1-7)
- Q-Switched: Short and more intense pulse can be obtained with the technique of Q-switching. By introducing a shutter into the resonant cavity of the laser, the energy in the active medium is raised to a level far above that is obtainable without the shutter or obstruction in the system. If the shutter is then rapidly opened or the obstruction is removed to permit light to traverse the resonant cavity, all of the stored energy is discharged in an extremely short period. [31]

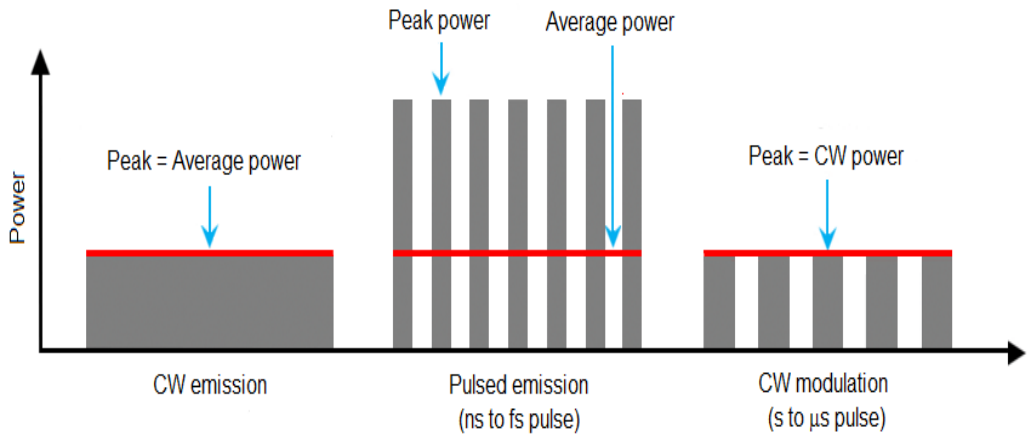


Figure 1-7 CW, Pulsed and chopped laser outputs

1.3.5 Laser parameters:

- **Wavelength:** Wavelength is the most important determinant in how light affects tissue.
- **Energy :** Energy is measured in joules (J) and is proportional to the number of photons.
- **Energy density**: Fluence is the energy delivered per unit area. It is measured in J/cm^2
- **Pulse duration:** This term is used in pulsed lasers. It refers to the full width at half maximum of the peak of the pulse. Pulse duration is measured in units of time (milliseconds, microseconds, nanoseconds, picoseconds or femtoseconds).
- **Repetition rate:** It is the number of pulses per one second.. It is measured in Hertz (Hz).
- **Duty cycle:** It is the useful proportion of the laser beam during which the light is transmitted by the chopped laser. It is a unit less quantity.
- **Power**: Power is the rate of delivery of the energy. It is measured in watts (W) where 1 W = 1 J/sec.
- **Power density**: Irradiance: Irradiance is the power per unit area. It is measured in W/cm^2.

- **Spot diameter:** It is the diameter of the irradiated area on the target. The spot diameter is considered to be equal to the beam diameter when the lenses are not be used. The units of the spot diameter are usually centimeters.[31]

1.3.6 Laser hazards effects:

As a consequence of increasing popularity, laser systems are now highly widespread in medical environment, where they are used also by personnel not highly specialized in optics and laser source management and in the presence of patients. This has greatly boosted the attention towards laser safety issues related to exposure to laser beams and to strictly assess the values of well-defined laser radiation standard parameters characterizing the level of hazard of laser sources.[32]

1.3.6.1 Types of laser hazards:

Laser radiation hazards must be identified and evaluated.

- Eye: Acute exposure of the eye to lasers of certain wavelength and power can cause corneal and retinal burns (or both). Chronic exposure to excessive levels may cause corneal or lenticular opacities (cataracts) or retinal injury
- Skin: Acute exposure to high levels of optical radiation may cause skin burn; while carcinogenesis may occur for ultraviolet and near ultraviolet wavelengths
- Chemical: Some lasers require hazardous or toxic substance operates (i.e., chemical dye)

- Electric shock: most lasers produce high voltage that can be lethal
- Fire hazards: The solvents used in dye lasers are flammable. High voltage pulse or flash lamps may cause fire. Direct beams may ignite flammable materials or a specular reflection from high power Continues Wave (CW) infrared lasers.

  Another hazard involves the potential inhalation of airborne biohazardous materials that may be released as a result of the surgical application of laser.[31]

1.3.6.2 Laser safety standards and hazard classification:

This standard was developed by the American National Standard Institute (ANSI) in year 1993. The classification is based upon the beam output power or energy from the laser. Basically, the classification is used to describe the capability of the laser to produce injury to personnel. The higher the classification number, the greater is the potential hazard. [33]As shown in table 1-1:

Class	Characteristic
Class 1	• Eye safe under all operating conditions • Does not 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 second 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 viewed 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 500 mW CW or greater than 0.03 J for a pulsed system. • Pose eye hazards, skin hazards, and fire hazards. Viewing the beam or specular reflections or exposure to diffuse reflections can cause eye and skin injuries. • All control measures explained in this document must be implemented.

Table1-1 Laser hazard classification

1.3.6.3 CONTROL MEASURES:

The control measures are devised to reduce the possibility of exposure of the eye and skin to hazardous levels of laser radiations. The ANSI series of laser safety provide detailed descriptions of control measures. [34-35]

Control measures may be broken down into three main types: The Laser Safety Officer (LSO) is responsible for making sure control measures are in place.

1) Engineering control measures: Involve design features or devices applied to the laser, or laser environment that restrict or reduce irradiance exposure. Such controls include beam shutters, beam attenuators, remote firing and monitoring systems, and the protective housing placed entirely around some laser systems.

2) Administrative and procedural control measures: Involve procedures and information rather than devices or mechanical systems. Some important administrative controls are posting of warning signs and labels, establishment of standard operating procedures (SOP), and safety training.

3) Personal protective equipment (PPE): Is worn by personnel using the laser or in the vicinity of the laser. It includes protective eyewear, gloves, and special clothing for Class 3b and Class 4 lasers and laser systems.

1.3.6.4 Important laser safety measures to follow:

1. Wear Laser Safety Glasses
2. Utilize Proper Storage
3. Follow Standards and Regulations
4. Work With Trained Personnel
5. Use Warning Signs [19]

1.3.7 Laser tissue interaction:

Today, lasers are widely used in biology and medicine, and the majority of health centers and hospitals utilize modern laser systems for diagnosis and therapy applications. Researchers have introduced different medical applications for different lasers used in surgeries and other medical treatments. Medical lasers can be categorized in both diagnosis and therapy branches. Main difference between diagnosis and therapy applications is the type of laser-tissue interactions. In diagnosis, one tries to arrange a noninvasive method to study the normal behavior of tissue without any damage or clear effect on tissue. But in therapy, such as surgery, surgeon uses laser as a knife or for affecting a specific region. So, the medical laser applications are defined by the interaction type between laser light and tissues. The knowledge of laser-tissue interaction can help doctors or surgeons to select the optimal laser systems and modify the type of their therapy.[36]

1.3.7.1 Effect of tissue on laser light:

When laser light strikes a tissue surface, it can be reflected and refracted, scattered, absorbed or transmitted. The fractional intensity that goes into these different processes depends on the optical properties of the tissue like it's reflectivity, scattering and absorption coefficients, particle size, as well as the laser parameters like wavelength, energy, pulse duration, operation mode and output spectral profile. In medical laser applications, refraction plays a significant role when irradiating transparent media like corneal tissue. In opaque media, usually, the effect of refraction is difficult to measure due to the absorption and scattering[37]. All the effects of light begin with the absorption of electromagnetic radiation. During absorption, the intensity of an incident light is attenuated by passing through a medium due to a partial conversion of light energy into heat motion or certain vibrations of molecules

of the absorbing material. The ability of a medium to absorb electromagnetic radiation depends on a number of factors, mainly the electronic constitution of its atoms and molecules, the wavelength of radiation, the thickness of the absorbing layer and internal parameters such as temperature or concentration [26]; Figure 1-8 shows these processes.

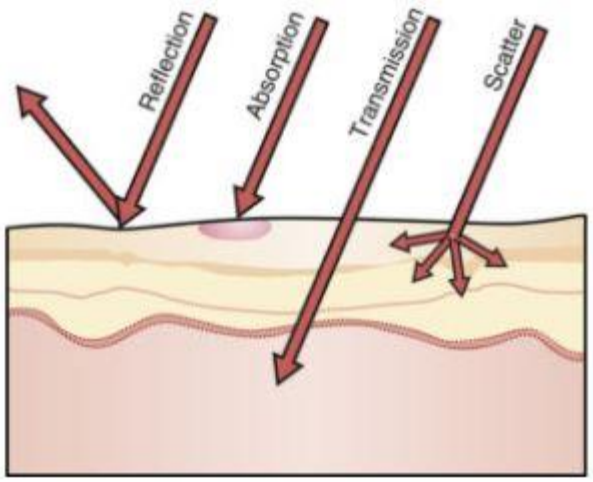


Figure 1-8. Laser tissue surface interaction.

1.3.7.2 Effect of laser light on tissue :

The variety of interaction mechanisms may occur when applying laser light to biological tissue due to specific tissue characteristics as well as laser parameters .

- Wavelength dependent mechanisms:

As shown in (Figure 1-9):

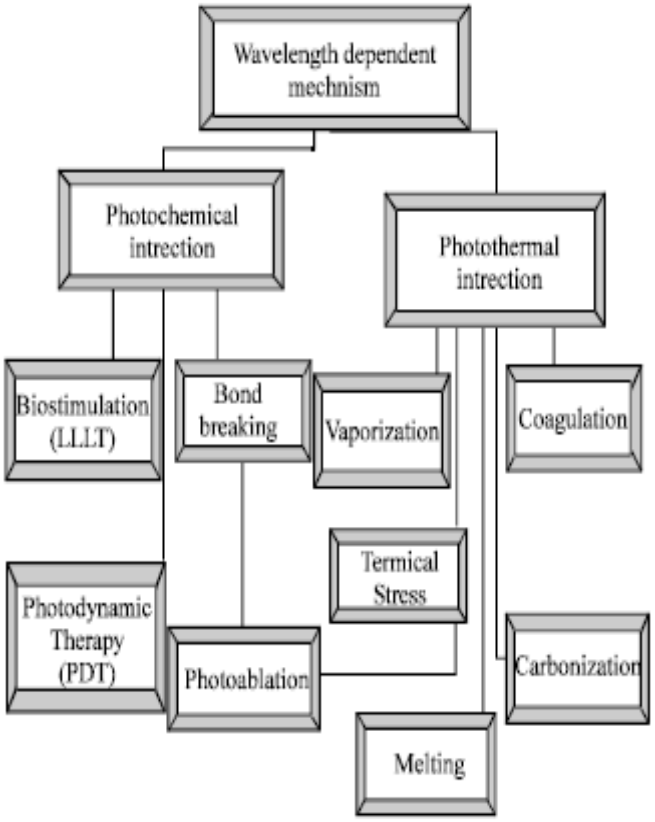


Figure 1-9 Interaction of light with biological tissue (Wavelength dependent mechanism) (Aboud, 2005)[38].

Photothermal interaction mechanisms:

The most frequently used mechanism of photon energy conversion in laser medicine is heating. Heating of irradiated sample occurs with all methods of tissue destruction (coagulation, vaporization, cutting, etc.). [39] Photons absorbed by the tissue are thought to cause biological effect via nonspecific Photothermal effects caused by kinetic mechanism, the external energy from the laser photons is deposited into the target materials via transitional, rotational and vibrational modes of movements of the target molecules. Depending on the duration and peak value of the tissue temperature achieved, different effects like coagulation, carbonization, vaporization and melting may be distinguished. [26], (as shown in table 1-2):

Temperature (degree Celsius)	Biological Effect
37 ^{0}C	Normal
45 ^{0}C	Hyperthermia
50 ^{0}C	Reduction in enzyme activity
60 ^{0}C	Denaturation of proteins and collagen, Coagulation
80 ^{0}C	Permeabilization of membranes
100 ^{0}C	Vaporisation, Thermal decomposition (ablation)
>150 ^{0}C	Carbonisation
>300 ^{0}C	Melting

Table (1-2) Tissue thermal effects of laser radiation (Neimz, 1996 p78)

The location and spatial extent of each thermal effect depend on the locally achieved temperature during and after laser exposure.[40]Figure (1-10).

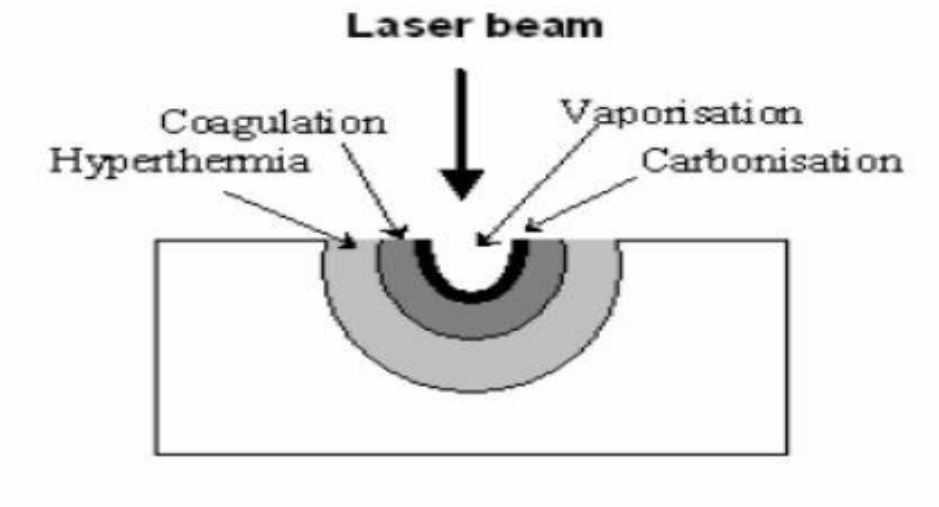


Figure 1.10 Spatial distribution of laser f thermal effects

- Wavelength independent mechanisms:

When using power densities exceeding 10^{11} W cm^{-2} in solids and fluids or 10^{14} W cm^{-2} in air, where the pulse duration is in picosecond or femtosecond range, multiphoton ionization of atoms and molecules may occur a phenomenon called optical breakdown occurs. 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. 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 as shown in (Figure 1-11). Uncontrolled, the effect of the plasma on the tissue surface can cause tissue damage[31].

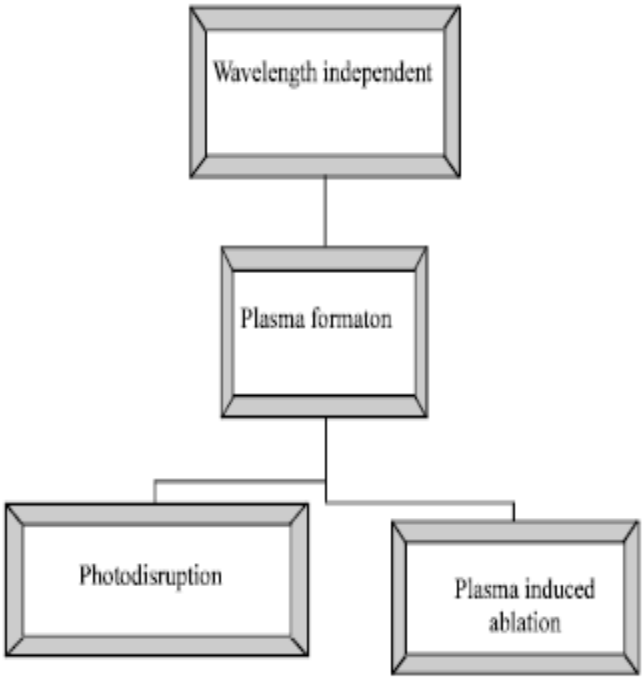


Figure 1-11 Interaction of light with biological tissue (Wavelength independent mechanism) (Aboud, 2005). [38]

1.3.8 Types of medical lasers.

Many types of lasers are available that vary in their wavelengths and their applications, table (1.3). Among the different active media, only a few types have the characteristics and properties that favor wide spread use and are suitable for medical application. The first laser by Maiman in 1960 used Ruby as a medium. Nowadays, a wide variety of solids, gases, liquids, or vapors are available as lasing media.[41]

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

Table 1-3 Types of lasers mostly applied in surgery.

1.3.9 Depth of optical penetration:

Optical properties of the epidermis and dermis are different. In pigmented epidermis, melanin absorption is usually the dominant process over the majority of the optical spectrum (200–1000 nm). In the dermis, there is strong, wavelength-dependent scattering by collagen fibers, which attenuates penetration of light. This scattering varies inversely with wavelength. In general, between 280 and 1300 nm, the depth of penetration increases with wavelength. Above 1300 nm, penetration decreases due to the absorption of light by water. The most deeply penetrating wavelengths are 650–1200 nm, while the least penetrating wavelengths are within the UV and IR regions.[42](Figure 1-12).

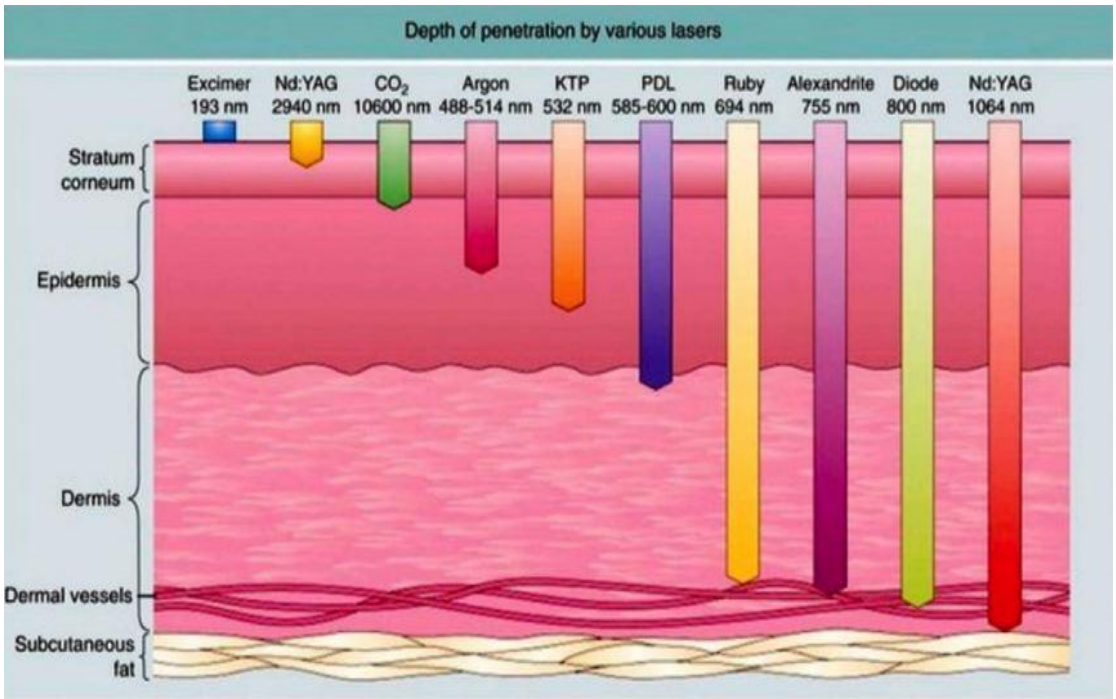


Figure 1-12 Various lasers penetration depth.

Medical Laser types can be divided into:

Ablative laser: This is a wounding laser that removes the thin outer layer of skin (epidermis) and heats the underlying skin (dermis), which stimulates the growth of new collagen fibers.

Nonablative laser: This is a non-wounding laser that stimulates collagen growth.

Fractional Lasers: Break up the laser energy into thousands of tiny beams to treat only a fraction of the skin in the area.

The depth of optical penetration for co2 laser is only about 20 microns, but Fractional co2 laser can vaporize nearly full thickness microchannels through the dermis.

Difference between Ablative , Non-ablative and Fractional lasers depth penetration.[42] shown in figure (1-13).

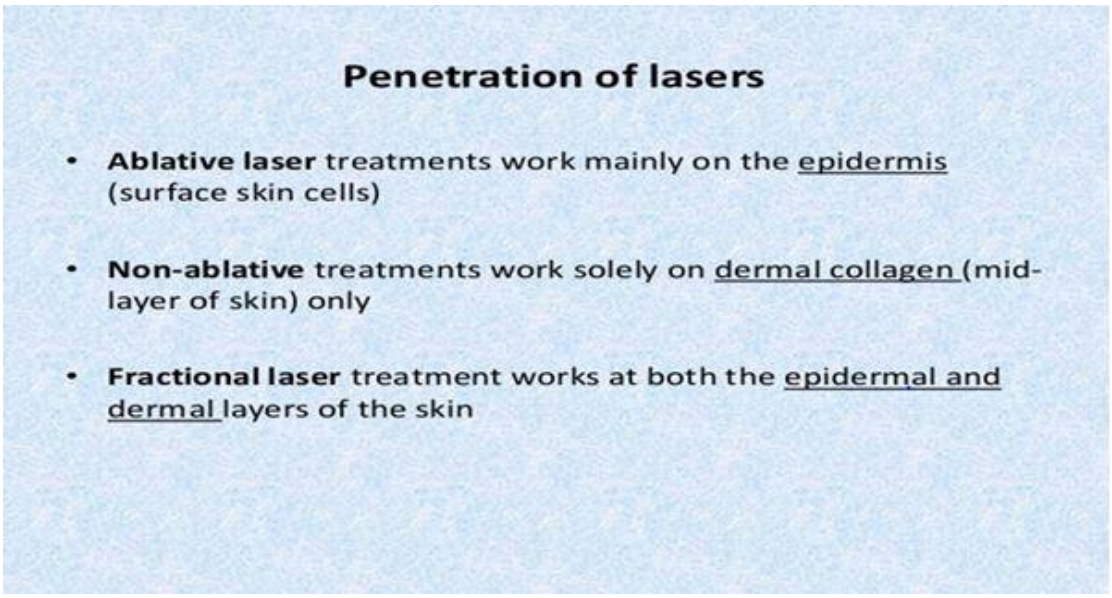


Figure 1-13 Skin penetration of Ablative, Non ablative and fractional laser types.

CO2 (10,600nm):

The carbon dioxide (CO2) 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 CO2 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 CO2 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 He-Ne or diode laser to mark the aimed focal spot.[40]

Because of its very long and Far-IR wavelength, the CO2 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 CO2 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 [43] . Developments in fiber optics made it possible to transmit far-infrared laser beams, increasing the flexibility of CO2 lasers for endoscopic surgery [44] .

Fractional CO2 laser:

The novel concept of fractional photothermolysis was introduced to the market by Dieter Manstein and Rox Anderson in the 20 year 2003.[40]

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. [45] Fractional lasers will act on the water chromophore, whose absorption rate varies in accordance with the wavelength used. [46] Figure (1-14)

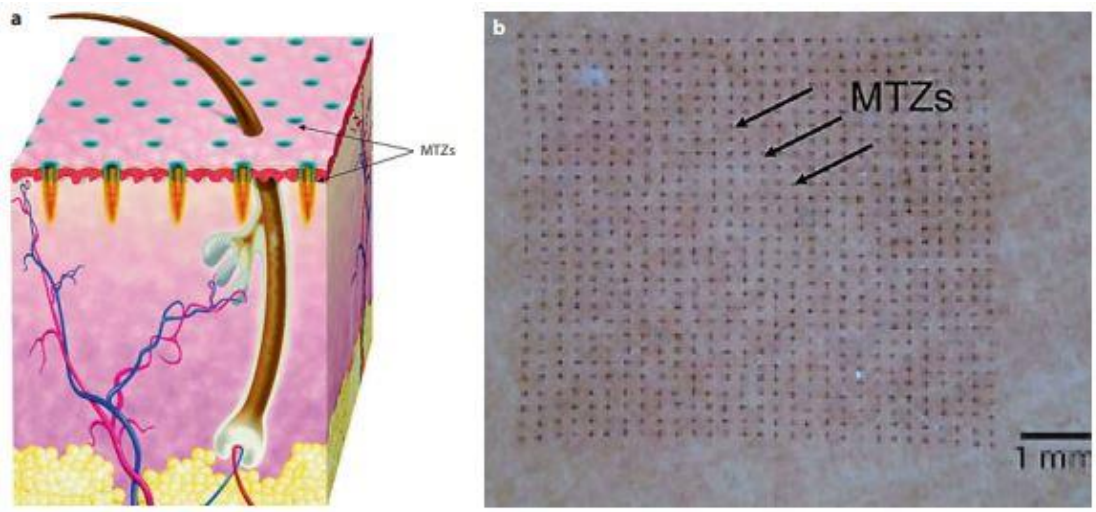


Figure 1-14. a- Schematic picture of FP depicting MTZs surrounded by unharmed tissue. Courtesy of Palomar Medical. b- Clinical picture depicting MTZs surrounded by unharmed tissue.(46)

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 nonablative [45] . 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. Fractional lasers “drill” the skin leaving some areas unharmed, areas which will in turn produce a fast recovery of the skin.[46] (figure 1-15)

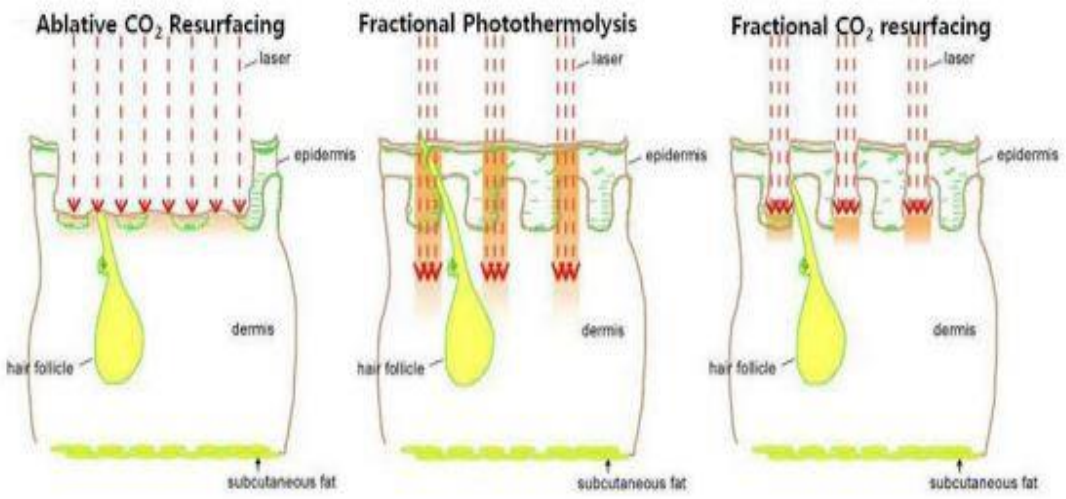


Figure 1-15 Basic concept of fractional photothermolysis.(46)

The basic concept of Fractional Photothermolysis is that the lesions damaged by CO2 laser ablation is first filled with keratinocyte within 48 hours and replaced by dermis through the remodeling process, a process that can be continued even after three months[(47)] .

1.3.10 PHYSICS OF FRACTIONAL LASERS:

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 [(46)], as shown in (Figure 1-16).

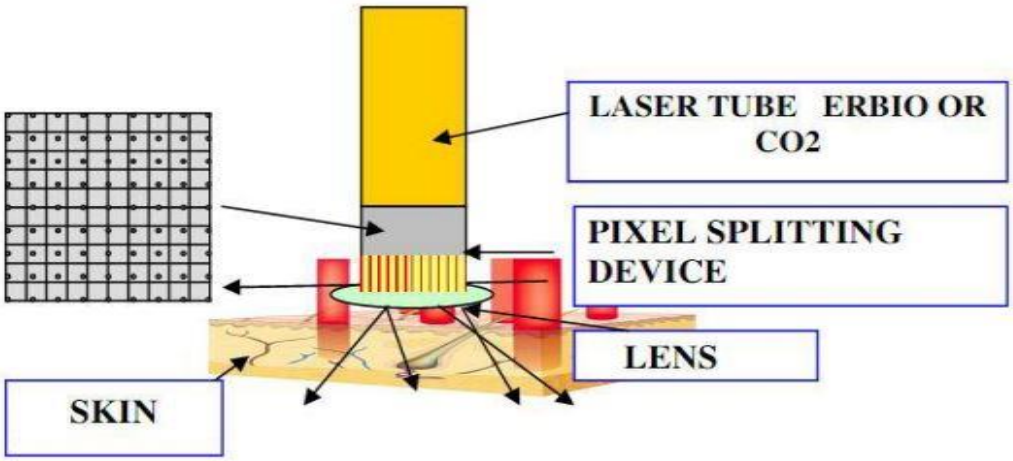


Figure 1-16 Fractional co2 laser components.(46)

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.

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, pulse width and on the energy this tissue absorbs.[41] Figure (1-17).

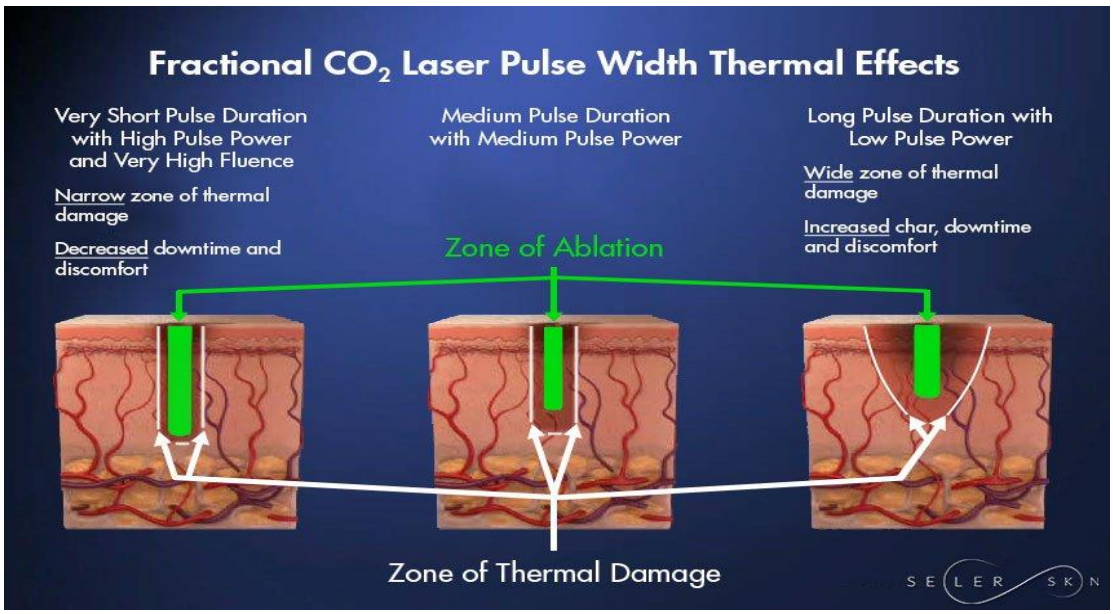


Figure 1-17 Thermal damage zone as effect of pulse power and pulse duration.

1.4 Basic principles of medical laser in SUI Literature Review:

Collagen is an important component of the pelvic floor supportive structures, and it makes up more than 80% of protein content of the endopelvic fascia. Childbirth trauma can lead to destruction of collagen fibers in the pelvic floor, while aging slows down the synthesis of new collagen, both resulting in decreasing collagen content. It was shown that pubocervical fasciae of incontinent women have a low collagen content, and also that SUI is more frequent in women with reduced collagen content in their anterior vaginal walls.[48]

It is well known that using laser energy to achieve heat pulsing (i.e., temporarily increasing the temperature) of collagen can improve collagen structure and initiate neocollagenesis. As a result of the temperature increase, intermolecular cross-links that stabilize collagen triple-helix structure are broken, which leads to the shrinkage of collagen fibrils and improvement in tissue firmness.[49]

The CO_2-laser was the first laser being developed and used in its microablative fractional mode as vaginal treatment for the genitourinary syndrome of menopause (GSM) and female UI. The mechanism behind this therapy it's related to the light emission at 10.600nm, which is absorbed by the water contained in vaginal mucosal tissues. This produces a thermal effect that stimulates tissues to synthetize collagen besides other molecular changes. The post-treatment effect of this neocollagenesis is newly formed connective tissue, recovery of sub mucosal capillaries as well as an increased thickness of the epithelium. This cause restoration of most vaginal functions that seems to be related to a clinical improvement in UI[50]

Scientific and technological progress has led to better clinical outcomes with less invasive procedures with shorter recovery times and lower implicated costs. In this sense, recent evidence supports laser treatment as an alternative and effective intervention for SUI.[49]

1.5 Aim of the study:

For clinical evaluation of the efficacy and safety of ablative fractional CO2 laser in treatment of SUI.

Chapter two

Materials And Methods

2.1 Introduction:

This chapter includes the criteria of choosing the Patients and their description and also including the procedure about preparing the patient before the laser treatment and parameters used in the treatment of the patients. In this study twenty women complained from urinary stress incontinence treated with fractional co2 laser three sessions three to four weeks a part.

This study was conducted over 8 months from July 2020 to February 2021 in private gynecology clinic in Baghdad city, Iraq.

2.2 patients selection:

Examination of all the patients done to determine their suitability and the inclusion and exclusion criterion are as following:

2.2.1 Inclusion criteria:

1-mild to moderate SUI: (The degree of incontinence was assessed with the International Consultation on Incontinence Questionnaire urinary incontinence –short form.

2-No/unsatisfactory response to conservative treatments and a preference for non-surgical management of bothersome SUI symptoms.

3-mild to moderate pelvic organ prolapse.

4-Negative urine examination.

5- No injuries and bleeding in the vaginal canal, introitus, and vestibule.

2.2.2 Exclusion criteria:

1-Women with sever pelvic organ prolapse

2- Genital tract infection.

3- Acute or recurrent urinary tract infections

4-Pregnancy

5-Any serious disease or chronic condition that could interfere or cause treatment side effect

6-Known cervical dysplasia

7-Undiagnosed abnormal uterine bleeding

8-Post void residual urine volume >150 ml.

2.3 Patient description:

This study includes twenty patients of SUI women with a mean age of 43.6±13.9 years suffering from SUI recruited via gynecology clinic advertisements. 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. Patient description as in table 2.1.

Age	25-34	35-44	45-55
	(n.4)	(n.7)	(n.9)
	20%	35%	45%
Parity	(1-5)	(n.7)	35%
	(6-10)	(n. 13)	65%
Delivery mode	NVD	(n.9)	45%
	Mixed	(n. 11)	55%
Menstruation status	Premenopause	(n.16)	80%
	Postmenopause	(n.4)	20%
Previous Urological and gynecological surgery reconstruction	Nil		

Table 2.1 Patient description

2.4 Clinical assessment:

2.4.1 Detailed history and physical examination:

General history which included questions about :

1. neurological and congenital abnormalities.
2. Previous obstetrics and gynecology history, including number of vaginal deliveries, mode of deliveries, symptoms of pelvic prolapse
3. Micturition symptoms, the severity of incontinence , degree of bother, previous surgery, urological diseases, bowel symptoms and symptoms of sexual dysfunction.

The physical examination of the patient with incontinence included:

1. General medical conditions that may affect the lower urinary tract as well as the problems related to urinary incontinence.
2. **Inspection:** urogenital atrophy, vulvovaginitis, abnormal vaginal discharge urethral diverticulum.
3. **neurological exam**.
4. Pelvic floor defect documented using pelvic organ prolapse (POP) grading.
5. **Bimanual pelvic examination:** pelvic mass (ovarian CA), uterine enlargement (fibroids).
6. **Assessment of pelvic floor musculature (tone and strength)**: place index finger 1-3 cm inside hymen at 4 and 8 o'clock. Voluntary control (ability to contract the pelvic floor muscles), muscle asymmetry, palpable defect/scaring.
   pelvic floor muscle strength (Oxford grading scale)
   Laycock.[45] developed the Modified Oxford Grading System to evaluate the strength of the pelvic floor muscles by using vaginal palpation. It consists of a six-point scale: 0 = no contraction, 1 = flicker, 2 = weak, 3 = moderate, 4 = good (with lift) and 5 = strong.
7. Cough stress test .
8. Q-Tip test to document urethral hypermobility. The test is performed after application of 2% lidocaine jelly, a sterile cotton-tipped swab was inserted transurethrally and withdrawn until resistance was met representing the urethrovesical junction, the angles relative to the horizontal plane were measured at rest and with maximum straining using a goniometer. The test was performed twice in the supine dorsal lithotomy position. After inserting a cotton-tipped swab, patients were asked to relax their pelvis each time prior to

measuring the resting angle. Materials used for this test are Swab stick and Goniometer as shown in Figure 2.1.

9. One hour pad test.
10. **PVR** (void at the end of exam and PVR measured via bladder scanner normal less than 100 - 150ml, and assessment of urethrovesical junction.

Fig. 2.1 Swab stick and Goniometer.

2.4.2 Pelvic Floor Questionnaire

All participants were asked to complete bladder function questions of modified Pelvic Floor Questionnaire (PFQ-UI), (Figure 2.2); at baseline then after one month following complete three co2 laser sessions. In our results we depend on the changes reported by the patients in this questionnaire.

PFQ-UI	**Patients name:** **Age:**	**Date of Birth:** **Date completed:**
How many times do you pass urine per day? - Up to 5 - Between 5-10 - Between 5-10 -More than 15	**Do you leak with coughing , laughing, sneezing?** -Never -Less than once per week -More than once per week -Daily	**Does urine leaking affect your daily activities?** -Not at all -Slightly -Moderately -Greatly
DO you have to wear pads because of urinary incontinence? -Never -As a precaution -During exercise -Daily	**Do you have pain in your bladder or urethra during micturition?** -Never -Less than once per week -More than once per week -Daily	**Do urine leaking affect your sexual life?** -Not at all -Slightly -Moderately -Greatly
Do you have frequent bladder infection? -No - 1-5 per year - 5-10 per year -More than 10 per year	**Do you need to rush to pass urine when you get urge?** -Never -Less than once per week -More than once per week -Daily	**Does your bladder problem bother you?** -Not at all -Slightly -Moderately -Greatly
How many times do you get up at night to pass urine? -0-1 -2 -3 - More than 3	**Does urine leak while you are rush to the toilet?** -Never -Less than once per week -More than once per week -Daily	**Do you need to strain to empty your bladder?** -Never -Less than once per week -More than once per week -Daily

Fig. 2.2 PFQ -UI

2.5 Investigations:

1- Complete blood count 2- Hepatitis tests 3- Covid 19 test (serology test) 4-GUE.

2.6 CO2 Laser specifications:

The laser machine used in this study is KES MED-870+ CO2 Laser Therapy System manufactured in China by Beijing KES Biology Technology Co.Ltd. Electronic electrician. Its clinical data is the following, as shown in the catalogue:

Wavelength	10600nm Laser
Power	40W U.S. RF Metal Tube
Spot Size	0.12mm and 1.25mm (adjustable)
Spot Density	Up to 102400 dot
Scan Size	Up to 20×20mm
Scan Shapes	Square; Rectangle; Circle; Triangle; Rhombus; Ellipse; Line
Scan Modes	Standard; Random; Scatter
Aiming Beam	5mW red diode laser, 635nm, adjustable intensity
Beam Delivery	360° Rotation Articulated 7 Joint Arm
Operating System	Fractional ; Ultrapulse ; CW; Gynaecology Vaginal Head
Cooling System	Air Cooling, self-contained; closed cycle
Display	10.4 Inch True Color LCD Touch Screen
Voltage	220V±10% 50/60Hz, 110V±10% 50/60Hz .
Dimension	52×38×117cm (W*D*H) Net
Weight	52KG

Fig 2.3 KES MED-870+ CO2 Laser system.

2.7 Treatment parameters:

Vaginal Fractional co2 laser used with following parameters protocol was :

Power	35 W
Pulse duration	1 ms
spacing	1 mm
scan rows	4
shoot times	4
Interval	0.5 sec

Fig.2.4 Laser parameters used

Fig 2.5 Gynaecological hand piece, speculum cage and lenses

2.8. Safety measures during the procedure:

In this study the laser employed was class IV laser. These types of laser can cause damage with direct intrabeam exposure and from specular or diffuse reflections. So safety measures must be taken to provide protection from energy emissions of these lasers. All persons wear protective glasses appropriate to the procedure to eliminate the risk of eye damage. These glasses are designed with special wavelength and optical density for CO2 laser. The doctor goggles . (Figure 2.6) In this research the

eyes of the patient were covered with mops of cotton or gauze, or to tell the patient to close eyes and to tilt the head away from the field.

Fig 2.6 Goggle for CO2 laser

2.9 Procedure of treatment:

1- Few days after menstruation (if still menstruating)
2- the patient asked to empty her bladder .
3- In lithotomy position.
4- Cleaning the vagina by mobbing with a with piece of cotton socked with normal saline.
5- . Participants were pre-treated with topical anaesthetic cream (Emla cream 5% (2.5 % lidocaine and 2.5 % prilocaine)) at the level of vestibulum, then ask the patient to wait 20 minutes for the area to be anaesthetized.
6- Eye protection for patient, physician and anyone else in the room is essential when using this laser by wearing proper goggles.
7- The laser beam was emitted from a 90° vaginal probe gently inserted up to the level of the bladder neck, then rotated and withdrawn in order to provide treatment of the anterior lower one third of the vagina and external urethral meatus.
   The probe inserted inside the vaginal canal about 4–6 cm from the introitus, with the laser's energy window oriented at 12 o'clock position It was then rotated by 1 h at a time after each laser pulse, between positions 10 o'clock and 2 o'clock. After completing the 10–2 o'clock rotation, the handpiece was pulled back by 1 cm and the rotation was repeated. Three such passes were repeated.

Each patient also received three total vaginal length laser treatments with a 360-degree probe as per Salvatore et al.[55].

8- The operative time taken about 20 minutes to complete.

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

Figure 2.7 Laser procedure

2.10 Follow up:

1- Assessment after each session.

2- The main outcome of this study is to describe the change in self-reported SUI symptoms based on urine leaking question of PFQ-UI.

3-The secondary outcomes were quality of life, sexual quality, dysuria, urgency, pad usage and Q tip test mean angles improvement.

Chapter Three

Results

Discussion

Conclusions

Recommendations

3.1 Introduction

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

3.2 Results

All patients 20 (100%) have completed their follow-up one month after the intervention. The mean age with standard deviation(SD) of the studied group was (43.6±13.9) years, mean of parity with (SD) was (5±1) and the mean time of treatment with (SD) was (20.5±3.7) minutes. All these were shown in table 3.1.

Table 3.1: Mean of patient's characteristics and time of treatment

PATIENTS CHARACTERISTICS	**MEAN±SD**
AGE (YEARS)	43.6±13.9
PARITY	5±1
TREATMENT TIME (MEAN±SD)/MIN.	20.5±3.7

Table 3.2 shows that grade of incontinence before the beginning of therapy was as follow; 13/20 (65.0%) of the patients presented as mild stress of incontinence, and 7/20 (35.0%) of the patients presented as moderate grade of SUI.

Table 3.2: Grades of SUI

GRADE OF SUI	**NO. (N=20)**	**%**
MILD	13	65.0
MODERATE	7	35.0

Change in SUI symptoms before and after fractionated CO2 laser women with SUI as following:

The primary result of this study depends mainly on change in self-reported SUI symptoms based on question two of PFQ-UI, (figure 3.1.). in which baseline data was 35% for once a week, 55% twice a week and 10% daily, while after one month; 60% not suffer from SUI symptoms, 10% with SUI symptoms for once a week, 25% twice a week and only 5% were daily.

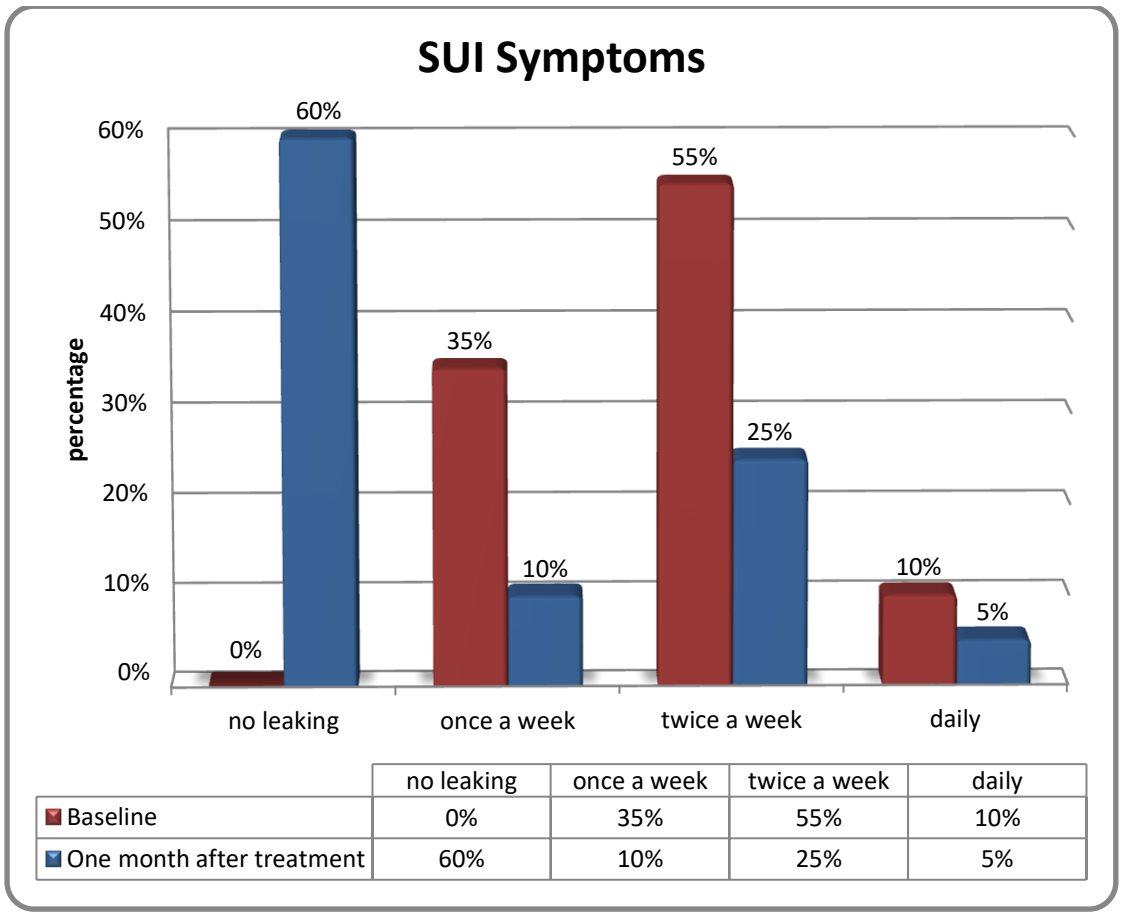


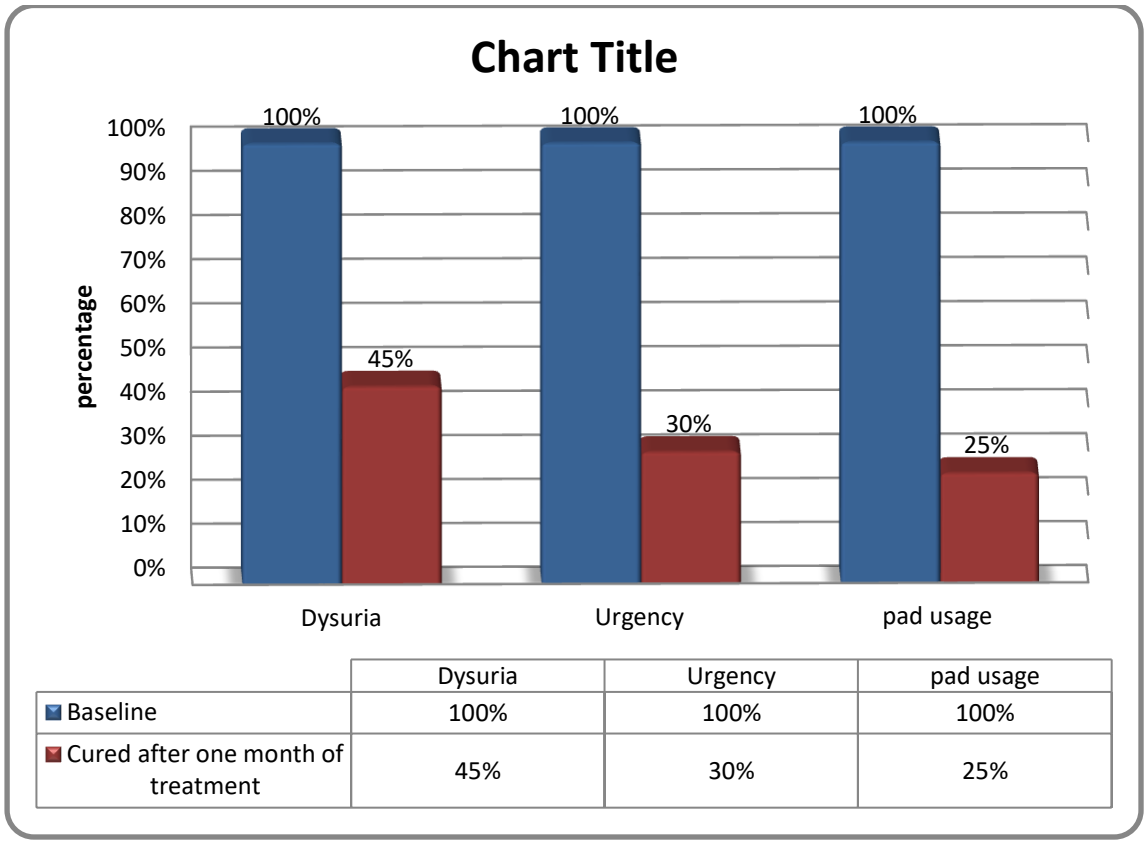
Figure 3.1: SUI symptoms before the treatment and at one month follow up

.

-Dysuria, urgency and pad usage:

As shown in figure 3.2, data shows that one month follow up after laser treatment, those patients complained from dysuria, urgency and pad using improvements as follows:

Dysuria improved in 45% of the patients, 30% of patients with urgency improved and 25% of patients no more pad using.



	Dysuria	Urgency	pad usage
Baseline	100%	100%	100%
Cured after one month of treatment	45%	30%	25%

Figure 3.2: Dysuria, urgency and pad using before the treatment and at one month follow -up .

-Q tip test angle table at baseline and at one month follow up:

The mean angle of the Q-tip was significantly decreased in follow-up compared to baseline.

In Figure 3.3, the results of the mean angle of the Q-tip before the treatment and at one month follow up are represented. The mean angle before the treatment was 61.5° and at one month follow up 47.3°.

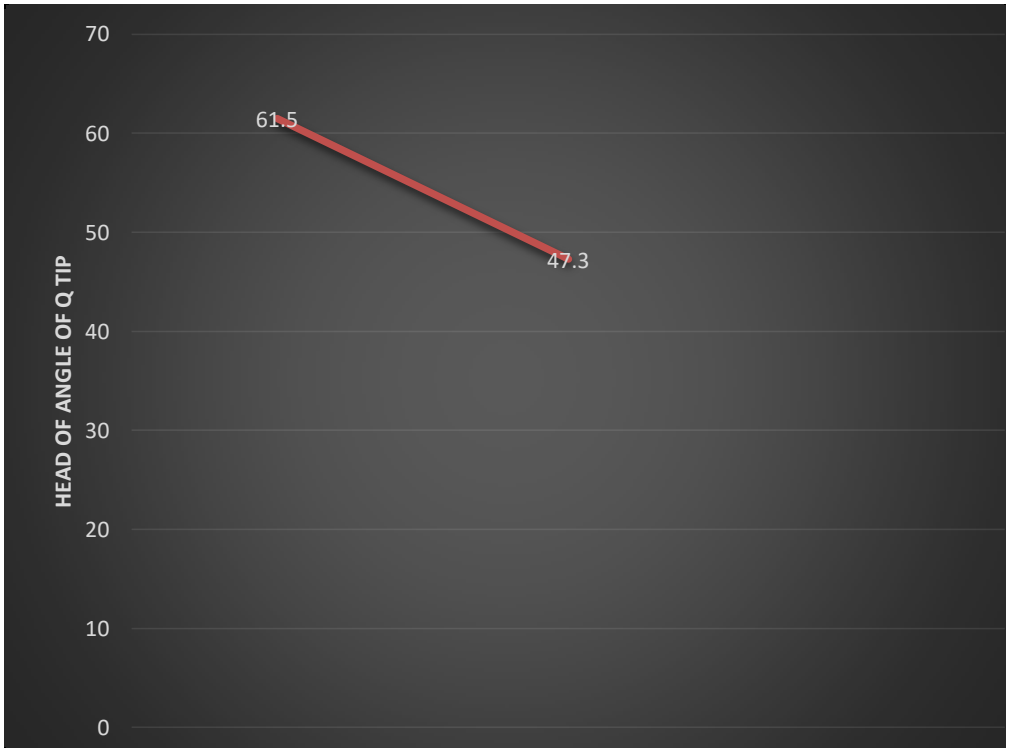


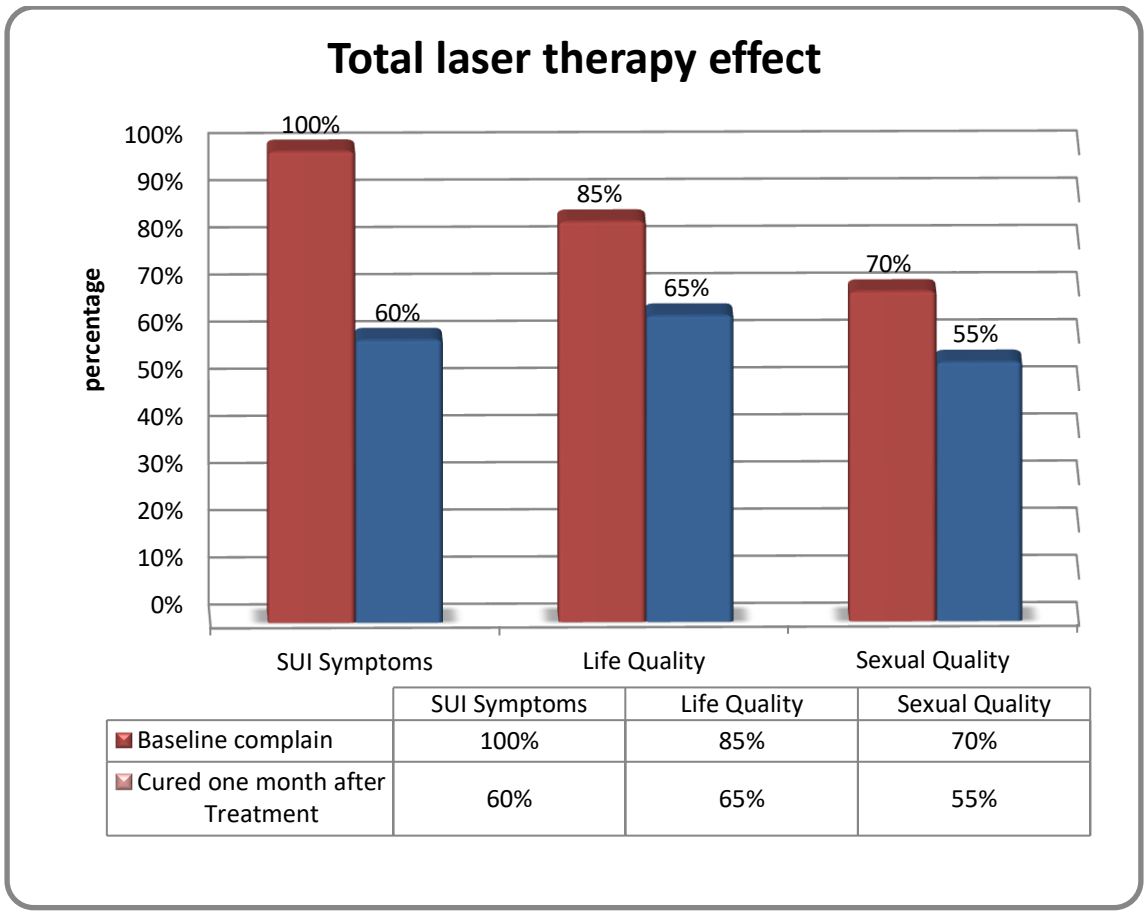
Figure 3.3: Angle of the Q-tip mean before the treatment and after one month follow up.

The overall laser therapy effect in this study:

As shown in figure 3.4, after one month following three laser treatment sessions 3-4 weeks apart regarding :

1-SUI Symptoms 60 % (12 patients) are completely cured, six patients improved, only two patients not improved.

2- Great changes in both life and sexual qualities.



	SUI Symptoms	Life Quality	Sexual Quality
Baseline complain	100%	85%	70%
Cured one month after Treatment	60%	65%	55%

Fig.3.4: overall laser therapy effect at one month after complete three session treatments.

The Patients overall satisfaction level with the treatment procedure and outcome was assessed at one month following treatments as can be seen in fig 3.5. At one

month after treatment follow-up 16 patients (80%) of women expressed satisfaction with the treatment and the rest 4 patients (20%) of the patients were unsatisfied.

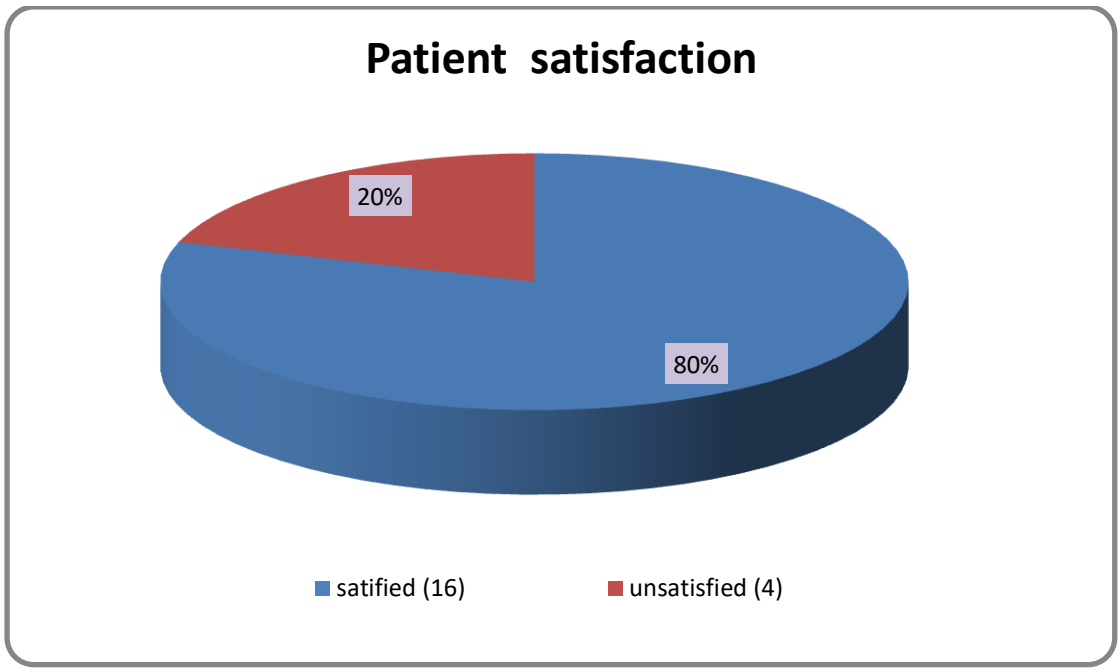


Fig 3.5: patient satisfaction after one month follow-up visit

3.3 Discussion:

Laser photothermal energy can improve collagen structure and initiate neocollagenesis in the skin and pelvic floor with nearby tissue [51]. Elevation in temperature up to 63°C increases the contraction of collagen fibers in vaginal epithelium and provokes neocollagenesis, elastogenesis, neoangiogenesis, and increased fibroblast. In addition, histopathology showed an increase in the volume density of blood capillaries and the thickness of the epithelial layer [29].

Data from our study shows an improvement in stress urinary incontinence symptoms in patients who underwent three sessions of fractional CO2 laser vaginal treatment three-four weeks a part, with the majority of patients reported improvement in urine leaking after exertion. The use of fractional CO2 laser is very effective in improving and reducing symptoms of SUI with short operating time, maximum operating time was 20 + 5minutes with minimum or no complication comparing with surgical technique .

In our study we found that SUI increase with age and parity, high percent of women with SUI coming at age ranged (35-55 year) which represent 16 (80%) most of them are vaginally delivered, that is mean the most predisposing factor for SUI is multiparty and the explanation of that frequent pregnancy cause frequent stretching effect on pelvic floor muscle that lead to weakness of the pelvic floor muscle.

Patients in this study showed improvement in SUI Symptom, life and sexual qualities. The Secondary outcomes improvement includes dysuria, urgency and pad using.

There are significant decrease in the mean of the Q tip angles at follow-up compared to baseline.

The overall patients satisfactions after treatment were 80% (16 patients) while 20% (four patients) were not satisfied.

Since 2014, a growing number of studies have been published exploring the use of trans-vaginal laser treatment for gynaecogical conditions such as SUI, mixed UI (MUI) and genitourinary symptoms of menopause (GSM) [52].

A study published by Jorge Alberto Elias [53] for treatment of 30 patients by CO2 for stress urinary incontinence (SUI). All 30 patients appropriately responded to SUI treatment, 60% presented resolution and 40% improved significantly. while in our study patients responded to SUI treated by CO2 laser as follows:60% completely cured, 30% improved and 10% not responded.

Behnia-Willison et al. showed in a study treating 102 women with GSM with fractional CO_2 laser having improvements up to 24 months by colposcopic examinations and responses to APFQ.[54]

Ogrinc et al. in a study included 175 women suffering from UI treated by Er: YAG Laser, a significant improvement was found after a year follow-up in 77% of patients by evaluating International Consultation on Incontinence Questionnaire–Urinary Incontinence (ICIQ-UI) and Incontinence Severity Index (ISI). [55]

3.4 Conclusions:

In this study patients had significant improvement in most parameters analyzed, There are significant improvement in SUI symptoms, great changes in both life and sexual qualities, dysuria, urgency.

Laser therapy seems to be a promising alternative approach to urinary incontinence in women. It seems effective in short term, well tolerated, with few and transient side effects.

3.5 Suggestions for future work:

1.Increase the number of patients in future studies.

2. Comparative study between Fractional CO2 laser and other lasers like Erbium laser.

3.Increase the follow up period for 24 months after completing all sessions.

4. Use of hormonal therapy and exercise with laser treatment and compare the results.

References:

1-Aoki, Yoshitaka et al. “Urinary incontinence in women.” *Nature reviews. Disease primers* vol. 3 17042. 6 Jul. 2017, doi:10.1038/nrdp.2017.42.

2- Berglund AL, Eisemann M, Lalos A, Lalos O. Social adjustment and spouse relationships among women with stress incontinence before and after surgical treatment. Social Sci Med 1996;41(11):1537–44.

3-Nygaard I, Barber MD, Burgio KL, Kenton K, M., Pelvic Floor Disorders Network. Prevalence of symptomatic pelvic floor disorders in US women. JAMA. 2008 Sep 17;300(11):1311-6.

4-Minassian VA, Yan X, Lichtenfeld MJ, Sun H, Stewart WF. The iceberg of health care utilization in women with urinary incontinence. Int Urogynecol J. 2012 Aug;23(8):1087-93.

5-Moore KL, Dalley AF. Clinically Orientated Anatomy. Canada: Lippincott Williams & Wilkins; 1999.

6-Corcos, Jacques The Urinary Sphincter (p. 18). CRC Press. Kindle Edition. (2001-08-30T22:58:59).

7- Kayigil O, Iftekhar Ahmed S, Metin A. The coexistence of intrinsic sphincter deficiency with type II stress incontinence. J Urol 1999;162:1365–6.

8- Bonney V. On diurnal incontinence of urine in women. J Obstet Gynecol Br Emp 1923;30:358–65.

9- Enho¨ rning G. Simultaneous recording of intravesical and intraurethral pressure: a study on urethral closure in normal and stress incontinent women. Acta Chir Scand Suppl 1961;276:1–68.

10-McGuire EJ, Lytton B, Pepe V, Kohorn EI. Stress urinary incontinence. Obstet Gynecol 1976;47:255–64.

11-Guarisi T, Pinto Neto AM, Osis MJ, Pedro AO, Paiva LH, Faúndes A, *et al.* Urinary incontinence among climateric Brazilian women: Household survey. Rev Saude Publica 2001;35:428-35.

12-Bump RC, Norton PA. Epidemiology and natural history of pelvic floor dysfunction. Obstet Gynecol Clin North Am. 1998;25:723–746.

13-Endoscopic suspension of the vesical neck for urinary incontinence.
Stamey TA Surg Gynecol Obstet. 1973 Apr; 136(4):547-54.

14-Raheela M. Rizvi and Mohammad Hammad. Assessment of Urinary Incontinence (UI) in Adult Patients, Synopsis in the Management of Urinary Incontinence, Ammar Alhasso and Holly Bekarma, IntechOpen, Ather (February 8th 2017) DOI: 10.5772/66953.

15. Swift SE, Yoon EA. Test-retest reliability of the cough stress test in the evaluation of urinary incontinence. Obstet Gynecol. 1999;94:99–102.

16- Newman DK, Wein AJ. Managing and treating urinary incontinence. ed 2. Baltimore, MD: Health Professions Press; 2009.

17-Krhut J, Zachoval R, Smith PP, et al. Pad weight testing in the evaluation of urinary incontinence. Neurourol Urodyn. 2014;33(5):507-510.

18-Meyer, I. et al. "Vaginal Swab Test Compared With the Urethral Q-tip Test for Urethral Mobility Measurement: A Randomized Controlled Trial." Obstetrics & Gynecology 127 (2016): 348–352.

19-Demirci, F., Fine, P.M. Ultrasonography in stress urinary incontinence. Int Urogynecol J **7,** 125–132 (1996). https://doi.org/10.1007/BF01894200.

20- Homma Y, Batista J, Bauer S, et al. Urodynamics. In: Abrams P, Cardozo L, Khoury S, Wein A, et al., editors. Incontinence. 2nd ed. Plymouth, UK: Health Publication Ltd; 2002. pp 317–372.

21. Coyne K, Kelleher C. Patient reported outcomes: The ICIQ and the state of the art. Neurourol Urodyn 2010;29:645-51.

22. Isherwood PJ, Rane A. Comparative assessment of pelvic floor strength using a perineometer and digital examination. BJOG 2000;107:1007-11

23-Klovning A, Avery K, Sandvik H, Hunskaar S. Comparison of two questionnaires for assessing the severity of urinary incontinence: The ICIQ-UI SF versus the incontinence severity index. Neurourol Urodyn 2009;28:411-5.

24-Eric S Rovner, MD and Alan J Wein, MD. Treatment Options for Stress Urinary Incontinence. Rev Urol. 2004; 6(Suppl 3): S29–S47.

25-Norton P BL. Urinary incontinence in women. Lancet. 2006;367(9504):57–67.

26-Gambacciani M, Palacios S. Laser therapy for the restoration of vaginal function. Maturitas. 2017;99:10–15.

27. Lapii G. A., Yakovleva A. Y., Neimark A. I. Structural reorganization of the vaginal mucosa in stress urinary incontinence under conditions of Er:YAG laser treatment. Bulletin of Experimental Biology and Medicine. 2017;162(4):510–514. doi: 10.1007/s10517-017-3650-0.

28-Elliott, D.J.,. Ultraviolet Laser Technology and Applications. Academic Press ,1995, USA.

29-Oshea, D.C., W.R. Callen and W.T. Rhodes. Introduction to Lasers and their Applications. 2nd Edn., Addison-Wesley Publicating Company, 1978, USA.

30-Keye, W.R., 1990. Laser surgery in gynecology and obstetrics. 2nd Edn., G.K. Hall and Co., Mosby, Montana.

31- Mohammed M. Jawad, Sarah T. Abdul Qader, A.A. Zaidan, B.B. Zaidan, A.W. Naji and Ibraheem T. Abdul Qader. An Overview of Laser Principle, Laser-Tissue Interaction Mechanisms and Laser Safety Precautions for Medical Laser Users. International Journal of Pharmacology, , 2011, 7: 149-160.

32- Daniele De Luca, Ines Delfino, Maria Lepore, "Laser Safety Standards and Measurements of Hazard Parameters for Medical Lasers", International Journal of Optics and Applications, Vol. 2 No. 6, 2012, pp. 80-86.

33-Niemz, M.H.. Laser-Tissue Interactions: Fundamentals and Applications. 3rd Ed., Springer, Germany, 2004.

34- Safety of laser products - Part 1: Equipment classification and requirements , Publication date: 2007-3-30.

35-LASER Safety Manual Radiation Safety Office Environmental Health and Safety University of Washington Box 354400 Seattle WA 98195-4400.

36-Ansari MA, Mohajerani E.
Mechanisms of laser-tissue interaction: I. optical properties of tissue. J Lasers Med Sci 2011; 2(3):119-25.

37-Niemz, M.H. Laser Tissue Interaction. Springer, Heidelberg, Germany, 1996.

38-Aboud, G.T. Treatment of oral ulcerations. M.Sc. Thesis, University of Baghdad, 2005.

39-Karu, T. Primary and secondary mechanisms of action of visible to near-IR radiations on cells. J. Photochem. Photobiol. , 1999, B, 49: 1-17.

40 –.Markolf H. Niemz .Biological and medical physics ,biomedical engineering Laser Tissue Inter actions Fundamentals and applications 3rd,Enlarged Edition.2007,P.1-6,201-203,248-254

41 -S.A.Dixon.Surgical Application Of Laser,Year Book Medical Publisher Inc, 1983.

42- Keyvan Nouri (ed.) Lasers in Dermatology and Medicine10.1007/ 978-0-85729-281-0_1 © Springer-Verlag London Limited 2011.

43- Dan Little, Technical Director, Laser Training Institute, Professional Medical Education Association, Inc. Laser Measurement in Medical Laser Service

44-Michael L. Geiges History of Lasers in Dermatology Bogdan Allemann I, Goldberg DJ (eds): Basics in Dermatological Laser Applications. Curr Probl Dermatol. Basel, Karger, 2011, vol 42, pp 1–6

45-Inja Bogdan Allemann I, Goldberg DJ (eds): Basics in Dermatological Laser Applications. (Laser Principles) Curr Probl Dermatol. Basel, Karger,

46- Gold MH. Fractional technology: a review and clinical approaches. J Drugs Dermatol. 2007 6:849–852. 2. ... European Academy of dermatology.

47- Hantash, B. M., V. P. Bedi, et al. (2007). "In vivo histological evaluation of a novel ablative fractional resurfacing device." Lasers Surg Med 39(2): 96-107.

48-Liu H, Dang Y, Wang Z, Chai X, Ren Q. Laser induced collagen remodeling: A comparative study in vivo on mouse model. Lasers Surg Med 2008;40:13-9.

49-Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev 2010;(1):CD005654.

50. Laycock J. Clinical evaluation of the pelvic floor. In: Schussler B, Laycock J, Norton P, Stanton SL, editors. Pelvic Floor Re-education. London, United Kingdom: Springer-Verlag; 1994. pp. 42–

51. Tadir Y., Gaspar A., Lev-Sagie A., et al. Light and energy based therapeutics for genitourinary syndrome of menopause: consensus and controversies. *Lasers in Surgery and Medicine.* 2017;49(2):137–159.

52-K Mackova, L Van daele, A-S Page, I Geraerts, L Krofta, J Deprest, Laser therapy for urinary incontinence and pelvic organ prolapse: a systematic review, BJOG: An International Journal of Obstetrics & Gynaecology, 10.1111/1471-0528.16273, **127**, 11, (1338-1346), (2020).

53. Jorge Alberto Elías MD; Agostina Larrazabal Ing; Florencia Dobanton Ing. Gynestetic Salud y Estética. Centro Privado de Atención de las Patologías del Piso Pelviano y la Cosmética Femenina. FEMILIFT: A New tool to treat urinary continence disorders (Stress an/on Urgency),2015

54.F. Behnia-Willison, S. Sarraf, J. Miller, B. Mohamadi, A.S. Care, A. Lam, *et al*.
Safety and long-term efficacy of fractional CO2 laser treatment in women suffering from genitourinary syndrome of menopause
Eur J Obstet Gynecol Reprod Biol, 213 (2017), pp. 39-44

55.U.B. Ogrinc, S. Sencar, H. Lenasi
Novel minimally invasive laser treatment of urinary incontinence in women
Lasers Surg Med, 47 (9) (2015), pp. 689-697.

الخلاصة :

الخلفية: سلس البول الإجهادي هو تسريب لا إرادي للبول خلال القيام باي مجهود مثل: السعال، العطس، رفع اوزان، الضحك او ممارسه الرياضة.

السلس البولي يؤثر على نوعية حياة المرأة بأشكال مختلفة، قد تحد من العلاقات الاجتماعية والشخصية للمرأة، فضلاً عن الحد من النشاط البدني. النسبة الأكبر من هؤلاء النساء لا يعرفن بوجود طرق سهلة و بسيطة وفعالة لعلاج سلس البول. ليزر ثاني أكسيد الكربون التجزيئي (١٠٦٠٠ نانومتر) هو الطريقة الحديثة لعلاج أعراض سلس البول الإجهادي لدى النساء .

الأهداف: كان الغرض من هذه الدراسة هو تقييم فعالية ليزر ثنائي اوكسيد الكاربون الـتجزيئي في عالج أعراض سلس البولي الإجهادي .

المواد والطرق: أجريت هذه الدراسة في عيادة خاصة من يوليو ٢٠٢٠ إلى شباط ٢٠٢١ .شملت الدراسة عشرون امرأة يعانين من أعراض سلس البولي الإجهادي في هذه الدراسة ، وتراوحت أعمارهم بين ٢٥ ـ ٥٥ سنة. كانت معلمات الليزر المستخدمة هي الطول الموجي لليزر ١٠٦٠٠ نانومتر ثاني اوكسيد الكاربون التجزيئي ، الطاقة 35 وات ، المدة واحد مللي ثانية ، المسافة واحد ملم ، وضع المسح العادي ، أوقات المسح الصفوف الرابع والمسح الضوئي اربعة .

النتائج: أبديت معظم النساء العشرون المشمولات في الدراسة ٨٠٪ عن رضاهم عن العلاج بعد ثلاث جلسات من ليزر ثاني أكسيد الكربون التجزيئي ١٠٦٠٠نانومتر.

الخلاصة: يعتبر العلاج بالليزر ثاني اوكسيد الكاربون التجزيئي طريقة فعالة لعلاج اعراض السلس البولي مع تأثير جانبي أقل.

وزارة التعليم العالي والبحث العلمي

جامعة بغداد

معهد الليزر للدراسات العليا

استخدام ليزر ثنائي اوكسيد الكربوني التجزيئي لعلاج سلس البول الإجهادي عند النساء

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

من قبل

شونم مجيد حميد

بكالوريوس طب وجراحه عامه / جامعة الموصل ١٩٩٤

دبلوم عالي نسائية وتوليد / جامعة المستنصرية ٢٠٠٢

بإشراف

الدكتورة نادية محمد سعيد

بورد عراقي نسائية و توليد

دبلوم عالي في الليزر/ النسائية

١٤٤٢ هـ ٢٠٢١م