EVALUATION OF THE USE OF 10,600 nm FRACTIONAL CARBON DIOXIDE LASER IN THE TREATMENT OF VITILIGO: A PILOT STUDY

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MASTER OF SCIENCE

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THIS THESIS HAS BEEN APPROVED

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Lastly, I would like to dedicate my work to my wife, my parents and all my brothers and sisters.

Abedrazak Mohammed Ibrahim

Thesis Title	Evaluation of the Use of 10,600 nm Fractional Carbon Dioxide Laser in the Treatment of Vitiligo: A Pilot Study
Author	Abedrazak Mohammed Ibrahim
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ABTRACT

The main objective of this study is to study effects of fractionally ablated skin by carbon dioxide laser and to see weather during healing process there will emigration of melanocytes from pigmentary skin in the boundaries toward the ablated areas, we included volunteers who met the inclusion criteria of the research then three monthly sessions of laser treatment were done .In the meantime, photos were taken during follow up visits every two weeks. The results of this study indicates that 10,600 nm fractional carbon dioxide laser may not be so beneficial in inducing repigmentation of vitiligo patches. However, vitiligo is known to be a slowly responding and non predictive disease. Therefore, follow up of the patients for a longer period and increasing the laser sessions may be needed to get a more positive outcomes.

Keywords: Vitiligo / Fractional carbon dioxide laser

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CHAPTER 1

INTRODUCTION

1.1 Background

Vitiligo is an idiopathic depigmentary skin disorder characterized by selective destruction of melanocytes. The estimated mass of all pigment cells within the body is about 1.5 g. most of these are melanocytes within the epidemis. (Anstey, 2010)

Millions of men and women worldwide have vitiligo, the most common clinical variety the so called non-segmental or generalized vitiligo. In which milky-white skin patches may appear all over the body because of the loss of functional melanocytes. Many patients with vitiligo experience psychological distress and social stigmatization (Porter, Beuf, Nordlund & Lerner,1979; Kent & Al'Abadie, 1996; Ongenae, Beelaert, Van & Naeyaert, 2006).

Because skin color plays a major role in individual's perception of health, wealth, worth and desirability, pigmentary disfigurements may influence social interactions (Grimes, 2004), vitiligo even may lead to social exclusion in certain societies, therefore vitiligo is considered to be one of the major medical problems in India (Chaturvedi, Singh & Gupta, 2005; Parsad, Dorga & Kanwar, 2003).

Vitiligo is a common skin disease reported to affect approximately 1% of the population worldwide, irrespective of skin color or ethnic origin (Srivastava, 1994). The cause of this condition is uncertain but seems to be dependant on the interaction of genetic, immunologic and neurogenic factors (Lerner & Nordlund, 1978). Recent observations support the role of altered cellular immunity, and a role for cytokines in the pathogenesis of vitiligo. (Ortonne, 2003). Although neither life threatening nor symptomatic (except that depigmented patches burn easily when exposed to sun) the effects of vitiligo can be cosmetically devastating resulting in low self-esteem, poor body image and difficulties in sexual relationships (Papadopoulos, Bor, & Legg,

1999; Porter et al., 1979; Porter, Beuf, Nordlund & Lerner, 1990). Because the disease is still not understood, there is a plethora of different treatments including topical corticosteroids, calcineurin inhibitors, vitamin D deravitives, Phototherapy (ultraviolet A, narrow band UVB), photochemtherpy (psoralen plus UVA [PUVA]), psoralen with sunlight (PUVAsol), surgical techniques and combination of topical therapies and light treatment (Whitton, Ashcroft, González, 2008). All approaches have advantages and disadvantages and none is approporiate for every patient with vitiligo (Rebat & Sumayah, 2008). There is 30 percent to 40 percent response rate with 6 months of corticosteroid use. Long term treatment with UVB induce accelerated photoaging (Calanchini, Postizzi & Frenk, 1987), cutaneous and systemic immunosuppresion (Beissert & Schwarz, 1999; Beissert & Schwarz, 2002) and an increased risk of skin carcinoma (de-Gruijl, 1999; van der Leun, 1984).

Carbone dioxide laser ablative fractional resurfacing produces skin damage with removal of the epidermis and variable portions of the dermis as well as associated residual heating, resulting in new collagen formation and skin tightening. The non resurfaced epidermis helps tissue to heal rapidly with short-term postoperative erythema.

Carbon dioxide laser resurfacing produces controlled skin damage with removal of the epidermis and variable portions of the dermis .Associated dermal heating results in collagen shrinkage and collagen remodelling. The dermal tightening achieved and the associated new epithelium gives a youthful appearance to the skin with Improved texture and reduced lines and wrinkles, Fractional ablative laser therapy is a new method of skin resurfacing which when practiced with CO2 laser offers an interesting alternative to the typical conventional procedure of eliminating the full layer of skin. The remaining epidermis that has not been resurfaced helps tissue to repair more rapidly which translates into speedy recovery time and a shorter postoperative period of erythema. The efficacy of the CO2 laser thermal effect is kept within a limited side-effect profile. During ablative fractional resurfacing treatment tiny microscopic pieces of skin are vaporized and a thermal deposit occurs in the dermis. At the time of repair tissue is restored with active fiber formation which produces a tightening effect and the external aspect of the skin is improved. The degree of improvement in the results of fractional CO2 laser resurfacing is related to the density of superficial microtissue elimination and the thermal deposit left in the dermis which to a large extent is related to laser power, pulse width and the density of

microzones of tissue elimination determined by the number of passes over the treated area. (Mario, Trelles, Micheal & Fernando, 2010). Recently the 308 nm excimer laser, a new technique allowing for targeted phototherapy, was used to treat localized plaques of vitiligo (Baltás et al., 2001). Two hundred and twenty-one patches of vitiligo in 97 patients were treated with this laser; 50.6% of patients achieved 75% pigmentation or more, 64.3% achieved 50% pigmentation or more. (Hadi et al., 2006)

1.2 Objective of the Study

To evaluate the efficacy of 10,600 nm fractional carbon dioxide laser in the treatment of vitiligo.

1.3 Benefits of the study

This study may open the windows of hope for patients suffering from vitiligo to be treated with less downtime, less side effects in the future, and it may put the first step toward management of this disease completely.

1.4 Hypothesis of the research

In histopathology of vitiligo, electron microscopic studies and immunohistochemistry studies using a panel of 17 monoclonal antibodies directed against melanocytes confirm the absence of melanocytes in areas of longstanding vitiligo. In the hypopigmented zones of expanding lesions, most studies have demonstrated peripheral damage to keratinocytes and melanocytes.

A combination of hair follicle split-dopa stains and hair follicle split-scanning electron microscopy showed inactive dopa negative melanocytes in the outer root sheeths of normal hair follicles, these inactive melanocytes are also present in the outer root sheaths of hair follicle from vitiliginous patches. Treatment of vitiligo stimulates these inactive melanocytes in the middle and

lower parts of the outer root sheaths to divide, proliferate and migrate upward to the dermal-epidermal junction of overlying skin, melanocytes then radiate to form the pigmented islands clinically visible in repigmented lesions. (Richard & Gary, 2005)

During studying of the biological effects of fractional photothermolysis on the skin, it showed an interesting histological changes ensue after mid-infrared fractional photothermolysis, columns of epidermal and dermal cell necrosis are seen immediately after treatment, with preservation of the stratum corneum. Each of the microscopic columns of thermal injury is surrounded by a heat-shock zone that releases cell mediators to signel the wound-healing cascade .specifically heat-shock protein (hsp) 70 expression is increased, most prominently within the epidermis in areas that underlie necrotic debris and in dermal tissues that surround the microscopic thermal zones (MTZ). Hsp 70 causes up-regulation of transforming growth factor (TGF) -beta which increases collagen production, thereby stimulating dermal remodelling . Evidence of increased dermal collagen III production is seen after one week. Within an hour of treatment, keratinocytes begin to move to the deep and lateral margins of the epidermal wound. By 12 hours viable cells surround the necrotic debris and begin to form a plug containing this microscopic epidermal necrotic debris (also known as MENDs) this compact material ranges from (50-200) micrometer in diameter and has been found to contain both melanin and elastin. By 24 hours MENDs are found within the epidermis above each area of the dermal injury with intact stratum corneum. Stem cells located in basal layer appear to be temporarily activated and begin to replace the epidermal tissues. (Brian & Susan, 2009)

1.5 Operational definitions

Fractional CO2 laser: It means the destruction or removal of a fraction of the skin including the full thickness of the epidermis and portions of the dermis where the depth of the injury is greater than the width and ratios of treated to non treated tissue > 10% and < 90%. The principle behind fractional photothermolysis is the formation of isolated and microscopic thermal wounds that are surrounded by zones of spared, viable tissue in a geometrical pattern that does not depend on chromophore distribution. (Brian & Susan, 2009)

Nonablative fractional resurfacing works threefold: (1) by nonablative mode of tissue coagulation with the stratum corneum remaining intact with no tissue vaporization (2) by the creation of multiple microthermal zones surrounded by islands of viable tissue and (3) by the extrusion and replacement of damaged tissue with reepithelization within 24 h. The use of appropriate wavelengths and depths of penetration enable collagen remodeling and creation of microthermal zones of rapid reepithelization. The chromophore for fractional photothermolysis is tissue water with targets being epidermal keratinocytes, dermal collagen, and dermal vascular structures. (Manstein, Herron, Sink, Tanner & Anderson, 2004)

1.6 Population and sample

Six patients were recruited in the study, all of Thai nationality. Three were males and three were females.

1.7 Keywords

1.7.1 Vitiligo is a common acquired disease affecting 1-2% of the population, localized or generalized areas of the skin completely lack melanin pigmentation. Melanocytes cannot be detected in depigmented areas even on inspection by electron microscopy.

1.7.2 Fractional Carbon Dioxide Laser (10,600 nm). The novel concept of non-ablative fractional photothermolysis was introduced to the market in 2003. Unlike conventional ablative and non-ablative photothermolysis, fractional ablative and non-ablative photothermolysis treats only a fraction of the skin, leaving up to a maximum of 95% of the skin uninvolved. The undamaged skin surrounding tissue allows for a reservoir of viable tissue, permitting rapid epidermal repair.

CHAPTER 2

LITERATURE REVIEW

Researches have shown that vitiligo carries a psychosocial impact, (Linthorst Homan et al., 2009) studied the burden of vitiligo and tried to determine the sociodemographic variables that adversely affect the quality of life in adult patients with generalized vitiligo, they found that generalized vitiligo is a serious skin disorder with an adverse impact on the emotional state, comparable with that of other major skin diseases.

The classic treatments used always for vitiligo can not give satisfaction for all patients and all cases, (Whitton et al., 2008) searched systematically a range of databases for randomized controlled trials .they sought to report a Cochrane review of all interventions for the treatment of vitiligo. Nineteen trials were included, they found short term benefit from topical steroids and various forms of UV light with topical preparations.

Recent discoveries of the role of the immunologic system in in vitiligo is important. (Basak, Adiloglu, Ceyhan, Tas, & Akkaya, 2009) Assessed the role of major cytokines produced by T-helper 1 and 2 cells as well as T-helper 17 and regulatory T cells in the pathogenesis of vitiligo. They found reduced serum transforming growth factor-β levels significantly which may contribute to enhanced cellular immunity, this may facilitate the occurrence of vitiligo by leading to diminished maturation of regulatory T cells, followed by impaired inhibition of inflammation.

Understanding vitiligo in cellular level may lead to some promising results in its management. (Brian & Susan, 2009) Studied the biological effects of fractional photothermolysis, they found an interesting histological changes ensue after mid-infrared fractional photothermolysis, columns of epidermal and dermal cell necrosis are seen immediately after treatment, with preservation of the stratum corneum. Each of the microscopic columns of thermal injury is surrounded by a heat-shock zone that releases cell mediators to signal the wound-healing cascade , specifically heat-shock protein (hsp) 70 expression is increased, most prominently within the epidermis in areas that underlie necrotic debris and in dermal tissues that surround the MTZ. Hsp

70 causes up-regulation of transforming growth factor (TGF) -beta which increases collagen production, thereby stimulating dermal remodelling. Evidence of increased dermal collagen III production is seen after one week. Within an hour of treatment, keratinocytes begin to move to the deep and lateral margins of the epidermal wound. By 12 hours viable cells surround the necrotic debris and begin to form a plug containing this microscopic epidermal necrotic debris (also known as MENDs) this compact material ranges from (50-200) micrometer in diameter and has been found to contain both melanin and elastin. By 24 hours MENDs are found within the epidermis above each area of the dermal injury with intact stratum corneum. Stem cells located in basal layer appear to be temporarily activated and begin to replace the epidermal tissues.

Laser has entered in the management of vitiligo, (Nicolaidou, Antoniou, Stratigos, & Katsambas, 2009) reviewed the efficacy of narrowband ultraviolet B Phototherapy and 308-nm excimer laser in the treatment of vitiligo. They found that the best results for NB-UVB efficacy have been reported in two studies from the same center in India with 71.4% and 75 % of patients achieving cosmetically acceptable repigmentation. Two studies from the same center in the Netherlands also have reported high rates (53% and 63%) of cosmetically acceptable repigmentation. The lowest response rates have been reported in Asian patients: 33% and 12.5% in studies from Thailand and Taiwan respectively.

CHAPTER 3

METHODS

3.1 Study Design

This is a prospective randomized controlled bilateral left-right comparison trial. It was performed in accordance with Good Clinical Practice. The treatment protocol has been reviewed with each patient who then signed the informed consent. The research was accomplished at Mae Fah Luang University Hospital, Bangkok (Outpatient department).

3.2 Population and sampling

Six patients were recruited in this study, all were of Thai nationality.

Table 3.1 Characteristics of the participants in the study

Item	Pt.1	Pt.2	Pt.3	Pt.4	Pt.5	Pt.6
Age (yr.)	35	50	25	36	34	65
Sex	Male	Male	Female	Female	Female	Male
Age of onset of vitiligo (yr.)	5-6	10	11	11-12	32	64
Type of vetiligo	Focal	Generalized	Generalized	Acrof- acial	Generalized	Segmental
Skin phototype	III	III	IV-V	III-IV	III	IV
Duration of vetiligo (yr.)	30	40	14	25	2	1
Number of treated vetiligo patches	1	1	3	4	5	3
Race	Thai	Thai	Thai	Thai	Thai	Thai

3.3 Inclusion criteria

3.3.1 Male and female patients, aged 18-65 years with depigmented vitiligo patches.

3.3.2 Any type of distribution of vitiligo.

3.3.3 Any skin phototype.

3.3.4 Depigmented patch appeared before six months or more.

3.4 Exclusion criteria

3.4.1 Pregnant or breast feeding women.

3.4.2 Personal history of hypertrophic scar.

3.4.3 Personal history of melanoma or any skin cancer.

3.4.4 Patients taking immunosuppressive or photosensitizing drugs.

3.4.5 Undergoing phototherapy past three months.

3.4.6 Patients taking drugs to treat vitiligo past three months.

3.5 Devices and Tools

3.5.1 CICU RF CO2 Laser Device.

Table 3.2 The features of the CICU RF laser device

Item	Feature
Laser type	RF CO2 ALL METAL SEALED TYPE
Laser power	up to 30 watt
Laser mode	TEMoo (10.6 μm)
Pulse duration	100-5000 μs
Repetition	0.2-1 s/single
Overlap	1-10 TH
Distance	0.1-2 mm
Treatment area	1*1 - 20*20 mm

Table 3.2 (Continues)

Item	Feature
Pixel quantity	up to 40,401
Pixel size	> 100 micron
Cooling	Air Cooling
Optical guide	Articulated arm

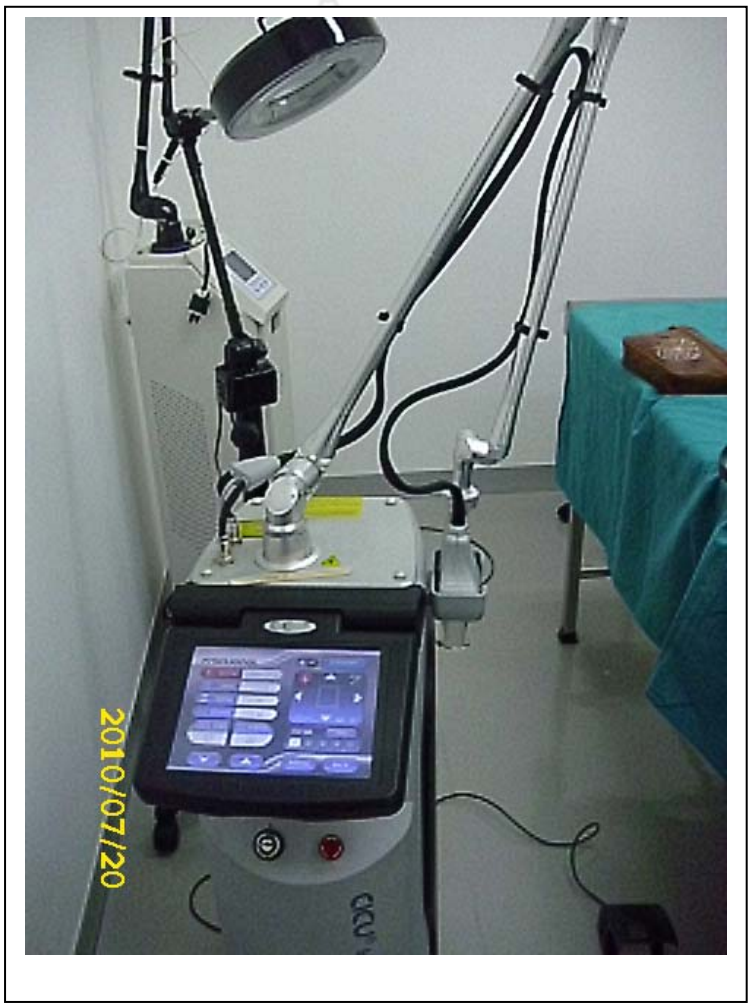

Figure 3.1 CICU RF CO2 laser device

3.5.2 Digital camera of brand BenQ DC L1020 10.0 MEGA PIXEL.

3.5.3 Magnifying lens.

3.5.4 LCD monitor.

3.6 Treatment Protocol

It included clinical assessment of each patient at each study entry and diagnosis of vitiligo by a dermatologist at the outpatient clinic, then choosing eligible patients who met the inclusion criteria, together with reviewing the treatment protocol and signing the informed consent. There were (3) sessions of laser treatment at one month interval (month 0, 1, 2) with two weekly follow up after each laser session. Choosing the treatment side was random and the other side was left without treatment as a control (only in case of multiple lesions but if single lesion no control is available).

Seventeen vitiligo patches were selected for treatment with laser in the study.

Table 3.3 Number of vitiligo patches treated with laser in the study

	Patient	**Number of vitiligo patches treated with laser**
	Patient no.1	1
	Patient no.2	1
	Patient no.3	3
	Patient no.4	4
	Patient no.5	5
	Patient no.6	3
Total	**6 Patients**	**17 patches**

At each treatment session, the treatment areas were cleansed of debris using mild cleanser and 70% isopropyle alcohol, lidocaine 2.5% and prilocaine 2.5% cream were applied under occlusion to the chosen patches of the treatment side, after an hour of application, occlusion was gently removed and left for drying the skin patches by alcohol. Protection of the patient's eyes by special goggles, and mask use together with all protective measures were performed then treatment of the vitiligo patches by using a fractional carbon dioxide laser of (10600 nm) wavelength of CO2 laser.

After each laser session topical antibiotic was applied to the treated areas for five to seven days.

All patients were given instructions not to use any vitiligo treatment during the period of the study.

3.7 The parameters

The parameters of laser treatment used in the study is shown in details in the following tables.

Table 3.4 Parameters of laser used in patient no.1 during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1500	2000	2500
Duration (mJ/cm2)	17.9	23.8	29.8
Repeat (s)	1	1	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	0.8	1
Shape	circle	circle	circle
Dots	120	56	56

Table 3.5 Parameters of laser used in patient no.2 during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1500	2000	2500
Duration (mJ/cm2)	17.9	23.8	29.8
Repeat (s)	1	1	single
Overlap (TH)	1	1	1
Distance (mm)	1	0.8	1
Shape	square	circle	square
Dots	360	204	85

Table 3.6 Parameters of laser used in patient no.3 (lesion no.1) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1500	1500	1600
Duration (mJ/cm2)	17.9	17.9	19
Repeat (s)	1	1	1
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	square	square	circle
Dots	420	420	296

Table 3.7 Parameters of laser used in patient no.3 (lesion no.2) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	2000	2000	1600
Duration (mJ/cm2)	23.8	23.8	19
Repeat (s)	2	1	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	1	1
Shape	square	square	circle
Dots	420	420	216

Table 3.8 Parameters of laser used in patient no.3 (lesion no.3) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1200	1200	1500
Duration (mJ/cm2)	14.3	14.3	17.9
Repeat (s)	1	1	single
Overlap (TH)	2	1	1
Distance (mm)	1	1	1
Shape	square	square	circle
Dots	420	420	216

Table 3.9 Parameters of laser used in patient no.4 (lesion no.1) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	3000	3100	3200
Duration (mJ/cm2)	35.7	36.9	38.1
Repeat (s)	1	1	single
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	square	square	circle
Dots	420	420	217

Table 3.10 Parameters of laser used in patient no.4 (lesion no.2) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	2000	2500	3000
Duration (mJ/cm2)	32.8	29.8	35.7
Repeat (s)	1	1	single
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	square	square	circle
Dots	420	420	217

Table 3.11 Parameters of laser used in patient no.4 (lesion no.3) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1500	2500	2500
Duration (mJ/cm2)	17.9	23.8	29.8
Repeat (s)	1	1	single
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	square	square	circle
Dots	270	420	217

Table 3.12 Parameters of laser used in patient no.4 (lesion no.4) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	non	1500	1000
Duration (mJ/cm2)		17.9	11.9
Repeat (s)		1	single
Overlap (TH)		1	1
Distance (mm)		1	1
Shape		square	square
Dots		420	420

Table 3.13 Parameters of laser used in patient no.5 (lesion no.1) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1400	2100	2700
Duration (mJ/cm2)	16.7	25	32.1
Repeat (s)	1	single	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	1	1
Shape	circle	circle	circle
Dots	40	125	40

Table 3.14 Parameters of laser used in patient no.5 (lesion no.2) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1300	2000	2500
Duration (mJ/cm2)	15.5	23.8	29.8
Repeat (s)	1	single	single
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	circle	circle	circle
Dots	40	125	40

Table 3.15 Parameters of laser used in patient no.5 (lesion no.3) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1200	1700	2200
Duration (mJ/cm2)	14/3	20.2	26.2
Repeat (s)	1	single	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	1	1
Shape	circle	circle	circle
Dots	40	125	40

Table 3.16 Parameters of laser used in patient no.5 (lesion no.4) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1000	1500	2000
Duration (mJ/cm2)	11.9	17.9	23.8
Repeat (s)	1	single	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	1	1
Shape	circle	circle	circle
Dots	40	125	40

Table 3.17 Parameters of laser used in patient no.5 (lesion no.5) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	2000	2500	3000
Duration (mJ/cm2)	23.8	29.8	35.7
Repeat (s)	1	single	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	1	1
Shape	circle	circle	circle
Dots	40	125	40

Table 3.18 Parameters of laser used in patient no.6 (lesion no.1) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	1500	2000	2100
Duration (mJ/cm2)	17.9	23.8	25
Repeat (s)	single	single	single
Overlap (TH)	1	1	1
Distance (mm)	0.8	1	1
Shape	circle	circle	circle
Dots	296	277	277

Table 3.19 Parameters of laser used in patient no.6 (lesion no.2) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	2000	2500	2600
Duration (mJ/cm2)	23.8	20.8	30.9
Repeat (s)	single	single	single
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	circle	circle	circle
Dots	296	277	296

Table 3.20 Parameters of laser used in patient no.6 (lesion no.3) during the three treatment sessions

Parameter	Session		
	1	**2**	**3**
Duration (μs)	2500	3000	3000
Duration (mJ/cm2)	29.8	35.7	35.7
Repeat (s)	single	single	single
Overlap (TH)	1	1	1
Distance (mm)	1	1	1
Shape	circle	circle	circle
Dots	296	277	296

All the patients completed the three sessions of laser therapy. They visited the clinic every two weeks after each laser session for follow up and photography. One month after the last laser session, photographs were taken to all treated patches to be used in the assessment.

3.8 Evaluation Criteria

3.8.1 Subjective Evaluation

It is accomplished by Patient Satisfaction Score (PSS), where All participants in the study are given questionnaire to evaluate their response after one month of the last laser session, They have been asked to choose one of four choices to answer the appreciation question.

Table 3.21 Patient Satisfaction Score (PSS)

After you have been treated with three sessions of laser therapy , how do You find your response to the laser treatment ?	
Choice	**put (X) to indicate your choice**
1- Poor response (no change in my lesion)	( )
2- Slightly satisfied	( )
3- Really satisfied	( )
4- Excellent response	( )

After self assessment sheet filled, a (4) point system is used in the analysis of Patient Satisfaction Score.

Table 3.22 A 4 unit system is given to the PSS

PSS	Point
Poor response	1
Slight satisfaction	2
Really satisfaction	3
Excellent response	4

3.8.2 Objective Evaluation

It is represented by Clinical Assessment of Repigmentation (CAR), where Clinical assessment of the the degree of repigmentation was performed by three unbiased dermatologyists, using comparative photographs taken by BenQ camera of the laser-treated lesions between baseline photographs and photographs taken one month after last laser therapy. The photos were defined and not blinded for the assessors.

The three dermatologists assess the photos individually by choosing one of percentages (0-100%) to indicate the rate of repigmentation for each lesion for all of the participants.

After all assessors completed their assessment, results taken and were scored into numbers to be analyzed statistically, as shown in table 3.23.

Table 3.23 Clinical Assessment of Repimentation (CAR) and scores given for each rate

	0%	1-24%	25-49%	50-74%	75-99%	100%
Rate of repigmentation Score	0	1	2	3	4	5

CHAPTER 4

RESULTS

4.1 Outcome

Six patients (3 male and 3 female) were included in this study with mean age of 40 ± 14 yr (minimu 25 yr and maximum 65 yr), all are Thai nationality, 17 vitiligo lesions (50% generalized, 23% acrofacial, 17% segmental and 5% focal type of vitiligo) were treated by laser. All patients completed the study. 1 month follow up visit after last laser session, patient satisfaction score were taken which showed 16.7% (1 patient) were really satisfied, 66.7% (4 patients) were slightly satisfied and 16.7% (1 patient) with poor satisfaction.

One female patient (16.7%) with generalized vitiligo detected repigmentation in vitiligo patches in areas like the neck and chest. (not treated by laser)

Table 4.1 Percentage results of Patient Satisfaction Score (PSS)

	Frequency	**Percent**
Poor response	1	16.7
Slight satisfaction	4	66.7
Real satisfaction	1	16.7
Excellent response	0	0
Total	6	100.0

Figure 4.1 Bar graph showing the frequency of Patient Satisfaction Score

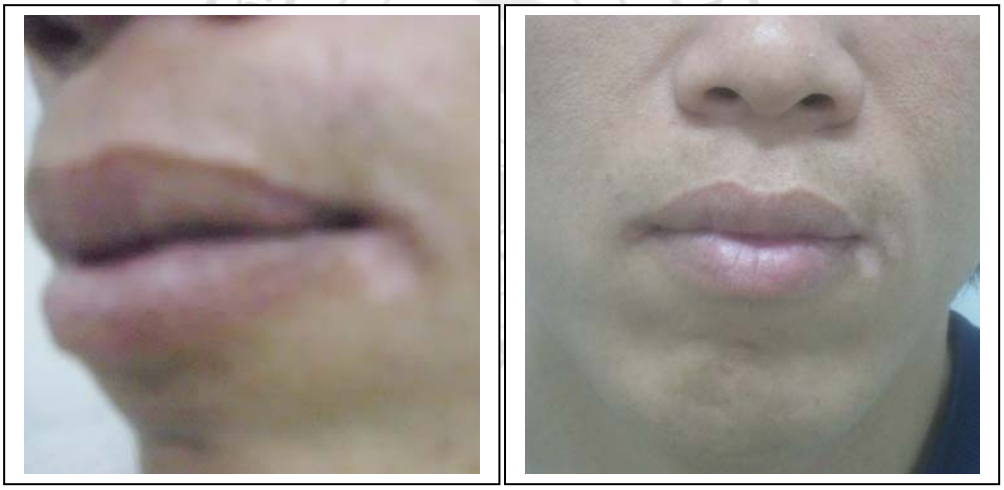

Figure 4.2 Patient (no.1) before (left) and after (right) laser treatment of a vitiligo patch near left angle of the mouth

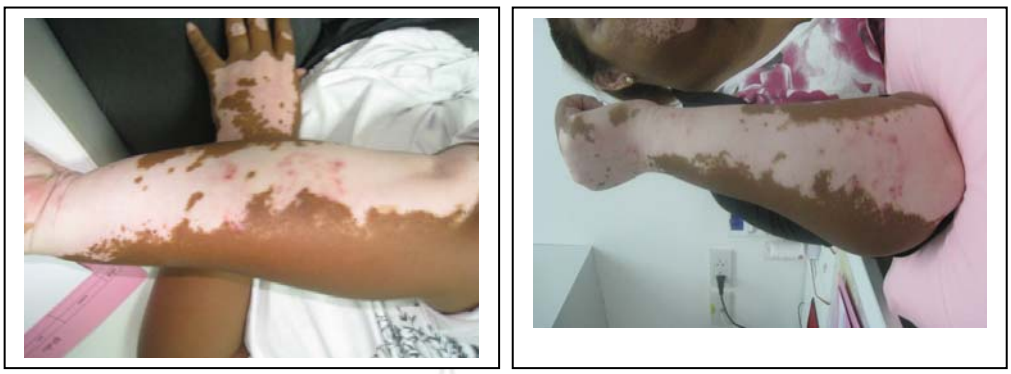

Figure 4.3 Patient (no.3) before (left) and after(right) laser treatment of right forearm

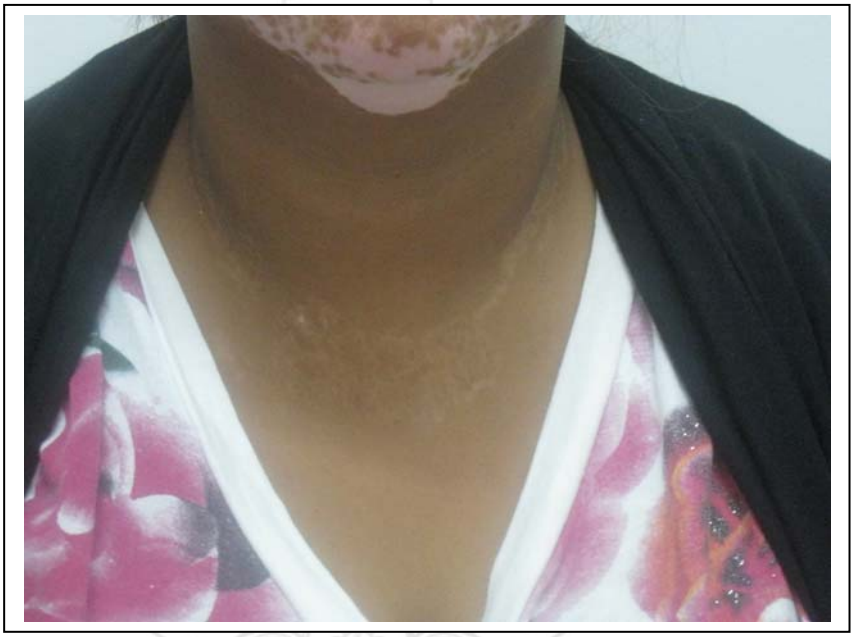

Figure 4.4 Patient (no.3) this female has noticed some repigmenation in her chest and neck areas during period of her recruitment in this study although these areas not treated by laser

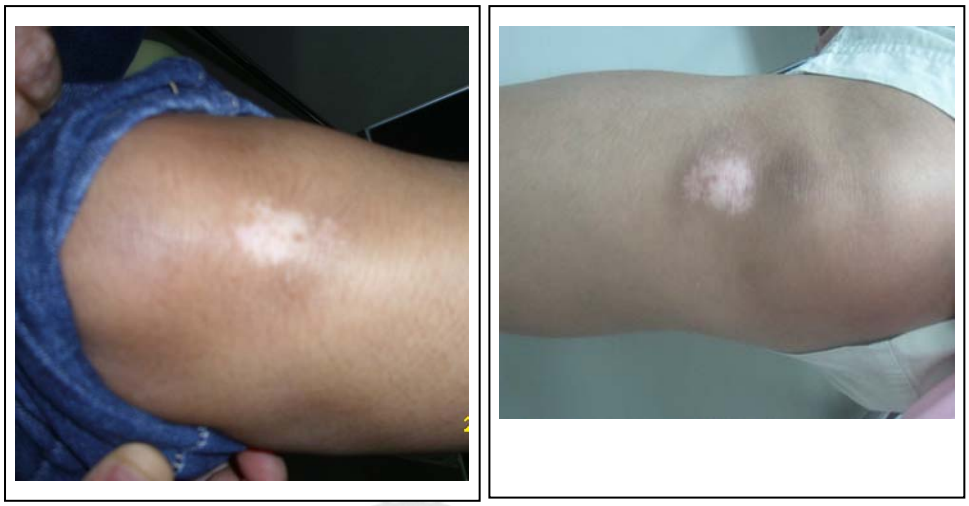

Figure 4.5 Patient (no.4) before (left) and after (right) laser treatment of a vitiligo patch near knee area

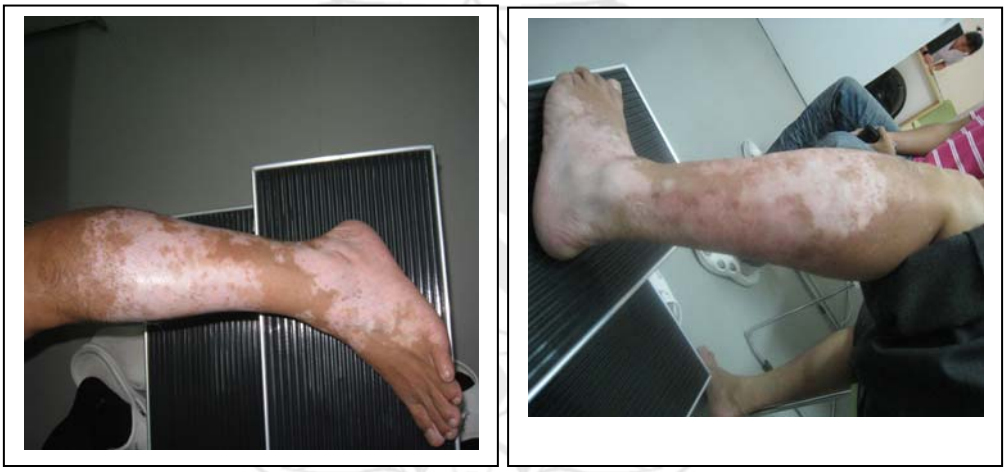

Figure 4.6 patient (no.6) before (left) and after (right) laser treatment of vitiligo skin in the left foot and leg, note the fading erythematous area in the calf which appeared two days after last laser session

4.2 Clinical Assessment of Repigmentation

According to the Clinical Assessment of Repigmentation (CAR), The mean results of the three dermatologists assessments showed 14 patches (82%) out of the 17 patches were given score 1 which means 1% - 24% repigmentation, while only 3 patches (18%) were given 0 score.

Table 4.2 Clinical Assessment of Repigmentation (CAR) of the patients accomplished by three dermatologists, with their mean values

Patient	CAR1	CAR2	CAR3	Mean
Pt. No. 1	1	1	1	1
Pt. No. 2	1	2	0	1
Pt. No. 3 lesion no.	1	1	1	1
Pt. No. 3 lesion no.	1	1	1	1
Pt. No. 3 lesion no. 3	0	1	1	0.67
Pt. No. 4 lesion no. 1	1	2	0	1
. Pt. No. 4 lesion no. 2	1	3	1	1.67
Pt. No. 4 lesion no. 3	0	2	0	0.67
Pt. No. 4 lesion no. 4	1	3	0	1.33
Pt. No. 5 lesion no. 1	0	2	0	0.67
Pt. No. 5 lesion no. 2	1	2	0	1
Pt. No. 5 lesion no. 3	0	3	2	1.67
Pt. No. 5 lesion no. 4	1	3	1	1.67
Pt. No. 5 lesion no. 5	1	2	1	1.33
Pt. No. 6 lesion no. 1	1	2	0	1
Pt. No. 6 lesion no. 2	1	1	2	1.33
Pt. No. 6 lesion no. 3	1	2	0	1

Note. Pt. for (patient), CAR for (Clinical Assessment of the Repigmentation)

4.3 Side Effects

Only one patient, two days after the third laser session he came complaining of pain, erythema and blistering in the treated leg (lesion no. 2). I treated him with antivira, antibiotic and pain relieving tablets together with cleaning the lesion and application of fucidin cream, after five days he came without any pain, erythema or blistering.

CHAPTER 5

CONCLUSION

After this relatively short period of follow up, the results, in conclusion, showed patient satisfaction score 16.7% (1 patient) were really satisfied, 66.7% (4 patients) were slightly satisfied and 16.7% (1 patient) with poor satisfaction.

According to the Clinical Assessment of Repigmentation degree, The mean results of the three dermatologists assessment showed 14 patches (82%) out of the 17 patches were given score 1 which means 1% - 24% repigmentation, while only 3 patches (18%) were given 0 score, 6 his means that carbon dioxide laser has achieved mild repigmentation effect in vitiligo patches.

One patient noticed repigmentation in areas not treated by laser, she claimed that repigmenation started to occur in her neck and chest during period of the study, this encouraging news need to be verified in the light of any immunological effects of carbon dioxide laser or it is just an accidental event or some thing else. But we know that Vitiligo is known as a slowly responding disease so three months of laser sessions may be not enough to achieve complete clinical improvement in repigmentation.

CHAPTER 6

DISCUSSION AND SUGGETIONS

6.1 Discussion

The results obtained after using fractional carbon dioxide laser in the treatment of vitiligo showed that it may have a mild effect in achieving repigmenation and what is interesting finding that its use is associated with repigmenation in distant areas not treated by the laser, a finding seen after using CO2 laser in treatment of warts, in which ablation of warts using the CO2 laser at a single site can stimulate spontaneous regression of warts at distant sites, the explanation was that it is possibly due to stimulation of the immune system following an acute inflammatory reaction (Dave, Monk, & Mahaffey, 2002), however this finding in vitiligo needs more clarification to establish whether this distant repigmentation is real and it is due to laser effects on immunologic system or it is not real and as a part of unpredictable behavior of vitiligo.

6.2 Suggestions

Owing to the fact that vitiligo follows unpredictable course, in some people the white patches can remain stable for many years but in others they can enlarge in size while new patches appear or disappear in large areas of the skin surface, So I suggest that, more treatment sessions of laser may be needed together with longer period of follow up to reach a sound decision about any role of fractional carbon dioxide laser in the treatment of vitiligo.

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APPENDIXES

APPENDIX A

INFORMED CONSENT FORM

หนังสือยินยอมเข้าร่วมโครงการวิจัย (Informed Consent Form)

วันที่.....เดือน.....พ.ศ .....

(ข้าพเจ้า) นาย/นาง/นางสาว ……อายุ……..

อยู่บ้านเลขที่ .....หมู่ที่ ..... ถนน .....ตำบล.....อำเภอ .....

จังหวัด .....รหัสไปรษณีย์ .....

ขอทำหนังสือแสดงความยินยอมเข้าร่วมโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่าข้าพเจ้ายินยอม

1. ข้าพเจ้ายินยอมเข้าร่วมโครงการวิจัยของ (หัวหน้าโครงการ).....

เรื่อง.....

ด้วยความสมัครใจ โดยมิได้มีการบังคับ หลอกลวงแต่ประการใด และพร้อมจะให้ความร่วมมือในการวิจัย

2. ข้าพเจ้าได้รับการอธิบายและตอบข้อสงสัยจากผู้วิจัยเกี่ยวกับวัตถุประสงค์การวิจัย วิธีการวิจัย ความปลอดภัย อาการ หรืออันตรายที่อาจเกิดขึ้น รวมทั้งประโยชน์ที่จะได้รับจากการวิจัย โดยละเอียดแล้วตามเอกสารชี้แจงผู้เข้าร่วมการวิจัยแนบท้าย

3. ข้าพเจ้าได้รับการรับรองจากผู้วิจัยว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ จะเปิดเผยได้เฉพาะในรูปแบบของการสรุปผลการวิจัยเท่านั้น

4. ข้าพเจ้าได้รับทราบจากผู้วิจัยแล้วว่า หากเกิดอันตรายใดๆ จากการวิจัย ผู้วิจัยจะรับผิดชอบค่ารักษาพยาบาลที่เป็นผลสืบเนื่องจากการวิจัยนี้

5. ข้าพเจ้าได้รับทราบว่า ข้าพเจ้ามีสิทธิที่จะถอนตัวออกจากการวิจัยครั้งนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบใด ๆ ต่อการรักษาพยาบาลตามสิทธิ์ที่ข้าพเจ้าควรได้รับ

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้แล้ว จึงได้ลงลายมือชื่อไว้เป็นสำคัญ พร้อมกับหัวหน้าโครงการวิจัยและพยาน

ลงชื่อ..... ผู้ยินยอม/ผู้ปกครอง

(.....)

ลงชื่อ.....หัวหน้าโครงการ

(.....)

ลงชื่อ..... พยาน

(.....)

ลงชื่อ..... พยาน

(.....)

APPENDIX B

PATIENT SATISFACTION SCORE FORM

คะแนนความพึงพอใจของผู้ป่วย

Patient Satisfaction Score

Name :

H N :

Date ;

หลังจากที่คุณได้รับการรักษาด้วยเลเซอร์เป็นจานวน 3 รอบ

After you have been treated with three sessions of Laser therapy ,

การตอบสนองของคุณต่อการรักษาด้วยเลเซอร์ได้ผลดีหรือไม่ อย่างไร,

How do you find your response to the laser treatment ?

กรุณาเลือกผลการตอบสนองหลังการรักษาผิวหนังของคุณด้วยเลเซอร์ ดังตัวเลือกที่กาหนดให้ต่อไปนี้

Please appreciate your lesion response to the laser treatment by choosing the appropriate choice that meets your response :

การตอบสนองไม่ดี หรือ ไม่มีการ เปลี่ยนแปลงในแผลของฉันหลังการรักษาด้วยเลเซอร์

Poor response (No change in my lesions after laser therapy) .

ผม/ดิฉัน พอใจเล็กน้อย ในการตอบสนองของแผลหลังการรักษาด้วยเลเซอร์

I am slightly satisfied about the response of my lesions to laser therapy .

ผม/ดิฉัน พอใจค่อนข้างมาก ในการตอบสนองของแผลหลังการรักษาด้วยเลเซอร์

I am really satisfied about the response of my lesions to laser therapy .

การตอบสนองดีเยี่ยม

ผม/ดิฉัน พอใจอย่างมาก พบว่ามีการตอบสนองที่ดีเยี่ยม หลังการรักษาแผลด้วยเลเซอร์ Excellent response

(I found an excellent response in my lesions to laser therapy) . ----------

Signature _____

Name _____

APPENDIX C

PATIENT DATA SHEET

Patient Data Sheet

Patient no. - - (/ / 20)

MY RESEARCH

FRACTIONAL DIOXIDE LASER IN THE TREATMENT OF VITILIGO

PATIENT DATA

Hospital no. (HN) :

NAME:

DATE OF BIRTH : / / . AGE : yr.

SEX:

MARITAL STATUS :

OCCUPATION :

ADDRESS:

MOBILE NO.:

E-MAIL:

WHEN FIRST VITILIGO APPEARD ?

WHERE IN BODY STARTED (SITE) ?

SIZE OF LESION :

WHAT DRUGS USED ?

WHEN LAST DRUG USED FOR VITILIGO ? WHAT DRUG ?

ANY PHOTOTHERAPY USED ? WHEN ? WHAT RESULT ? NON

KEBNERIZATION :

Site	Time	notes
-		

ANY OTHER SKIN DISEASE ? .

ANY OTHER DISEASE ?

ANY HOSPITAL ADMISSION ? WHEN ? WHY ?

ANY SURGICAL OPERATION ? WHEN ? WHAT FOR ?

ANY ACCIDENT ?

ALLERGY TO DRUGS ?

HABBITS : SMOKING

DRINKING

For female patients –is she pregnant or breast feebding ?

Is patient using immunosuppressive or photosensitizing drug ? WHAT ?

Is patient undergoing phototherapy during last 3 months ?

Is patient taking any drug for treating vitiligo during last 3 months ? what drug ?

Personal history of hypertrophic scar ?

Personal history of melanoma or skin cancer ?

Summary of Hx.

PHYSICAL EXAMINATION

1- SKIN PHOTOTYPE (SPT) :

2-

3-

4-

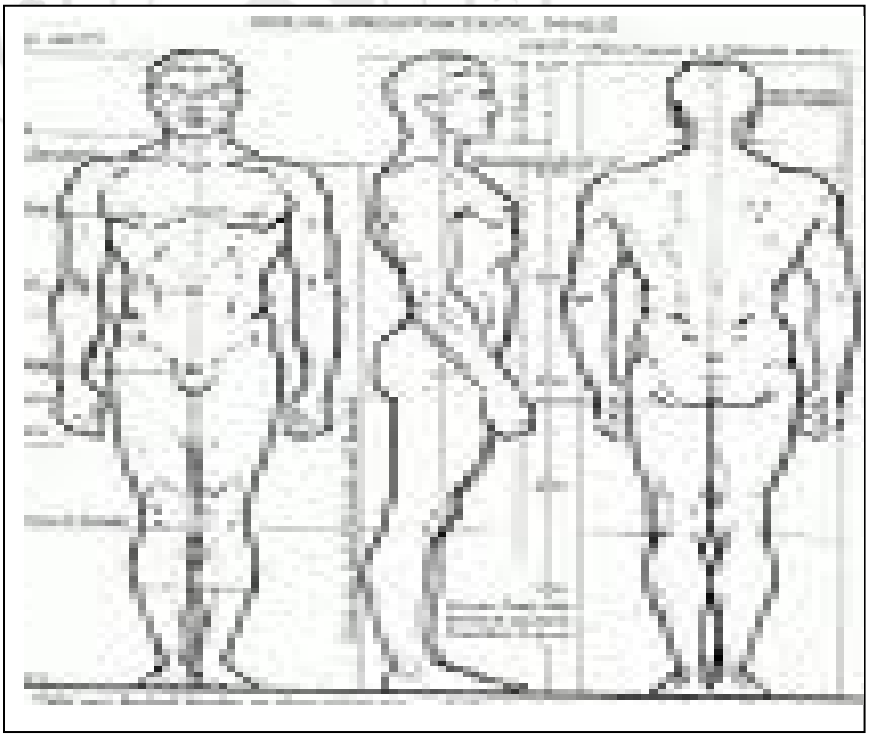
5-

6-

Distribution of lesions

	Site of lesion	Size	Color & notes
1-			
2-			
3-			
4-			
5			
6			

Sites of vitiligo Lesions in the Body



Parameters & Sessions

of Fractional dioxide laser treatment

1- Date: / / . Time: . Day: F. St. S. M. T .W .Th.

2- Parameters

	1st Session	2nd Session	3rd Session	Notes	Notes
Duration µs					
Duration mJ/cm2					
Overlap Th					
Distance Mm					
Shape					
Dots					

Dates :

DATE	**ACTIVITY**	**NOTE**
	1st visit	**Laser & photography**
	2nd visit	**follwup & photography**
	3rd visit	**Laser & photography**
	4th visit	**follwup & photography**
	5th visity	**Laser & photography**
	6th visit	**follwup & photography**

APPENDIX D

CLINICAL ASSESSMENT OF REPIGMENTATION FORM

Assessment of Repigmentation (CAR)

Please indicate your choice by applying (X) ;

Patient no. 1						
Lesion no. 1						
Rate of Repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%

Patient no. 2						
Lesion no. 1						
Rate of Repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%

Patient no. 3						
Lesion no. 1						
Rate of Repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 2						
Rate of Repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75%- 99%	100%
Lesion no. 3						
Rate of Repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%

Patient no. 4						
Lesion no. 1						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 2						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 3						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 4						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 1		Patient no. 5				
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 2		Patient no. 5				
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 3						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 4						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 5						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%

Patient no. 6						
Lesion no. 1						
Rate of Repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%
Lesion no. 2						
Rate of repigmentation	0%	1% - 24%	25% -49%	50% - 74%	75% - 99%	100%
Lesion no. 3						
Rate of repigmentation	0%	1% - 24%	25% - 49%	50% - 74%	75% - 99%	100%

Name of evaluator ,Dr :

.....

Signature :.....

Date :...../.....

CURRICULUM VITAE

CURRICULUM VITAE

NAME	Mr. Abedrazk Mohammed Ibrahim
DATE OF BIRTH	5 October 1970
ADDRESS	Asoke Place Condominuim Juristic Person Apartment no. 27, 38 Asoke Place Building Asoke Road Klong toey, Wattana, Bangkok 10110 Thailand

EDUCATIONAL BACKGROUND

1998	M.B.Ch.B. in Medicine and Surgery College of Mdicine University of Mosul, Iraq

WORK EXPERIENCE

1998 - 2000	Medical internship and training Mosul hospitals
2001 - 2003	Resident doctor in Dialysis Unit Ibn-Sina hospital in Mosul, Iraq
2003 - 2009	General Practitioner doctor Al-Aqsah HC, Mosul, Iraq