COMPARISON OF A PULSED DYE LASER: 595 NM AND AN INTENSE PULSED LIGHT FOR THE TREATMENT OF POSTINFLAMMATORY ERYTHEMA FROM ACNE VULGARIS

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IN
DERMATOLOGY

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Maytharat Tussanatapprasert

Thesis Title	Comparison of a Pulsed Dye Laser: 595 nm and an Intense Pulsed Light for the Treatment of Postinflammatory Erythema from Acne Vulgaris
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ABSTRACT

Background: Postinflammatory erythema occur as a result of inflammatory acne. Some acne erythema lesions may improve with time, but the persistent erythema. Currently, Target of treatment to reduce vascular include the pulsed dye laser (PDL) and intense pulsed light devices also have been approved for safety in human. To date there are no published studies that compare clinical efficacy about postinflammatory erythema from acne vulgaris between this two treatments.

Objectives: To compare the clinical improvement of postinflammatory erythema from acne vulgaris, side effect and satisfaction of the Pulsed dye laser: 595 nm with those of Intense pulsed light device in treatment of postinflammatory erythema.

Materials and methods: In randomized split-face controlled trial, 20 Thai subjects with with postinflammatory erythema from acne vulgaris on both sides of the cheeks, Fitzpatrick skin types III to V were enrolled. All subjects received treatment with both device. Half of the patient's face was treated with the pulsed dye laser (PDL): 595 nm device (V-beam Pecfecta laser®) and another half with the intense pulsed light (IPL) device (Quantum SR®) were randomly assigned to the treatment. The treatments were

performed once a month for three months. Photographic by VISIA® was done before treatment and four weeks after each treatment (on weeks 4, 8 and 12).

Measurements of erythema from erythema index by Mexameter at four weeks after each treatment. The was measured same sites on three selected acne erythema lesions at baseline and 4 weeks after each treatment. Clinical improvement of postinflammatory erythema and postinflammatory erythema lesion counts was independently evaluated by two masked dermatologists. Patients were asked to evaluate their satisfaction score and choose the preferred each device. Adverse events were recorded

Results: The mean reduction of postinflammatory erythema lesion counts and the mean reduction of erythema index after completing both devices treatments with statistical significance. The result showed no statistically significant difference of the erythema index and postinflammatory lesion counts in two groups. Clinical improvement grading by two independently dermatologists showed better at PDL treated side than IPL treated side with statistically significant differences. There was no statistical significance in the difference between the numbers of patients who preferred each device and patient satisfaction scores. The pain score of pulsed dyelaser:595 nm device was higher than intense pulsed light device and the durational of facial edema (hrs) in the pulsed dyelaser: 595 nm (Vbeam) was longer than the intense pulsed light device. One case with skin type V of postinflammatory hyperpigmentation after treat with intense pulsed light device was reported.

Conclusions: Both intense pulsed light device (Quantum SR®), and the pulsed dye laser: 595 nm device (V-beam laser®; Candela Laser Corporation) are safe and effective treatment modality for the treatment of postinflammatory erythema from acne vulgaris in patients with Fitzpatrick Skin Types III to V. Most of the patients were very satisfied with the result of treatment. Both devices have similar effectiveness for

postinflammatory erythema from acne vulgaris treatment. Although there were some differences regarding side effects from both devices, they were mild and transient.

Keywords: Postinflammatory erythema from acne vulgaris/Pulsed dye laser: 595 nm /Intense pulsed light

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ABBREVIATIONS AND SYMBOLS

PDL	pulsed dye laser
IPL	intense pulsed light
NM	nanometer
KTP	potassium-titanylphosphate
Nd:YAG	neodymium:yttrium- aluminum-garnet
MTZs	microscopic treatment zones

CHAPTER 1

INTRODUCTION

1.1 Background

Acne is a chronic and multifactorial skin condition affecting about 80% of persons aged 11 to 30 years, the majority of whom are adolescents (Shamban & Narurkar, 2009) Acne lesions occur in the pilosebaceous unit resulting from four factors involved in acne are increased sebum production, Abnormal desquamation of keratinocytes, the presence of *Propionibacterium acnes*, and inflammation (Ramanathan & Hebert, 2011). Most inflammatory acne lesions can result in postinflammatory erythema because blood vessels may become permanently dilated as part of a wound healing response at the sites of focal inflammation. Some lesion is perceived as areas of persistent redness. Acne patients usually complain of troublesome persistent erythema after acute inflammation has been reduced by treatment. Postinflammatory erythema consists of telangiectasia and erythematous papules, without a comedone, which occur as a result of inflammatory acne Some acne erythema lesions may improve with time, but the persistent erythema (Yoon, Lee, Kim, Park & Youn, 2008). Deeper and highly concentrated capillaries create a dull red skin surface appearance, whereas superficial and less concentrated blood vessels make the scar appear bright red. Take months to years to resolve. There are many options for postinflammatory erythema treatment, pink to red colour of lesion are related to capillaries dilatation therefore target of treatment to reduce vascular such as topical vasoconstrict, lasers and light sources that used to reduce the red coloration of postinflammatory erythema include the pulsed dye laser (PDL), the potassium-titanylphosphate (KTP) laser, intense pulsed light (IPL), and theneodymium: yttrium-aluminum-garnet (Nd: YAG) laser. Usually, 3 to 4 or more treatments are required, at approximately 1-month intervals (Rao, 2011). Fractional photothermolysis creates hundreds of microthermal treatment zones (MTZs) while sparing the surrounding

tissue.Report marked improvement of postinflammatory erythema in two patients after one treatment session with fractional photothermolysis (Glaich, Goldberg, Friedman, & Friedman, 2007)

This is best treated with a vascular-target laser such as pulsed dye laser. The potassium-titanylphosphate (KTP) laser, intense pulsed light (IPL), and theneodymium: yttrium- aluminum-garnet (Nd: YAG) laser

Lasers differ from non-laser light sources in that they emit minimally divergent, coherent light that can be focused to a small area of tissue to provide very high irradiances. Pulsed-dye lasers (PDLs) emit visible light that is mainly absorbed by oxyhaemaglobin, so high irradiation energy densities (fluences) are used to treat vascular lesions such as port wine stains.Whereas high fluences ablate small blood vessels and cause purpura, lower non-ablative fluences do not.

Some study shows the improvement of postinflammatory erythema by long-pulsed 595-nm pulsed-dye laser treatment. Patients demonstrated reductions in acne erythema lesion counts. This postinflammatory erythema lesion counts to a 24.9% reduction after the first treatment and a total decrease of 57.6% after the second treatment with minimal discomfort (Yoon et al., 2008) and the 585-nm pulsed dye laser (PDL) (Alster & McMeekin, 1996) can significantly improve the clinical appearance of postinflammatory erythema or hypertrophic facial acne scars after one or two treatments.

Intense pulsed light (IPL) devices are not true lasers. Instead, noncoherent light of multiple wavelengths (approximately 500–1200 nm) is released by a flashlamp within the device. IPLdevices have the ability to target pigment, erythema, and telangiectasia via a variety of wavelengths but poor specificity compare with true lasers. Purpura is rare with IPL treatment (Rao, 2011) .Many studies show IPL can improve inflammatory acne vulgaris. One study (Yeung et al., 2007) show significant reduction of non- inflammatory lesions was observed in IPL groups (43%) after treatment and some studies (Sami, Attia & Badawi, 2008) shows the percent reduction in acne lesions was 41.7% by IPL. Few studies (Chang et al., 2007) shows improve postinflammatory erythema of 63% were good or excellent on the laser-treated side compared to 33% on the untreated side with minimal down time

or purpura. This study, Therefore is conducted to compare the clinical efficacy and side effects of the pulsed-dye laser with those of the intense pulsed light .The pulsed-dye laser and the intense pulsed light has the similar basic principle of IPL devices is the selective thermal damage of the target structure used for treatment of postinflammatory erythema from acne vulgaris.

1.2 Objective

To compare the clinical improvement of postinflammatory erythema from acne vulgaris, side effect and satisfaction of the Pulsed dye laser: 595 nm with those of Intense pulsed light device in treatment of postinflammatory erythema.

1.3 Research Hypothesis

The Pulsed dye laser: 595 nm has higher effectiveness and lower side effect than the Intense pulsed light for the treatment of postinflammatory erythema.

1.4 The Scope of Research

Twenty patients with postinflammatory erythema. On both sides of the face both males and females, ages 18-55, were randomly assigned to the treatment with the Pulsed dye laser: 595 nm device and the intense pulsed light on each half of the face. The treatments were performed once a month for three months at Mae Fah Luang University Hospital, Bangkok. Photographic documentation using identical camera setting, patient positioning and environmental light by VISIA® Complexion Analysis System was done before treatment and four weeks after each treatment. Measurements of erythema with Mexameter were used to quantitatively evaluate erythema reductions four weeks after each treatment. The erythema index was measured on three selected acne erythema lesions at baseline and 4 weeks after each treatment. Same sites at each of the three visits and then calculated the average erythema index .Clinical improvement of postinflammatory

erythema and postinflammatory erythema lesion counts was independently evaluated by two masked dermatologists. Patients were asked to evaluate their satisfaction score and choose the preferred each device.

1.5 Conceptual Framework

After occurring of inflamed acnes, in wound healing process, Dilatation of blood vessels is part of the skin's normal healing response to dermal injury. Increased amounts of red blood cells within areas of dilated blood vessels give the skin surface above this area a varying degree of skin surface redness. Postinflammatory erythema may be self limited but can take months to years to resolve. According to the theory of selective photothermolysis, pulsed dye laser: 595 nm device and intense pulsed light device both have the same chromophore as haemoglobin and the vessel wall is target. So both devices can improve postinflammatory erythema.

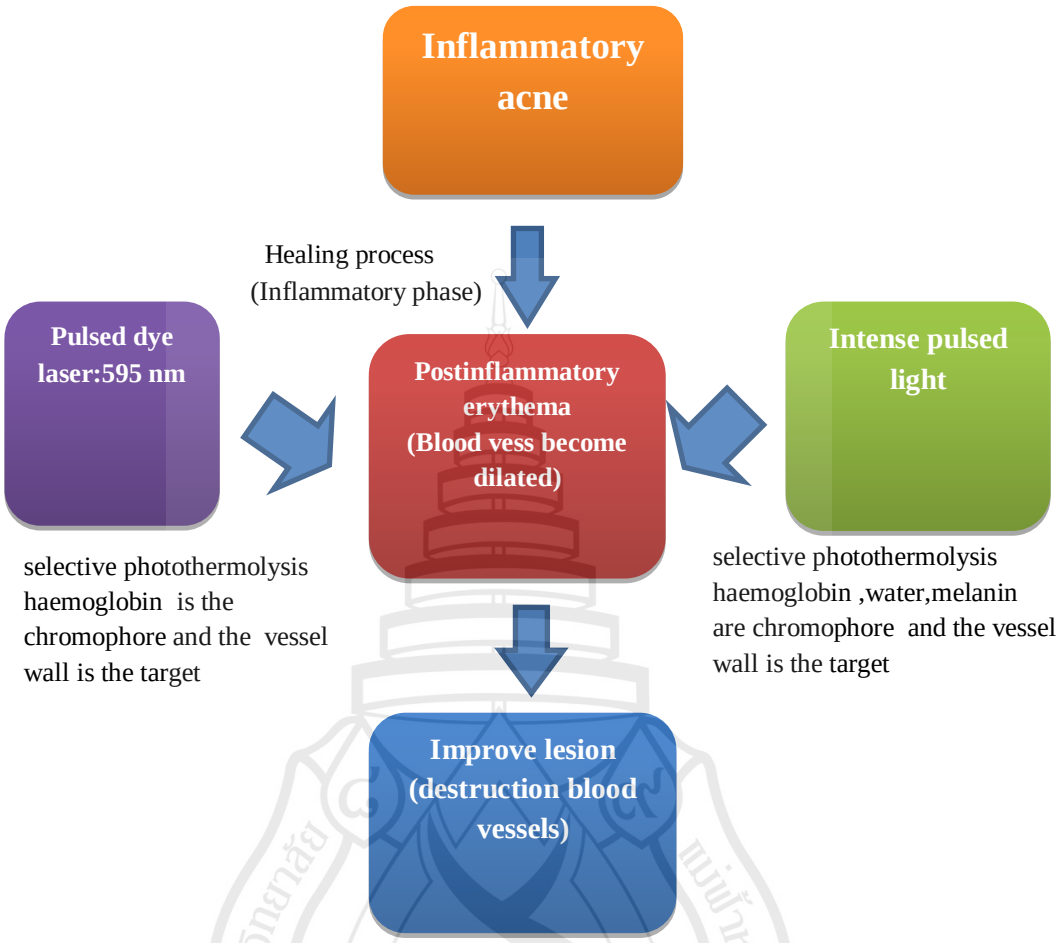


Figure 1.1 Conceptual Frameworks

1.6 Operational Definition

1.6.1 Postinflammatory erythema is common sequelae of inflammatory acne vulgaris. Lesion may appear red from angiogenesis beneath the skin's surface (Dierickx, Goldman & Fitzpatrick, 1995). Dilatation of blood vessels is part of the skin's normal healing response to dermal injury. Postinflammatory erythema may be selflimited but can take months to years to resolve.

1.6.2 Pulsed dye laser (PDL): 595 nm: produce light at a wavelength that is absorbed by haemoglobin, causing a selective photothermolysis to the dermis. So Pulsed dye laser is effective for treatment of vascular lesions. Minimal downtime after treatment but can have purpura about 7-14 days after treatment.

1.6.3 Intense pulsed lights (IPL) describe the use of intense pulses of non-coherent light distributed over a range of wavelengths from 500 nm to 1200 nm. Selective photothermolysis is the basic principle of Intense Pulsed Light treatment. The most common chromophores encountered in the skin are: hemoglobin, melanin, water and foreign pigmented tattoos. The main target structures for Intense Pulsed Light treatment are melanin and blood vessels. So intense pulsed light can improve postinflammatory erythema from acne vulgaris.

1.6.4 Fitzpatrick skin phototype Data derived from Fitzpatrick-skin color types (Fitzpatrick, 1988)

Skin type	Skin color	Susceptibility to sun burn	Susceptibility to skin cancer
Type I	Blond or red hair (freckles, fair skin, blue eyes)	Always burns easily; never tans	High
Type II	Blond or red hair (freckles, fair skin, blue eyes)	Usually burns easily; tans with difficulty	High
Type III	Darker Caucasian, light Asian	Burns moderately; tans gradually	Low
Type IV	Mediterranean, Hispanic, Asian	Rarely burns; always tans well	Low
Type V	Latin, light-skinned black, Indian	Very rarely burns; tans very easily; dark skin tone	Very low
Type VI	Dark-skinned black	Never burns; very dark skin tone	Very low

Figure 1.2 Fitzpatrick-skin color types

1.7 Limitation of the Study

1.7.1 The population of the experimental group is small.

1.7.2 Limitation in term of the duration of the study.

CHAPTER 2

LITERATURE REVIEW

Acne lesions happen in the pilosebaceous unit. Pathogenesis of acne is caused by four

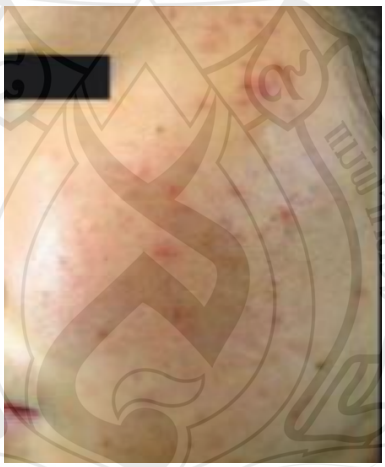
Factors; increased sebum production, abnormal desquamation of keratinocytes, the presence of *Propionibacterium acnes* and inflammation. Initialy when the microcomedone enlarges, it becomes either an open comedone with a widely dilated orifice (blackhead) or a closed comedone (whitehead). The black color reflects the oxidation of melanin within the open orifice not an absence of hygiene. This condition is called comedonal acne. Inflammatory acne is characterized by erythematous papules, pustules (less than 5mm in diameter) and nodules (more than 5mm in diameter) (Ramanathan & Hebert, 2011). Most inflammatory acne lesions can result in postinflammatory erythema because blood vessels may become permanently dilated as part of a wound healing response at the sites of focal inflammation. Some lesions are perceived as areas of persistent redness. Dilatation of blood vessels are part of the skin's normal healing responses to dermal injury, designed to provide oxygen, chemical factors, and nutrients necessary for the skin to adequate recover from the injury. A red blood cells contains hemoglobin, which is red in color. Increased amounts of red blood cells in an area of dilated blood vessels gives the skin surface above this area a varying degree of skin surface redness. Deeper, highly concentrated capillaries create a dull red skin surface appearance, whereas superficial and less concentrated blood vessels make the scar appear bright red. Postinflammatory erythema may be self-limited but can take months to years to resolve (Rao, 2011). Postinflammatory erythema is common in acne patients; no satisfactory medical or surgical treatment is available for this condition. Postinflammatory erythema is cosmetically unacceptable, and can lead to frustration and psychological distress (Yoon et al., 2008).

2.1 Pathogenesis of Postinflammatory Erythema

Postinflammatory erythema is the result of dilated capillaries beneath the skins surface. The intensity of the erythema depends on;

1. The concentration of blood vessels inside the scar
2. The average caliber or lumen size of the blood vessels at the site
3. The distance of the blood vessels from the skin surface (ie, depth).

Bright erythema within scars is suggestive of vessels that are not concentrated, have a relatively small diameter lumen, and are in the superficial dermis (relatively close to the skin surface). Dull erythema is typically seen in scars where blood vessels are concentrated, deep and large caliber. These clinical signs may be useful in selecting appropriate treatment modalities to normalize erythema (Rao, 2011)



Source Yoon et al. (2008)

Figure 2.1 Physical finding of postinflammatory erythema from acne vulgaris

2.2 Treatment of Postinflammatory Erythema

There are many options for postinflammatory erythema treatment (Rao, 2011)

2.2.1 Topical vasoconstrictors like Brimonidine tartrate. It usually used in rosacea lesion but not popular for postinflammatory erythema.

2.2.2 Vascular-Targeting Laser Treatment

Laser (Patil & Dhami, 2008)

Laser is an acronym for "Light Amplification by Stimulated Emission of Radiation." Stimulated emission is based on Einstein's quantum theory of radiation. Laser has 4 properties (Nelson & Lask, 2011).

1. It is monochromatic, meaning that it's of 1 specific wavelength.
2. It is collimated, meaning that the rays of light are parallel.
3. It's coherent, meaning that the rays of light are in phase with each other.
4. It is of high intensity.

These properties allow lasers to produce a single high intensity wavelength, which can be focused and targeted accurately, and to specifically target tissue while sparing surrounding structures, producing a predictable clinical end point.

Terminology (Patil & Dhami, 2008)

Fluence: Fluence is the energy delivered per unit of area. It is measured in J/cm2.

Pulse duration**:** The pulse duration determines how long the tissue is exposed to the laser energy. Longer pulse duration allow the skin to heat up slower and is safer for darker skin tones.

Spot size (spot diameter): Spot size will determine the area to be treated. Lasers vary widely on the spot sizes available for use. Spot sizes determine the depths of penetration. The larger the spot size deeper is the penetration.

Wavelength: The distance between the two subsequent peaks or troughs of a light wave. Usually it's expressed in nm (nanometer)

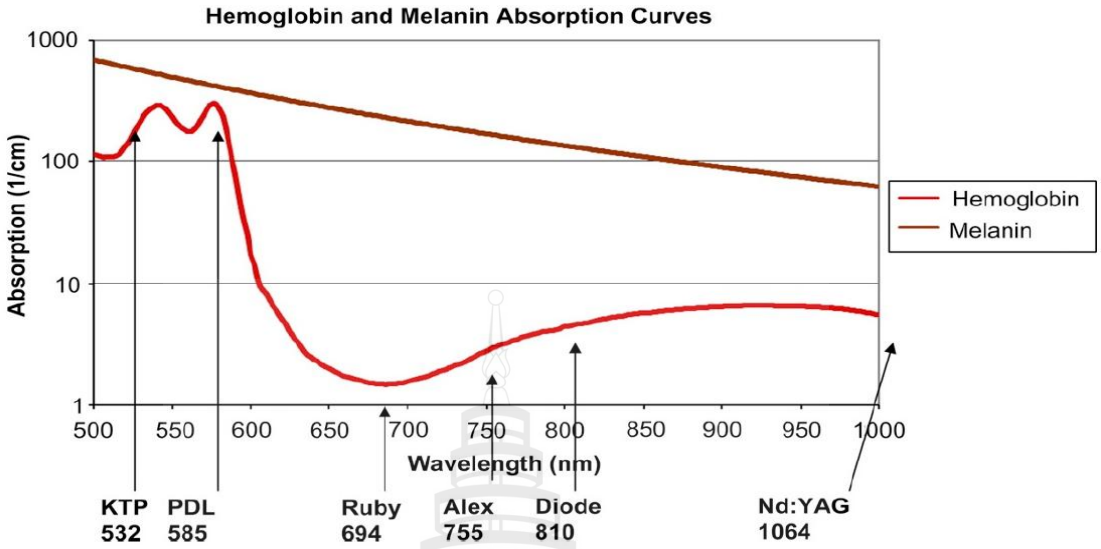
Chromophore: Chromophore is a material, present either endogenous in the tissues or exogenous which absorbs particular wavelengths depending on its absorption coefficient. In skin, there are 3 main chromophores: melanin, hemoglobin, and water.

Exogenous compounds like different colors of tattoo ink also act as chromophores. These chromophores absorb certain wavelength of light, which results in heat produced in the targeted tissue through transfer of energy. It's possible to target a specific chromophore by selecting a wavelength that is absorbed by that chromophore, with minimal absorption by other competing chromophores (Anderson & Parrish, 1983). For example, hemoglobin has a relative absorption peak at approximately 595 nm, which is the wavelength of PDLs. Thus, PDLs are used to specifically target hemoglobin and vascular structures, while attempting to spare competing chromophores such as melanin and water.

Target: The target tissue for tissue damage such as target of hair removal is hair follicle.

TRT (Thermal Relaxation Time): is defined as the time required by an object to cool down to 50% of the initial temperature achieved. The TRT is related to the size of the target. As a general rule, larger the chromophore, longer is the TRT as large objects take long time to cool.

In 1983, Anderson and Parrish described the theory of selective photothermolysis, which has revolutionized laser therapy by explaining a method of producing localized tissue damage sparing the surrounding tissues (Anderson & Parrish, 1983). The basic concept is that by using a laser with a preferentially absorbed wavelength, adequate fluence, and pulse duration relatively equal to or less than the thermal relaxation time. So, by understanding the importance of the 3 main parameters, it is possible to use selective photothermolysis to target specific tissue components while avoiding damage to surrounding, unintended targets.



Source Rao (2011)

Figure 2.2 Hemoglobin and melanin absorption curves with the superimposition of various lasers with their output wavelengths.

The currant clinical applications in skin conditions and cosmetology which most concern a plastic surgeon can be grossly divided into following 5 categories (Patil & Dhami, 2008):

1. Unwanted hairs
2. Vascular lesions, acne and scars
3. Pigmented lesions and tattoo
4. Skin rejuvenation by ablative and non ablative laser resurfacing
5. Leg veins and varicose vein

2.2.2.1 Pulsed dye laser (PDL): 585,595 nm

The PDL is indicated for postinflammatory erythema that has superficial blood vessel dilatation, flat red scars respond better than elevated ones. Although nonpurpuric settings can reduce erythema, more treatments are usually required to achieve the same effects seen with purpuric parameters. PDL treatments can be safely performed on all skin types (with additional caution encouraged in darker-skinned individuals) and over hair-bearing areas without fear of follicular destruction.

Dynamic cooling in the form of forced air or cryogen spray can be used to improve tolerability of laser treatment but may reduce efficacy by diminishing photocoagulation of blood vessels. With PDL treatment of postinflammatory erythema, purpura is advocated as an endpoint.

Purpura is the clinical sign of extravasated red blood cells indicating immediate vascular Photocoagulation. Usually in healthy individuals, purpura lasts a maximum of 7 to 10 days and resolves without sequelae. When using PDL, purpura can be achieved by using large spot sizes (7 to 10 mm), short pulse durations (less than 3 ms), and high fluences (greater than 6 J/cm2) with minimal dynamic cooling. PDL is safe to use on ethnic skin with minimal postinflammatory hyperpigmentation, even at purpuric settings (Rao, 2011).

1. Pulsed dye laser (PDL): 585,595 nm for treating postinflammatory erythema from acne vulgaris

There have been many studies about the efficacy of the pulsed dye laser:

585, 595 nm for the treatment postinflammatory erythema (Dierickx et al., 1995; Alster & Mcmeekin, 1996; Yoon et al., 2008). Alster and Mcmeekin (1996) investigated the efficacy of the pulsed dye laser (585 nm flashlamp-pumped pulsed dye laser, average fluence, 6.5 J/cm2; range, 6.0 to 7.0 J/cm2; 7 mm spot size) in treating erythematous or hypertrophic acne scarring in twenty-two patients. Erythema measurements were much lower than those obtained at baseline after one or two laser treatments. Yoon et al. (2008) researched the ability of the pulsed dye laser with integrated dynamic cooling device (V-beam laser);

Candela Laser Corporation (Wayland, MA, USA) in treatment postinflammatory erythema from acne vulgaris and Fitzpatrick skin phototypes III–IV in twenty patients. Cryogenic cooling set at 30 ms with a 10-ms delay. Treatments were performed using the following parameters: wavelength 595 nm, spot size 7 mm, pulse duration10 ms and fluence 9.5–11 J/cm^2. Measurement erythema by Mexameter (MX18; Courage+Khazaka Electronic GmbH, Ko¨ ln, Germany). All patients received two treatment sessions with 4-week intervals. A total of 90% of postinflammatory erythema patients achieved clinical improvements. Lesion counts decreased 24.9% after the first treatment and by 57.6% (versus baseline) after the second treatment. Significant

improvements were also seen in erythema indexes after each treatment. Treatment-related pain was well-tolerated and adverse effects were limited to transient erythema and edema at treatment sites which in most patients resolved within 24 hours.

2. Side effect from pulse dye laser

1) Purpura causes adjusted parameter, fluence more than 7 J/cm^2 and pulse duration less than 10 ms. This effect can be reduced by using pulsed dye laser with the Dynamic Cooling Device set spray on time about 20-40 msec and spray off time about 20-30 msec.

2) Transient erythema and edema most common occur resolved within 1-3 days.

3) Hyperpigmentation or hypopigmentation .This side effects can occur especially in darker skin types III-VI

4) Blisters can occur with setting high fluence or short pulse duration.

2.2.2.2 Potassium titanyl phosphate or KTP laser (Rao, 2011)

The KTP laser, known as a frequency-doubled Nd: YAG laser, has an output wavelength of 532 nm, which has a high target specificity for the first peak of the oxyhemoglobin absorption curve. As such, the KTP laser is ideal for erythema where the causative dilated capillaries are superficial. Erythema caused by deeper vessels has limited improvement with the KTP laser, the penetrative depth of which is confined to the papillary dermis of the skin. Generally,

KTP lasers cause only mild, if any, purpura. Like PDL, the KTP laser is safe to use on ethnic skin with minimal postinflammatory hyperpigmentation. The KTP laser is especially successful for postinflammatory erythema with spot sizes of 4 mm to 5 mm, pulse durations of 20 ms to 30 ms, and fluences of 6 J/cm^2 to 9 J/cm^2

2.2.2.3 Nd: YAG laser (Rao, 2011)

Nd: YAG lasers might be useful in treating deep erythema of postinflammatory hyperpigmentation due to dilated blood vessels within the deep dermis. Purpura is rare with Nd: YAG laser treatment and, in general, darker skin types can be treated safely. Usually for the postinflammatory hyperpigmentation, however, Nd: YAG lasers penetrate the skin well-beyond the target depth of the superficial vessels in question. To achieve success in reducing superficial erythema, new microsecond-pulsed Nd: YAG lasers have

shown good results by bulk heating the papillary dermis through small spot size (5 mm), a short pulse duration (0.3 ms), low fluence (14 J/cm2), and quick (5–10 Hz) repeated laser bursts. Within these parameters, temperature increases in the superficial dermis not only cause reduction in erythema but also stimulate collagen production without inducing injury to surrounding tissue. This laser may be used for any skin type.

2.2.3 Intense pulsed light (IPL)

Intense pulsed light (IPL) systems are high-intensity pulsed sources that emit polychromatic light in broad wavelength spectrum. The xenon flash lamp is a gas-discharged and high-intensity lamp filled with xenon gas that produces bright light when an electrical current passes through the gas. The light is filtered by different means to select wavelengths anywhere from the blue/UV through the far IR. However, the most common systems emit radiations between 400 and1, 200 nm, with cut on and cutoff wavelengths depending upon the indications to be treated. Cutoff filters are placed over the window of the optical treatment head or are imbedded into the quartz or sapphire light guides to eliminate wavelengths less than the filter. Although some IPL devices have one or two cutoff filters, available cutoff filters are 515, 550, 560, 570, 590, 615, 645, 690, and 755 nm. Finally, to allow optimal transmission of light by decreasing the index refraction of light to the skin and promoting a “heat-sink” effect, filter crystals are optically coupled to the skin with various thicknesses of a transparent water-based gel (Goldman, Weiss & Weiss, 2005).

Manufacturer	*Brand Name*	*Output, nm*	*Spot Sizes, mm*	*Fluence (maximum)*
Lumenis	Photoderm VL/PL	515–1,200	4 × 8,	90 J/cm²
	Epilight	590–1,200	8 × 35, 10 × 45	
	Multilight HR	515–1,200		
	Vasculight HR	515–1,200 and 1,064 laser		
	Quantum SR	560–1,200		
	Quantum HR	560–1,200 and		
	Vasculight–SR	1,064 laser		90 J/cm²
	Lumenis One	515–1,200	20× 50	
Energis Technology	Energis Elite IPL	600–950	10 × 50	19 J/cm²
Danish Dermatologic Development A/S,	Ellipse	Wavelength 400–950	10 × 48 Footprint (spot size) Ø8	22 J/cm²
Medical Bio Care	OmniLight FPL	515–920		45 J
OptoGenesis	EpiCool–Platinum	525–1,100		60 J
Primary Tech	SpectraPulse	510–1,200		10–20 J
Syneron	Aurora DS	580–980		10–30 J/cm²
Palomar	Starlux Y	525–1,200		15 J
	G	500–670/870–1,400		30 J
Alderm	Prolite	550–900 20 × 25	10 × 20 and	10–50 J

Source Goldman et al. (2005)

Figure 2.3 Manufacturers and Brand Names of Intense Pulsed Light Devices

In 1995 the first IPL device obtained United States Food and Drug Administration (FDA) clearance for treatment of lower extremity telangiectasias. Selective photothermolysis is the basic principle of Intense Pulsed Light treatment. It consists of matching a specific wavelength and pulse duration to obtain optimal effects on a target tissue with minimal effect on the surrounding tissues. The structures of the tissues that absorb the photons are known as chromophores. They have varying wavelengths of absorption. The most common chromophores in the skin are: hemoglobin, melanin, water and foreign pigmented tattoos. The best target structures for intense pulsed light treatment are melanin and blood vessels. The fluence delivered to the chromophores must be high enough to destroy them. The pulse durations of IPL are technically restricted to the millisecond range and should be lower than the thermal relaxation time of the target structure so that the surrounding tissue will not be damaged. IPL can target oxyhemoglobin (predominantly found in clinically red lesions), deoxygenated

hemoglobin (predominantly in blue lesions), and methemoglobin, with absorption peak wavelengths of 418, 542, and 577nm (Anderson & Parrish, 1983). Bright red lesions (oxyhemoglobulin) are better treated with 515 to 590 nm filters. Blue lesions (deoxyhemoglobulin) should be treated with 590 nm or higher filters and darker skin types should be treated with the highest filter available, double pulses, accompanied by increasing delay times between pulses (typically 20–40 milliseconds) to allow for increased skin thermal relaxation times (Goldman et al., 2005).

2.2.3.1 Indications for IPL Treatments (Goldberg, 2012)

1. Removing hair

2. Pigmented lesions and dyschromia such as Ephelides, senile, and solar lentigines, freckles (superficial pigmentation), nevus spilus

3. Vascular lesions including cavernous hemangiomas, venous and capillary malformations, facial and leg telangiectasias, poikiloderma of Civatte, port wine stains and cherry angiomas

4. Photoageing or photorejuvenation such as rhytids and fine superficial wrinkles

2.2.3.2 IPL for treat postinflammatory erythema from acne vulgaris and other cutaneous vascular lesion

IPL devices (Rao, 2011) have the great benefit of larger spot sizes allowing for larger surface areas to be treated deeper and more quickly. IPL treatments are useful in reducing postinflammatory erythema from acne vulgaris. Although parameters vary greatly depending on individual patients, typical settings are 560-nm to 650-nm filters, 2.4 ms to 4.0 ms, single pulsed or double pulsed, and 15 J/cm2 to 30 J/cm2, depending on a patient's background skin pigmentation. Multiple treatments may be required to achieve the patients satisfaction, typically at 1-month intervals. Purpura is rare with IPL treatment; however, care must be taken to prevent postinflammatory hyperpigmentation in the darker skin types. There have been many studies about the efficacy of intense pulsed light for treatment inflammatory acne vulgaris but only few studies for treatment postinflammatory erythema (Chang et al., 2007; Choi et al., 2010). Chang et al. (2007) investigated the efficacy of the intense pulsed light quipped with a 530- to750-nm filter (I2PL, Ellipse Flex, DDD, Horsholm, Denmark.) in treatment of postinflammatory erythema from acne vulgaris. Topical anesthesia was not used; the energy fluence was 8.0

J/cm2 for skin type III (11 patients) and 7.5 J/cm2 for skin type IV (19 patients) using pulse durations of 2.5 ms and double light pulse with 10-ms interval. Enough cooling gel had been applied immediately before IPL treatment and no pressure was applied to the handpiece. Resulting for postinflammatory erythema, 63% was good or excellent (by improvement scoring) on the IPL treated side compared to 33% on the untreated side. The results of colorimeter were compatible with clinical improvement of postinflammatory erythema. No side effects were seen except a few, mild postinflammatory hyperpigmented spots lasting for less than 2 weeks in three patients (10%). Papageorgiou, Clayton, Norwood, Chopra and Rustin (2008) assessed the efficacy of an IPL device (QuantumSR, Lumenis, London, UK; lem=560–1200nm, double pulses of 2.4 and 4.0, 5.0, or 6.0ms (depending on the skin type), fluence: 24–32J/cm2) for the treatment (four treatments at three-weeks interval) of stage I rosacea (flushing, erythema, and telangiectasia) in 34 patients. Photographic assessment showed significant improvement of erythema (46%) and telangiectasias (55%). Side effects were minimal and self-limiting. Fodor et al. (2006) assessed the efficacy an IPL device (Vasculight, Lumenis, London, UK; filter: 515, 550, or 570nm, fluence: 15–38J/cm2; pulse duration not stated) with telangiectasias leg veins, or cherry angiomas. Patients with telangiectasias, cherry angiomas, or leg veins <1mm were more satisfied after IPL treatment. Retamar, Chames and Pellerano (2004) investigated the effectiveness and safety of an IPL device (515–1200 nm ,The filters employed were 515, 550, 570 and 590 nm, total fluence ranged from 22 to 50 J/cm^2 A single-, double or triple-pulse sequence was administered. Pulse duration ranged from 0.5 -25 ms in the short-pulse mode and up to 30 ms in the long-pulse mode. In the treatment of linear and spider facial telangiectasias in 140 patients. In this study, the response of 94 (67.1%) patients was excellent (80-100%), 43 (30.7%) was good (40–80%) and 3 (2.1%) had poor clearance (40%). Posttreatment side effects were minimal and transient.

	IPL	Laser
Physics	Polychromatic	Monochromatic
	Inconsistence of emitted spectrum and fluence	Reliable dosimetry
	Pulse duration: in ms range	Pulse duration: ns–ms
	Large spot size	Smaller spot size
Practical aspects	High weight of handpiece	Low weight of handpiece
	Restricted maneuverability	Convenient handling
	High skin coverage rate	Low skin coverage rate
	Gel application required[a]	
	Direct contact of handpiece to the skin required[a]	
Economics	Robust technology	Fragile technology
	Lower purchase price	High purchase price
	High versatility	

Source Babilas (2010)

Figure 2.4 Comparison of IPL vs. laser technology

2.2.3.3 Side Effect of Intense pulsed light (Barikbin, Ayatollahi, Hejazi, Saffarian, & Zamani, 2011)

Common complication

1. Pain
2. Transient erythema

Rare complication especially in dark-skinned patients

1. Blister
2. Purpura
3. Crust
4. Dyspigmentation (hypopigmentation, hyperpigmentation)
5. Atrophic scar, hypertrophic scar, keloid
6. Infection

2.2.4 Fractional Photothermolysis

Unlike selective photothermolysis, which produces bulk thermal injury to specific targets in the skin, fractional photothermolysis (Fraxel, Reliant Technologies, Inc., Mountain View, CA) creates hundreds of microthermal treatment zones (MTZs) and sparing the surrounding tissue. Report marked improvement of postinflammatory erythema after the resolution of inflammatory acne vulgaris in two patients after one treatment session with fractional photothermolysis. (Glaich et al., 2007)

Compared with pulsed dye laser, intense pulsed light is said to have two advantages as follows:

1. PDL might be more effective than IPL because Pulsed dye laser has an output wavelength of 585 nm or 595 nm, targeting oxyhemoglobin within red blood cells by approximating a major hemoglobin absorption peak at 577 nm. Treatments may be safely performed on all skin types and over hair-bearing areas without fear of follicular destruction.

2. PDL is safe to use on ethnic skin with minimal postinflammatory hyperpigmentation, even at purpuric settings. Purpura occurs with extravasated red blood cells, indicating immediate vascular photocoagulation. It is advocated as a clinical endpoint of treatment, lasting a maximum of 7–10 days and resolving without sequelae.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Study Design

Randomized split-face controlled trial

3.2 Study Population

Thai patients, ages 18-55 years old, Fitzpatrick skin types III-V, with facial postinflammatory erythema from acne vulgaris.

3.3 Sample

Thai patients, ages 18-55 years old, Fitzpatrick skin types III to V, with postinflammatory erythema from acne vulgaris on both sides of cheeks, who want to treat their postinflammatory erythema from acne vulgaris at Mae Fah Luang University Hospital, Bangkok.

3.4 Sample Size Determination

The sample size was calculated from the formula of one sample, using the ratio of measurement from the previous study (Yoon et al., 2008).

From the formula

$$n = \frac{(Z_{\alpha/2}+Z_{\beta})^2 \, \delta_d{}^2}{d^2}$$

n = sample size

Assign α = 0.05 , $Z_{\alpha/2}$ = 1.96

Asssign β = 0.2 , z_{β} = 0.842

$(Z_{\alpha/2} + Z_{\beta})^2$= 7.851204

$\sigma_d{}^2$ = variance of variable values = $(SD_1+SD_2)^2 / 2$,

SD_1, SD_2, from Yoon et al. (2008)

SD_1, SD_2 = Standard Deviation of population 1 and 2 from postinflammatory erythema lesion count

$\sigma_d{}^2 = (6.9+3.5)^2/2 = 54.08$

d = Effect Side = 5

$$n = \frac{(54.08)(1.96+0.842)^2}{(5)^2}$$

n =16.9837, $n \approx 17$

A drop-out rate of 17% was expected, so twenty patients (n = 20) were recruited.

3.5 Selection Criteria

3.5.1 Inclusion Criteria

3.5.1.1 Healthy Thai patients with postinflammatory erythema from acne vulgaris on both sides of the cheeks

3.5.1.2 Both males and females, ages 18-55, Fitzpatrick skin types III to V

3.5.1.3 All subjects were able to participate in the treatment once a month for the duration of three months and could be followed up at one month after the last treatment.

3.5.1.4 All female of child-bearing potential had an acceptable form of birth control during the study.

3.5.1.5 All subjects were required to sign an informed consent form of benefits, risks and possible complications of the treatment and publication of photographs.

3.5.2 Exclusion Criteria

3.5.2.1 Pregnancy and lactation

3.5.2.2 Medical illnesses such as poorly controlled diabetic mellitus, coagulopathy, photosensitivity, electrical implantation and immunosuppressant

3.5.2.3 History of ablative and non-ablative laser resurfacing within three months before the study

3.5.2.4 History of botulinum toxin or filler injection within six months before the study or permanent implant in the treatment area.

3.5.2.5 History of microdermabrasion and chemical peeling within three months before the study

3.5.2.6 Used of isotretinoin, hormones, prednisolone, antiplatelet and anticoagulant within six months and NSAIDS within one week before the study

3.5.2.7 Active inflammatory skin disease, open wound in the treatment Area

3.5.2.8 History of malignant or premalignant lesions in the treatment area

3.5.2.9 History of herpes simplex and herpes zoster on the face

3.5.3 Discontinuation Criteria

3.5.3.1 Participant wants to discontinuation the program due to any reason.

3.5.3.2 Participant encounters serious complication from the treatment.

3.5.3.3 Participant receives other treatment for postinflammatory erythema from acne vulgaris.

3.5.3.4 Pregnancy, serious illness, and dying

3.5.3.5 Failure in follow up appointment

3.6 Study Location

Mae Fah Luang University Hospital, Bangkok

3.7 Intervention

Half of the patient's face was treated with the pulsed dye laser: 595 nm device (V-beam Pecfecta laser®; Candela Laser Corporation, Wayland, MA, USA) and another half with the intense pulsed light device (Quantum SR®, Lumenis Inc. San Jose, CA). Both devices were approved by US FDA and FDA Thailand.

3.7.1 System Specifications of the pulsed dye laser: 595 nm

LaserType	Pulsed Dye	
Wavelength	595 nm	
Pulse duration	0.45-40 ms	
Spot Sizes (diameter) with maximum energy	3 mm - 40 J/cm^2	12 mm - 7 J/cm^2
	5 mm - 30 J/cm^2	3x10 mm - 25 J/cm^2
	7 mm - 20 J/cm^2	7 mm PL - 15 J/cm^2
	10 mm - 10 J/cm^2	10 mm PL - 10 J/cm^2
Beam Delivery	Lens-coupled 3 m optical fiber with handpiece	
Pulse Control	Finger switch, foot switch	

Optional Dynamic Cooling Device Integrated controls cryogen container and handpiece with distance gauge

Cryogen	HFC 134a
DCD Spray Duration	User adjustable range: 20-100 ms
DCD Delay Duration	User adjustable range: 10-100 ms
DCD Post Spray Duration	User adjustable range: 0-50 ms

Figure 3.1 The Pulsed dye laser: 595nm Device (V-beam Pecfecta laser®)

3.7.2 System Specification of the the intense pulsed light device (Quantum SR®, Lumenis Inc. San Jose, CA)

Light Source	IPL- intense pulsed light
Standard Spectrum	515–1200 nm
Optional Spectra	590–1200 nm, 640–1200 nm
Fluence	15–45 J/cm2
Pulse Duration	6–26 ms
Pulse Delays	5–60 ms

Spot Size	34 x 8 mm
Repetition Rate	0.5 Hz
Integrated Skin Cooler	Yes

Figure 3.2 The Intense pulsed light Device (IPLQuantum SR®, Lumenis Inc.)

3.7.3 Parameter of the Treatment with pulsed dye laser: 595 nm Device (V-beam Pecfecta laser®)

Treatments were performed using the following parameters: wavelength 595 nm, non-overlapping single pulses , spot size 7 mm, pulse duration 10 ms and fluence 9.5–11 J/cm2 x 1 pass (Fluence levels were determined by patient pain tolerance and condition severity such as a higher fluence was used for more severe erythema). All patients received three treatment sessions at 4-week intervals (The energy would be selected and adjusted according to the severity of postinflammatory erythema, reaction of the patient's skin, patient tolerance, and patient's skin types to make the best parameter for each patient and each treatment session.

3.7.4 Parameter of the Treatment with Intense pulsed light Device (IPLQuantum SR®)

3.7.4.1 Spectra: 515–1200 nm.

3.7.4.2 Program 2: Skin type III-IV

Program 3: Skin type IV-V

3.7.4.3 Pulse energy 20 J/-25 J/cm^2 x 1 passes (depending on a patient's background skin pigmentation)

3.7.4.4 Filters: 560-nm, pulse duration 2.4 ms - 4.0 ms, double light pulsed with 20-40 ms interval. Pulse energy and filters would be selected and adjusted according to the severity of postinflammatory erythema, reaction of the patient's skin, patient tolerance, and patient's Fitzpatrick skin types to make the best parameter for each patient and each treatment session.

3.7.4.5 Enough cooling gel was applied immediately before IPL treatment and no Pressure was applied to the handpiece.

3.8 Study Procedures

3.8.1 Generate Randomization Sequence

The researcher generated randomization sequence which randomly determined which side of the patient's face to be treated with the pulsed dye laser and which side with the intense pulsed light. By using "Random Allocation Software" and conceals the sequence in opaque envelopes.

3.8.2 Preparation of Research Subjects

3.8.2.1 Patients were selected to enroll in the study according to the selection criteria.

3.8.2.2 The researcher intensively explained the purpose of the research, process during the study, benefits and possible complications of the treatment.

3.8.2.3 The patients signed an informed consent form for participation in the study.

3.8.2.4 The information of the patient was recorded.

3.8.2.5 The researcher selected the randomization sequence envelop.

3.8.3 Treatment Process

3.8.3.1 Before each treatment, the researcher took a photograph of each patient using VISIA® Complexion Analysis System (Canfield, Fairfield, NJ) of which the following were required:

1. 12 megapixel resolution
2. Automatic focus
3. Automated white balance correction
4. Facial positions: Left 45°, Center 0°, Right 45°
5. Multi-spectral Imaging (standard daylight fluorescent lighting, cross Polarized flash, and ultraviolet lighting)

3.8.3.2 Before each treatment, the researcher were evaluated the erythema indexes of each patient using Mexameter Hb (MX18; Courage+Khazaka Electronic GmbH, Ko¨ ln, Germany) The erythema index was measured on three selected postinflamtory erythema lesions.

Figure 3.3 The probe of Mexameter® (MX18; Courage+Khazaka Electronic GmbH, Ko¨ ln, Germany)

The measurement is based on absorption/reflection. The probe of the Mexameter® MX 18 emits 3 specific light wavelengths. A receiver measures the light reflected by the skin. As the quantity of emitted light is defined, the quantity of light absorbed by the skin can be calculated. The erythema measurement specific wavelengths are corresponding to the spectral absorption peak of haemoglobin and to avoid other colour influences.

3.8.3.3 Before the treatment procedure, the treatment areas were cleansed with a mild soap. The skin was then dried with a non-humid dryer for five to ten minutes, until the skin was completely dry. Apply cooling gel immediately before IPL treatment side.

3.8.3.4 The researcher did the intervention on each side of the patient's cheek according to the prepared randomized sequence. The treatment was done once a month for three months consecutively. The device treating each side of the face was the same in all the three treatment sessions.

3.8.3.5 The researcher evaluated the patients during and post-treatment about their discomfort (tenderness and burning sensation), erythema, and other side effects.

3.8.3.6 After the treatment, the researcher applied cold compression to relieve the patient's burning sensation.

3.8.3.7 After the burning sensation was relieved, the researcher advised the patient to follow the post-treatment care suggestions

1. After treatments, apply sunscreen with SPF 50 (Pharmapure sunblock spf 40) in the morning and wash their face with mild soap (Pharmapure Gentle Skin Cleanser).
2. The researcher advised the patient to avoid exposure to the sun for at least 1-2 weeks after the treatment.

3.8.3.8 The patients were given a "side effect record" sheet to record the side effects of the treatment. If the patients experienced any severe side effects, they had to go to see the researcher before the next treatment session. The researcher would treat the side effects.

3.8.4 Follow Up

4 weeks after the each treatment, there searcher took a photograph of each patient by using VISIA® Complexion Analysis System. The level of erythema was determined by Mexameter®. The erythema index was measured on three selected postinflammatory erythema lesions (same postinflammatory erythema lesions at baseline) at 4 weeks after each treatment. We used these sites at each of the three visits and then calculated the average erythema index.

3.8.5 Outcome Measurement, Data Collection and Analysis

3.9 Outcome Measurement & Data Collection

3.9.1 Clinical Evaluation

3.9.1.1 Two independent dermatologists compared the patients's photographs taken by VISIA® to evaluate the improvement of postinflammatory erythema between before treatment and one month after completing three times treatments using the grading scale : 0 = no improvement, 1= <25% (mild) improvement, 2 = 25-50% (moderate) improvement, 3= 51-75% (good) improvement, 4=>75%(excellent)

3.9.1.2 The patients's photographs taken by VISIA® to evaluate postinflammatory erythema lesion counts from the same two dermatologists between before treatment and 4 weeks after each treatment (at weeks 4, weeks 8, weeks 12 after baseline).

3.9.1.3 Improvement of postinflammatory erythema, evaluated by comparing erythema index scores obtained from Mexameter ®. The erythema index was measured on three selected acne erythema lesions at baseline and 4 weeks after each treatment (at weeks 4, weeks 8, weeks 12 after baseline). We used these sites at each of the three visits and then calculated the average erythema index.

3.9.2 Patient Assessments

3.9.2.1 Patients were asked to evaluate their satisfaction with the treatments between before treatment and one month after completing three times treatments using

using the quartile grading scale: 0= dissatisfied, 1= less satisfied, 2=moderately satisfied, 3= very satisfied, 4= most satisfied

3.9.2.2 The patients were asked to choose the preferred device.

3.9.3 Measurement of Side Effects

The patients were asked to record the following side effects after each treatment

3.9.3.1 Pain score, ranging from no pain (0) to the most pain (10)

3.9.3.2 Duration (days) of purpura

3.9.3.3 Duration (hours) of erythema

3.9.3.4 Duration (hours) of edema

3.9.3.5 Others, such as infection, ulceration, scar formation, postinflammatory hyperpigmentation and hypopigmentation, acneiform eruption

3.10 Data Analysis

Significance levels for all analyses were set at p-value < 0.05.

3.10.1 Effectiveness as Evaluated by Dermatologists

The researcher did the following:

3.10.1.1 Calculated the mean of postinflammatory erythema improvement scores from the same two dermatologists.

3.10.1.2 Calculated the mean of postinflammatory erythema lesion counts from the same two dermatologists (baseline, after 1st treatment, 2nd treatment and 3rdtreatment).

3.10.1.3 Compared the mean of postinflammatory erythema improvement scores of the side of the face treated with the pulsed dye laser: 595 nm devices with the mean of another side treated with the intense pulsed light device after the each treatment. The Wilcoxon Signed Ranks test statistics was employed to analyze possible differences.

3.10.1.4 Compared the mean of postinflammatory erythema lesion counts reduction after completing the treatment of each treatment devices. The paired t-test

statistics was used to evaluate the difference.

3.10.1.5 Compared the mean of postinflammatory erythema lesion counts reduction after completing the treatment between two devices. The paired t-test statistics was used to evaluate the difference.

3.10.2 Erythema index Scores as Evaluated by MEXAMETER®

The researcher did the following:

3.10.2.1 Compared the mean of Erythema index scores before the treatment with the mean of the scores 4 weeks after the treatment of each treatment devices. The paired t-test statistics was used to evaluate the difference.

3.10.2.2 Compared the mean of Erythema index scores reduction after completing the treatment between two devices. The paired t-test statistics was used to evaluate the difference.

3.10.3 Patient Assessments

The researcher did the following:

3.10.3.1 Compared the mean of the satisfaction scores of the side of the face treated with the pulsed dye laser: 595 nm devices with the mean of another side treated with the intense pulsed light device. The paired t-test statistics was used to evaluate the difference.

3.10.3.2 Compared the number of patients preferring each device by Chi-square

3.10.4 Measurement of Side Effects

The researcher compared the means of side effects between end of treatment with the pulsed dye laser: 595 nm device and end of the treatment with the intense pulsed light.

3.10.4.1 Pain score: using paired t-test statistics.

3.10.4.2 Purpura lasting days: using paired t-test statistics.

3.10.4.3 Erythema lasting hours: using paired t-test statistics.

3.10.4.4 Edema lasting hours: using paired t-test statistics

3.10.4.5 Others: used descriptive statistics

CHAPTER 4

RESULTS

4.1 General Characteristics of the Sample

Demographic information

Twenty Thai patients, 2 men (10%) and 18 women (90%), with postinflammatory erythema from acne vulgaris on both sides of cheeks were enrolled in the study. One of the patients was excluded from the study due to the side effect from the treatment which was burn and had postinflammatory hyperpigmentation .

Details of the demographic data were shown in Table 4.1

Table 4.1 Demographic Data

Characteristics	**Data**
Age (years)	**Mean ±SD 26.16±3.63**
	Number of patients
20-30	12
31-40	7

Table 4.1 demonstrates the demographic data of the subjects. The mean age of the subject was 26.16±3.63 years old. Most of the subjects had Fitzpatrick skin type III (14/20), the others were type IV (4/20) and V (2/20).

4.2 The Parameter of Treatment

All of the patients were treated with the same parameter shown in Table 4.2. Each treatment session was done four weeks apart.

Table 4.2 Parameter of Treatment

Treatment Session	Intense pulsed light Device (IPLQuantum SR®)	Pulsed dyelaser:595 nm (V-beam Pecfecta laser®)
1	Pulse energy 20 J/-25 J/cm^2 x 1 passes Filters: 560-nm, pulse duration 2.4 ms - 4.0 ms, double light pulsed with 20-40 ms interval	non-overlapping single pulses , spot size 7 mm, pulse duration 10 ms and fluence 9.5–11 J/cm2 x 1 pass
2	Pulse energy 20 J/-25 J/cm^2 x 1 passes Filters: 560-nm, pulse duration 2.4 ms - 4.0 ms, double light pulsed with 20-40 ms interval	non-overlapping single pulses , spot size 7 mm, pulse duration 10 ms and fluence 9.5–11 J/cm2 x 1 pass
3	Pulse energy 20 J/-25 J/cm^2 x 1 passes Filters: 560-nm, pulse duration 2.4 ms - 4.0 ms, double light pulsed with 20-40 ms interval	non-overlapping single pulses , spot size 7 mm, pulse duration 10 ms and fluence 9.5–11 J/cm2 x 1 pass

4.3 Clinical Evaluation

Among twenty subjects, nineteen patients had completed the three sessions of treatments. One subject was discontinued from the study due to prolonged postinflammatory hyperpigmentation on the side of the face treated with the Intense pulsed light Device after the first session of treatment.

4.3.1 Clinical evaluation by dermatologists

Grading from the two dermatologists calculated to get mean improvement grade after treatment with each device is also shown in Table 4.3.

Table 4.3 Improvement grades after treatment on 12th week evaluated by dermatologists

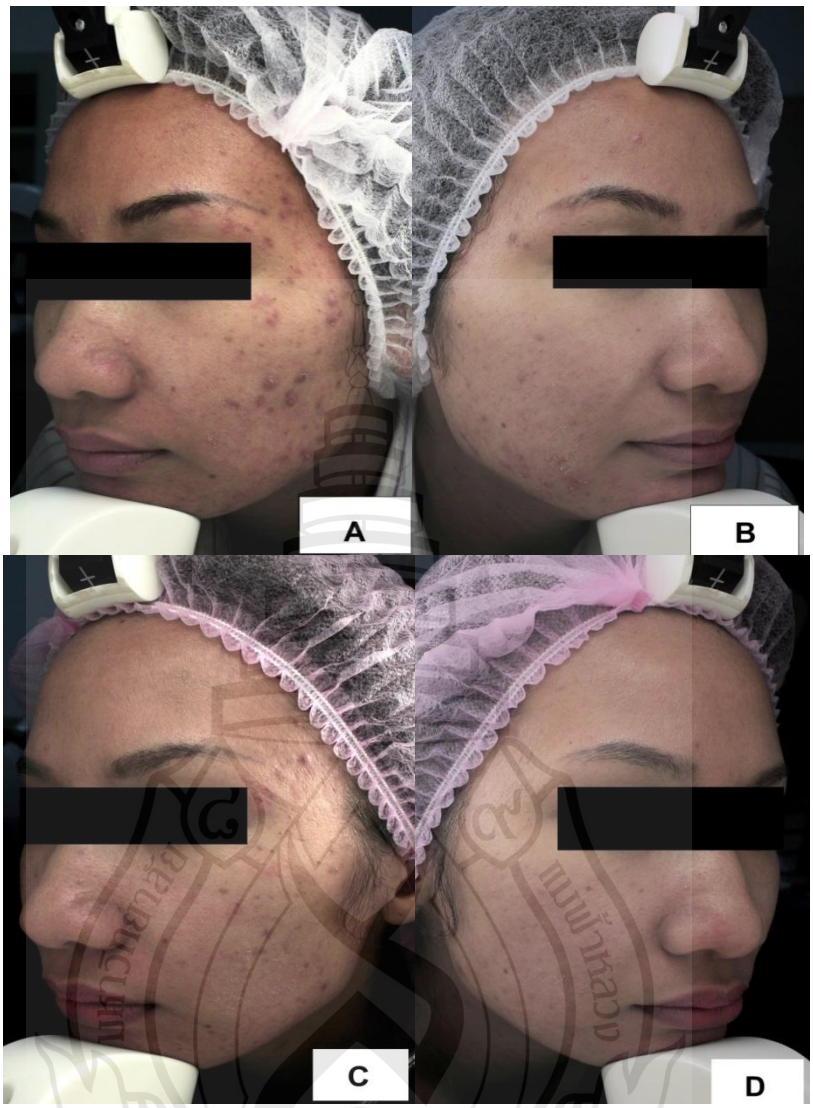
Dermatologist Evaluation Scores							
Number of patient	**Intense pulsed light**			**Number of patient**	**Pulsed dyelaser: 595 nm (V-beam)**		
	Doctor1	**Doctor2**	**Mean**		**Doctor1**	**Doctor2**	**Mean**
1	3	3	3.0	1	3	3	3.0
2	4	4	4.0	2	4	4	4.0
3	2	3	2.5	3	2	2	2.0
4	2	2	2.0	4	3	3	3.0
5	1	1	1.0	5	4	4	4.0
6	2	2	2.0	6	4	4	4.0
7	4	4	4.0	7	4	4	4.0
8	4	4	4.0	8	4	4	4.0
9	1	2	1.5	9	3	3	3.0
10	3	3	3.0	10	2	3	2.5
11	4	4	4.0	11	4	4	4.0
12	2	2	2.0	12	4	4	4.0
13	0	0	0.0	13	0	0	0.0
14	4	4	4.0	14	4	4	4.0
15	2	2	2.0	15	1	2	1.5
16	4	4	4.0	16	4	4	4.0
17	4	4	4.0	17	4	4	4.0
18	2	2	2.0	18	4	3	3.5
19	3	2	2.5	19	4	4	4.0

Table 4.4 Comparison improvement grades between two treatments

	Dermatologist Evaluation Scores (n=19)	
	Intense pulsed light	**Pulsed dyelaser: 595 nm**
Mean ± S.D.	2.71 ± 1.21	3.28 ± 1.11
Median (Min-Max)	2.5 (0-4)	4 (0-4)
P-value	0.027	

P-value compared between 2 groups with Wilcoxon Signed Ranks test, Significant at $p < 0.05$

When comparing the mean of the postinflammatory erythema improvement grade from each device, the mean of improvement grade after treatment with Intense pulsed light device was 2.71 ± 1.21 and the mean of improvement grade after treatment with Pulsed dyelaser: 595 nm device was 3.28 ± 1.11. There was statistical significance in the difference between the mean of improvement grade after treatment with both devices ($p = 0.027$).



Note. (A) before treatment, (C) one month after 3 treatment sessions of the Pulsed dyelaser:595 nm device. (B) before treatment, (D) one month after 3 treatment sessions of the intense pulsed light device

Figure 4.1 Patient with postinflammatory erythema from acne vulgaris on both sides of cheeks.

4.3.2 Reduction of postinflammatory erythema lesion counts

Postinflammatory erythema lesion counts of the patients was evaluated from the same two dermatologists (patients's photographs taken by VISIA®) between before treatment and 4 weeks after each treatment (at weeks 4, weeks 8, weeks 12 after baseline).

Table 4.5 Postinflammatory erythema lesion counts before treatment evaluated by dermatologists

Postinflammatory erythema lesion counts							
Number of patient	**Intense pulsed light**			**Number of patient**	**Pulsed dyelaser: 595 nm (V-beam)**		
	Doctor1	**Doctor2**	**Mean**		**Doctor1**	**Doctor2**	**Mean**
1	13	13	13	1	19	20	19.5
2	32	33	32.5	2	45	46	45.5
3	12	12	12	3	5	5	5
4	18	18	18	4	16	16	16
5	22	23	22.5	5	23	23	23
6	18	18	18	6	17	17	17
7	7	7	7	7	8	8	8
8	54	52	53	8	63	64	63.5
9	37	38	37.5	9	45	44	44.5
10	12	12	12	10	17	17	17
11	13	13	13	11	7	7	7
12	15	15	15	12	25	26	25.5
13	37	35	36	13	20	20	20
14	12	13	12.5	14	15	15	15
15	44	45	44.5	15	29	29	29
16	20	21	20.5	16	10	10	10
17	33	32	32.5	17	36	35	35.5
18	17	19	18	18	30	30	30
19	27	28	27.5	19	29	30	29.5

Table 4.5 shows the Postinflammatory erythema lesion of nineteen patients, evaluated by 2 dermatologists from VISIA Complexion Analysis System, before the treatment.

Table 4.6 Postinflammatory erythema lesion counts at 4th week after treatment treatment evaluated by dermatologists

Postinflammatory erythema lesion counts							
Number of patient	**Intense pulsed light**			**Number of patient**	**Pulsed dyelaser: 595 nm (V-beam)**		
	Doctor1	**Doctor2**	**Mean**		**Doctor1**	**Doctor2**	**Mean**
1	9	9	9	1	10	10	10
2	16	16	16	2	17	17	17
3	8	8	8	3	3	3	3
4	11	11	11	4	11	11	11
5	17	17	17	5	7	7	7
6	11	11	11	6	7	7	7
7	3	3	3	7	3	3	3
8	23	23	23	8	27	28	27.5
9	30	31	30.5	9	19	19	19
10	6	6	6	10	12	12	12
11	6	6	6	11	1	1	1
12	11	11	11	12	8	8	8
13	18	17	17.5	13	18	18	18
14	8	8	8	14	7	7	7
15	14	14	14	15	11	11	11
16	7	7	7	16	3	3	3
17	14	14	14	17	16	16	16
18	14	14	14	18	18	18	18
19	14	13	13.5	19	18	17	17.5

Table 4.6 shows the Postinflammatory erythema lesion of nineteen patients, evaluated by 2 dermatologists from VISIA Complexion Analysis System in period of 4th week after treatment

Table 4.7 Postinflammatory erythema lesion counts at 8th week after treatment treatment evaluated by dermatologists

Postinflammatory erythema lesion counts							
Number of patient	**Intense pulsed light**			**Number of patient**	**Pulsed dyelaser: 595 nm (Vbeam)**		
	Doctor1	**Doctor2**	**Mean**		**Doctor1**	**Doctor2**	**Mean**
1	7	7	7	1	7	7	7
2	7	7	7	2	13	13	13
3	5	5	5	3	4	4	4
4	6	6	6	4	5	5	5
5	18	17	17.5	5	5	5	5
6	10	10	10	6	6	6	6
7	2	2	2	7	1	1	1
8	14	14	14	8	17	16	16.5
9	17	17	17	9	17	17	17
10	4	4	4	10	11	11	11
11	2	2	2	11	1	1	1
12	10	10	10	12	6	6	6
13	30	29	29.5	13	22	23	22.5
14	6	6	6	14	3	3	3
15	26	25	25.5	15	17	17	17
16	3	3	3	16	2	2	2
17	5	5	5	17	8	8	8
18	10	10	10	18	10	10	10
19	9	9	9	19	8	8	8

Table 4.7 shows the Postinflammatory erythema lesion of nineteen patients, evaluated by 2 dermatologists from VISIA Complexion Analysis System in period of 8th week aftertreatment

Table 4.8 Postinflammatory erythema lesion counts at 12th week after treatment treatment evaluated by dermatologists

Postinflammatory erythema lesion counts							
Number of patient	**Intense pulsed light**			**Number of patient**	**Pulsed dyelaser: 595 nm (Vbeam)**		
	Doctor1	**Doctor2**	**Mean**		**Doctor1**	**Doctor2**	**Mean**
1	5	5	5	1	4	4	4
2	3	3	3	2	7	7	7
3	5	5	5	3	3	3	3
4	4	4	4	4	4	4	4
5	15	15	15	5	2	2	2
6	12	12	12	6	4	4	4
7	2	2	2	7	0	0	0
8	7	7	7	8	13	13	13
9	22	21	21.5	9	13	13	13
10	3	3	3	10	7	7	7
11	1	1	1	11	1	1	1
12	9	9	9	12	4	4	4
13	33	31	32	13	33	30	31.5
14	3	3	3	14	2	2	2
15	30	29	29.5	15	9	9	9
16	1	1	1	16	1	1	1
17	2	2	2	17	4	4	4
18	8	8	8	18	5	5	5
19	8	8	8	19	7	7	7

Table 4.8 shows the Postinflammatory erythema lesion of nineteen patients, evaluated by 2 dermatologists from VISIA Complexion Analysis System in period of 12th week after treatment

Table 4.9 Comparison of means and standard deviations of postinflammatory erythema lesion counts between two treatments

Difference from baseline of postinflammatory erythema lesion counts	**Intense pulsed light (n=19)**		**V-beam (n=19)**	
	Mean	**S.D.**	**Mean**	**S.D.**
4th week - Before treatment	-10.82	8.52	-12.87	9.40
8th week - Before treatment	-13.44	9.50	-15.66	11.94
12th week - Before treatment	-14.42	10.80	-17.84	14.03

Tables 4.10 shows the mean reduction of postinflammatory erythema lesion counts after completing treatments representing the improvement of postinflammatory erythema from acne vulgaris. The mean reduction of postinflammatory erythema lesion counts after treatment with Intense pulsed light device was 14.42 ±10.82 and after treatment with Pulsed dyelaser:595 nm (Vbeam) was 17.84±14.03

Table 4.10 Comparison of the mean reduction of postinflammatory erythema lesion counts between the two treatment

Group Comparison (IPL-VB)	**Paired Difference**	**S.D.**	**p-value**
4th week - Before treatment	2.05	8.62	0.295
8th week - Before treatment	2.21	7.35	0.222
12th week - Before treatment	3.42	8.64	0.102

P-value compared between 2 groups with paired t-test and Wilcoxon Signed Ranks test, Significant at $p < 0.05$

Table 4.10 shows comparison of difference of postinflammatory erythema lesion counts from baseline of nineteen patients, evaluated by 2 dermatologists from VISIA Complexion Analysis System before the treatment and 4^{th} week follow up after each treatment session. There was no statistically significant difference in the mean reduction of postinflammatory erythema lesion counts between the two treatment devices (p=0.102)

Table 4.11 Reduction of postinflammatory erythema lesion counts before treatment and after treatment of each session

Groups of comparison	**Postinflammatory erythema lesion counts**	
	Intense pulsed light	**V-beam**
Before treatment - 4^{th} week	< 0.001	< 0.001
Before treatment - 8^{th} week	< 0.001	< 0.001
Before treatment - 12^{th} week	< 0.001	< 0.001

P-value compared between 2 groups with paired t-test and Wilcoxon Signed Ranks test, Significant at $p < 0.05$

Tables 4.11 shows the reduction of postinflammatory erythema lesion counts before treatment and after treatment of each session by both devices with statistical significance ($p = 0.00$)

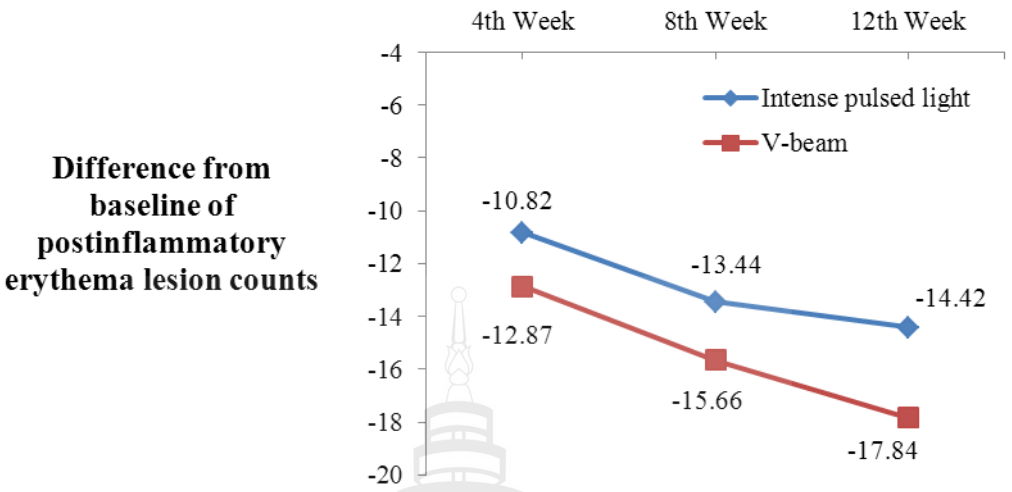


Figure 4.2 Linear graph shows mean changes of difference from baseline of postinflammatory erythema lesion counts in each period between lesions performed intense pulsed light and V-beam

Figure 4.2 presents comparison of difference of postinflammatory erythema lesion counts from baseline before the treatment and 4th week follow up after each treatment session. The reduction of mean postinflammatory erythema lesion counts indicates the improvement postinflammatory erythema lesion.

Table 4.12 Mean Erythema index scores by Mexameter® before treatment

Number of patient	Intense pulsed light				V-beam			
	Lesion1	**Lesion2**	**Lesion3**	**Mean**	**Lesion1**	**Lesion2**	**Lesion3**	**Mean**
1	477.0	404.0	366.0	415.67	451.33	398.0	412.33	420.55
2	440.33	450.0	333.67	408.00	472.0	446.67	417.33	445.33
3	384.0	396.33	392.0	390.78	325.0	357.0	317.67	333.22
4	321.33	351.33	408.33	360.33	480.12	386.0	423.67	429.93
5	392.67	389.33	420.67	400.89	452.0	418.67	383.0	417.89
6	333.0	385.67	298.0	338.89	289.0	345.0	422.0	352.00
7	383.33	385.33	513.33	427.33	363.33	262.0	521.33	382.22
8	397.0	358.0	293.67	349.56	420.67	305.0	253.0	326.22
9	445.33	419.33	382.67	415.78	385.33	390.33	450.0	408.55
10	332.0	393.67	355.0	360.22	356.33	387.67	399.0	381.00
11	332.0	552.33	489.67	458.00	549.33	235.0	456.0	413.44
12	453.33	441.0	582.67	492.33	464.33	371.33	512.67	449.44
13	338.4	492.0	454.0	428.13	389.67	537.33	419.0	448.67
14	361.33	382.67	444.0	396.00	472.0	408.0	389.0	423.00
15	487.33	497.33	536.67	507.11	413.33	437.33	531.33	460.66
16	444.0	463.67	414.33	440.67	450.67	470.67	419.67	447.00
17	375.0	479.67	411.67	422.11	524.0	548.0	542.33	538.11
18	584.67	433.67	368.0	462.11	369.0	425.0	464.0	419.33
19	439.67	445.67	493.33	459.56	450.33	415.33	478.0	447.89

Table 4.13 Mean Erythema index scores by Mexameter® at 4th week after treatment

Number of patient	Intense pulsed light				V-beam			
	Lesion1	**Lesion2**	**Lesion3**	**Mean**	**Lesion1**	**Lesion2**	**Lesion3**	**Mean**
1	435.33	353.67	386.67	391.89	468.0	457.0	418.0	447.67
2	504.33	471.33	406.0	460.55	467.0	406.67	361.33	411.67
3	375.0	278.0	308.0	320.33	292.0	287.33	310.67	296.67
4	402.33	462.67	370.21	411.74	368.67	348.0	422.33	379.67
5	354.67	343.0	437.0	378.22	440.0	408.67	380.0	409.56
6	321.33	361.33	297.0	326.55	285.0	309.33	420.0	338.11
7	363.0	366.33	503.0	410.78	401.0	225.0	515.33	380.44
8	353.0	351.0	255.0	319.67	283.0	257.67	252.0	264.22
9	419.33	362.67	408.0	396.67	372.0	375.0	429.33	392.11
10	454.0	387.0	355.0	398.67	273.33	325.0	306.0	301.44
11	281.67	508.0	484.0	424.56	447.0	221.0	447.0	371.67
12	433.33	452.0	492.0	459.11	446.0	327.67	477.33	417.00
13	412.67	367.0	329.0	369.56	328.33	476.0	403.0	402.44
14	357.0	314.0	409.0	360.00	464.33	383.67	357.67	401.89
15	318.33	444.0	587.33	449.89	428.33	372.33	443.0	414.55
16	352.33	316.67	313.67	327.56	371.67	456.33	414.67	414.22
17	358.0	502.0	572.0	477.33	506.0	480.0	576.0	520.67
18	382.0	430.0	317.33	376.44	360.0	424.0	384.0	389.33
19	385.33	446.33	513.33	448.33	437.0	378.0	443.67	419.56

Table 4.14 Mean Erythema index scores by Mexameter® at 8th week after treatment

Number of patient	Intense pulsed light				V-beam			
	Lesion1	**Lesion2**	**Lesion3**	**Mean**	**Lesion1**	**Lesion2**	**Lesion3**	**Mean**
1	395.0	323.333	333.33	350.55	323.67	323.0	458.0	368.22
2	418.0	440.2	368.0	408.73	365.33	406.67	361.33	377.78
3	367.0	229.67	265.0	287.22	252.0	275.0	278.67	268.56
4	317.67	380.0	361.67	353.11	317.67	340.33	366.67	341.56
5	353.0	350.0	351.0	351.33	435.67	466.0	351.0	417.56
6	312.0	268.33	243.0	274.44	238.0	239.0	407.0	294.67
7	402.0	385.0	454.33	413.78	364.0	208.0	449.67	340.56
8	350.0	315.0	228.0	297.67	272.33	223.33	218.0	237.89
9	361.0	375.0	394.5	376.83	484.0	346.67	336.67	389.11
10	228.0	382.0	316.0	308.67	283.67	309.67	275.67	289.67
11	247.33	487.67	467.0	400.67	406.0	219.0	401.33	342.11
12	345.67	424.33	490.0	420.00	423.0	390.0	419.33	410.78
13	304.0	311.67	323.0	312.89	404.67	379.33	448.67	410.89
14	418.0	312.0	405.0	378.33	440.0	378.0	341.0	386.33
15	466.0	410.33	501.0	459.11	344.33	422.0	321.0	362.44
16	328.0	350.0	289.33	322.44	345.0	389.67	329.67	354.78
17	366.0	430.67	485.0	427.22	359.67	473.33	506.67	446.56
18	367.67	326.67	295.0	329.78	390.0	378.0	380.0	382.67
19	333.0	409.0	513.33	418.44	435.0	360.33	421.33	405.55

Table 4.15 Mean Erythema index scores by Mexameter® at 12th week after treatment

Number of patient	Intense pulsed light				V-beam			
	Lesion1	**Lesion2**	**Lesion3**	**Mean**	**Lesion1**	**Lesion2**	**Lesion3**	**Mean**
1	366.0	257.0	340.67	321.22	334.33	284.33	363.0	327.22
2	401.0	345.33	347.0	364.44	381.0	341.0	349.67	357.22
3	330.33	233.67	261.67	275.22	250.0	275.0	270.33	265.11
4	281.33	406.0	333.67	340.33	337.67	312.0	443.33	364.33
5	351.0	337.0	351.0	346.33	390.0	422.0	434.0	415.33
6	233.33	296.67	233.33	254.44	235.0	233.0	367.33	278.44
7	347.0	350.0	437.0	378.00	340.0	250.0	432.33	340.78
8	315.67	305.67	220.0	280.45	270.0	195.0	188.0	217.67
9	370.0	382.0	402.0	384.67	327.0	363.0	295.0	328.33
10	259.67	258.67	293.0	270.45	251.33	280.33	265.67	265.78
11	208.0	477.0	451.0	378.67	453.0	201.0	336.0	330.00
12	351.67	375.67	415.67	381.00	381.33	350.67	232.0	321.33
13	303.0	426.67	303.0	344.22	311.0	393.67	402.0	368.89
14	352.0	336.0	354.0	347.33	393.67	384.33	372.0	383.33
15	364.0	342.33	408.33	371.55	325.33	329.67	271.0	308.67
16	339.67	315.67	274.0	309.78	289.0	338.33	305.0	310.78
17	269.0	370.0	373.33	337.44	317.0	399.0	428.0	381.33
18	327.62	316.0	275.0	306.21	346.0	373.0	447.0	388.67
19	341.0	423.0	434.0	399.33	361.67	351.0	437.0	383.22

Table 4.16 Comparison of means and standard deviations of mean erythema index between the two treatment

Mean Erythema Index Score	Intense pulsed light (n=19)		V-beam (n=19)	
	Mean	**S.D.**	**Mean**	**S.D.**
Before treatment	417.55	46.36	418.13	49.19
4th week	395.15	50.25	388.05	57.67
8th week	362.70	54.08	359.35	54.79
12th week	336.37	43.40	333.50	51.03
Before -12th week	81.18	36.83	84.63	41.25

Table 4.17 Reduction of mean erythema index score before treatment and after each of treatment session

Groups of comparison	Mean Erythema Index Score		
	Paired Difference	**S.D.**	**P-value**
Intense pulsed light			
Before treatment - 4th week	22.40	46.31	0.049
Before treatment - 8th week	54.55	40.23	< 0.001
Before treatment - 12th week	81.18	36.83	< 0.001
V-beam			
Before treatment - 4th week	30.08	23.37	< 0.001
Before treatment - 8th week	58.78	28.11	< 0.001
Before treatment - 12th week	84.63	41.25	< 0.001

Note. P-value compared between 2 groups with paired t-test, Significant at $p < 0.05$

Table 4.16 and 4.17 shows the mean erythema index of nineteen patients, evaluated from Mexameter®, before the treatment and 4th week follow up after each treatment session. The reduction of mean erythema index between before treatment and 4th week after each treatments session representing the improvement of postinflammatory erythema from acne vulgaris. The reduction of mean erythema index after completing three treatment sessions with Intense pulsed light device was 81.18 ± 36.83 and after treatment with Pulsed dyelaser: 595 nm (Vbeam) was 84.63 ± 41.25. The reduction of mean erythema index after completing treatments by both devices with statistical significance ($p < 0.001$)

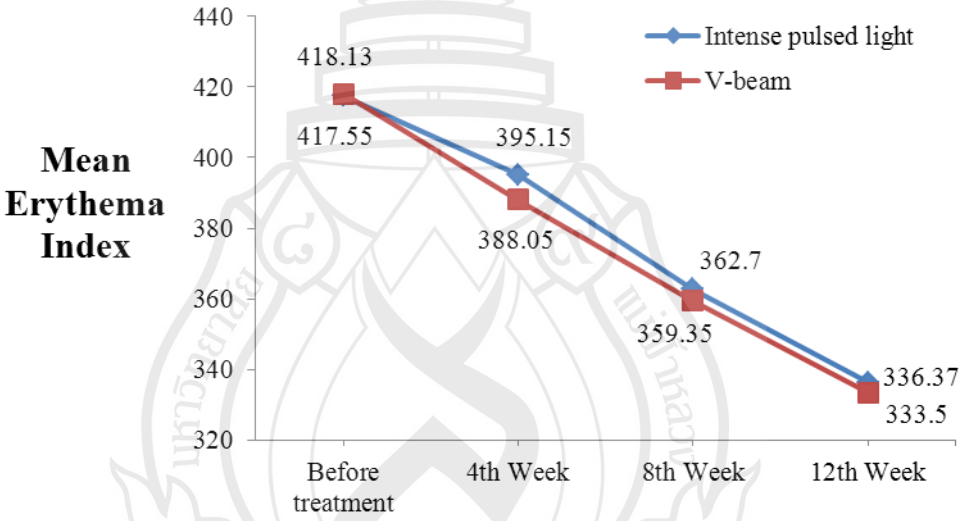


Figure 4.3 Linear graph shows comparison of means erythema index scores in each period between lesions performed intense pulsed light and Pulsed dyelaser: 595 nm (Vbeam)

Figure 4.3 presents the mean erythema index before treatment and 4 weeks after treatment of each session. The reduction of mean erythema index indicates the improvement of postinflammatory erythema from acne vulgaris.

Table 4.18 Comparison of the mean erythema index score between the two treatment

(IPL – V-beam)	Mean Erythema Index Score		
	Paired Difference	**S.D.**	**P-value**
Before treatment	-0.58	44.53	0.955
4th week	7.10	47.00	0.518
8th week	3.35	48.70	0.768
12th week	44.25	2.88	0.780

P-value compared between 2 groups with paired t-test, Significant at $p < 0.05$ Tables 4.18 shows the reduction of mean erythema index between before treatment and 4th week after each treatments session there was no statistically significant difference in the reduction of mean erythema index between the two treatment devices ($p = 0.780$).

4.4 Patient Satisfaction

Table 4.19 Patient satisfaction scores of each patients after treatment on 12th week

Patient Satisfaction Scores					
Number of patient	**Intense pulsed light**	**V-beam**	**Number of patient**	**Intense pulsed light**	**V-beam**
1	4.0	4.0	11	4.0	3.0
2	4.0	4.0	12	3.0	4.0
3	4.0	3.0	13	2.0	2.0
4	2.0	3.0	14	4.0	3.0
5	2.0	4.0	15	3.0	2.0
6	2.0	4.0	16	4.0	4.0
7	4.0	4.0	17	4.0	4.0
8	4.0	4.0	18	3.0	4.0
9	3.0	4.0	19	4.0	3.0
10	3.0	2.0			

Table 4.20 Comparison of patient satisfaction scores between the two treatment

	Patient Satisfaction Scores (Percent) (n=19)	
	Intense pulsed light	**V-beam**
4 = Most satisfied	10 (52.6%)	11 (57.9%)
3 = Very satisfied	5 (26.3%)	5 (26.3%)
2 = Moderately satisfied	4 (21.1%)	3 (15.8%)
1 = Less satisfied	-	-
0 = Dissatisfied	-	-
Mean ± S.D.	3.32 ± 0.82	3.42 ± 0.77
Median (Min-Max)	4 (2-4)	4 (2-4)
P-value	0.614	

Note. P-value compared between 2 groups with Wilcoxon Signed Ranks test, Significant at $p < 0.05$

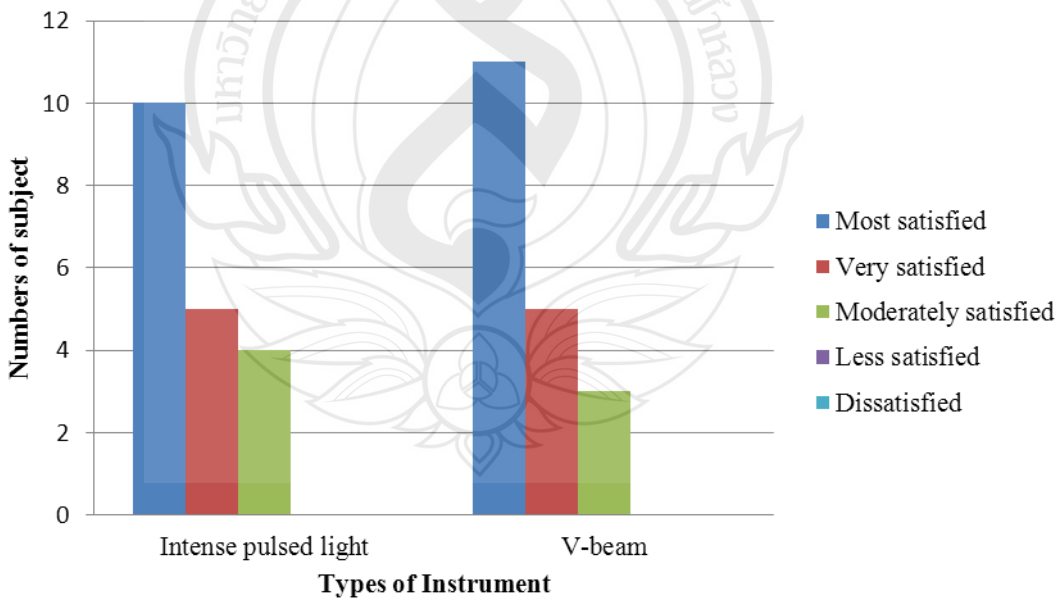


Figure 4.4 Bar chart shows the numbers of subject divided by patient satisfaction score in lesions performed intense pulsed light and V-beam after treatment on 12th week

According to Table 4.20 and Figure 4.4, after being treated with intense pulsed light device, four patients (21.1%) rated their satisfaction as moderately satisfied. Five patients (26.3%) rated as very satisfied. The rest (52.6%) rated as the most satisfied. After being treated with Pulsed dyelaser: 595 nm (Vbeam) device, three patients (15.8%) rated their satisfaction as moderately satisfied. Five patients (26.3%) rated their satisfaction as very satisfied. And the rest (57.9%) rated as the most satisfied. The mean of satisfaction grades of the patients after being treated with intense pulsed light device was 3.32 ± 0.82, and with Pulsed dyelaser: 595 nm(Vbeam) device the mean was 3.42 ± 0.77. There was no statistical significance in the mean difference of improvement grade between the two devices (p = 0.614).

4.5 Preferred Device

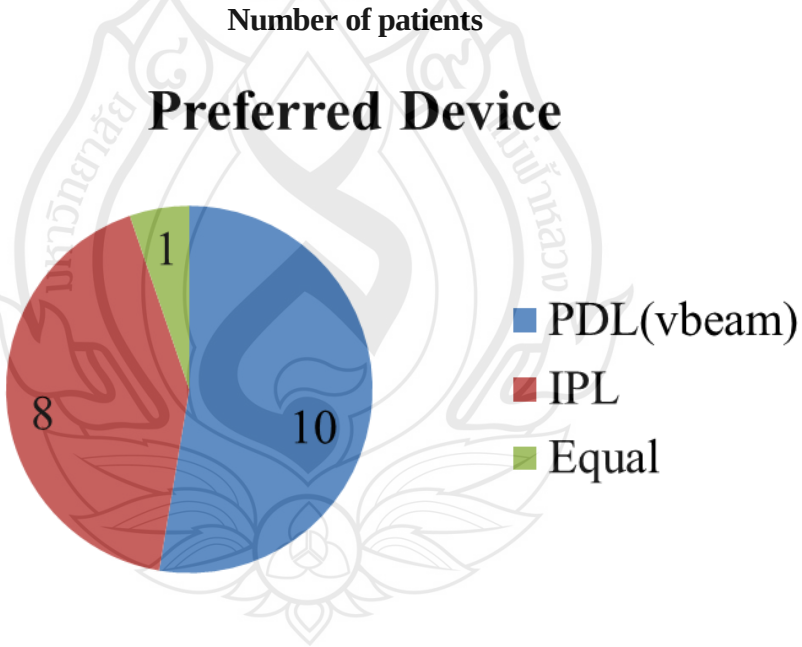


Figure 4.5 Preferred Device

Table 4.21 The number of patients who choose each preferred device

Preferred device	Number of patients
Intense pulsed light	8(42.1%)
Pulsed dyelaser: 595 nm (Vbeam)	10(52.6%)
Equal	1(5.3%)
Total	**19**

P-value compared between 2 groups: intense pulsed light and V-beam with McNemar test for Significance of change, Significant at $p < 0.05$

Based on Figure 4.4 and Table 4.21, eight patients (42.1%) preferred Intense pulsed light device and ten patients (52.6%) preferred Pulsed dyelaser: 595 nm (Vbeam). One patient (5.3%) liked both devices equally. There was no statistical significance in the difference between the numbers of patients who preferred each device ($p = 0.814$).

4.6 Side Effects

Table 4.22 Pain score evaluated by patient after each treatments

Side effects: Pain Scores									
Number of patient	**Intense pulsed light**				**Number of patient**	**V-beam**			
	4th week	**8th week**	**12th week**	**Mean**		**4th week**	**8th week**	**12th week**	**Mean**
1	3	8	7	6	1	5	9	9	7.67
2	6	5	5	5.33	2	7	7	7	7
3	5	4	4	4.33	3	6	5	6	5.67
4	3	2	3	2.67	4	4	4	4	4
5	5	4	3	4	5	8	7	8	7.67
6	7	4	6	5.67	6	6	5	6	5.67
7	6	5	5	5.33	7	7	7	6	6.67
8	6	6	5	5.67	8	5	8	6	6.33

Table 4.22 (continued)

Side effects: Pain Scores									
Number of patient	**Intense pulsed light**				**Number of patient**	**V-beam**			
	4th week	**8th week**	**12th week**	**Mean**		**4th week**	**8th week**	**12th week**	**Mean**
9	0	0	0	0	9	4	4	4	4
10	1	1	0	0.67	10	5	4	4	4.33
11	4	3	4	3.67	11	5	5	5	5
12	1	4	3	2.67	12	4	4	4	4
13	6	5	6	5.67	13	7	8	7	7.33
14	6	7	6	6.33	14	7	8	7	7.33
15	4	8	6	6	15	2	6	6	4.67
16	7.5	5	5	5.83	16	7	8	8	7.67
17	3	8	5	5.33	17	5	8.5	7	6.83
18	2	3	2	2.33	18	7	6	7	6.67
19	6	5	5	5.33	19	7	5	7	6.33

Table 4.23 Time of post-treatment edema evaluated by patient after each treatments

Side effects: Time of post-treatment edema (hr)									
Number of patient	**Intense pulsed light**				**Number of patient**	**V-beam**			
	4th week	**8th week**	**12th week**	**Mean**		**4th week**	**8th week**	**12th week**	**Mean**
1	1	1	0	0.67	1	3	2	3	2.67
2	0	1	1	0.67	2	1	3	4	2.67
3	2	1	2	1.67	3	3	3	3	3
4	3	2	3	2.67	4	3	2	2	2.33
5	1	3	3	2.33	5	3	1	2	2
6	3	3	3	3	6	1	3	2	2
7	2	2	1	1.67	7	2	2	3	2.33

Table 4.23 (continued)

Side effects: Time of post-treatment edema (hr)									
Number of patient	**Intense pulsed light**				**Number of patient**	**V-beam**			
	4th week	**8th week**	**12th week**	**Mean**		**4th week**	**8th week**	**12th week**	**Mean**
8	2	1	2	1.67	8	3	2	3	2.67
9	2	2	1	1.67	9	1	2	3	2
10	1	2	1	1.33	10	3	3	1	2.33
11	1	1	1	1	11	2	3	2	2.33
12	1	0	0	0.33	12	2	3	3	2.67
13	1	2	2	1.67	13	2	1	1	1.33
14	2	3	3	2.67	14	2	3	3	2.67
15	3	1	1	1.67	15	1	3	1	1.67
16	3	3	2	2.67	16	1	2	1	1.33
17	2	2	2	2	17	2	3	3	2.67
18	1	2	2	1.67	18	2	3	3	2.67
19	2	2	2	2	19	3	3	3	3

Table 4.24 Time of post-treatment erythema evaluated by patient after each treatments

Side effects: Time of post-treatment erythema (hr)									
Number of patient	**Intense pulsed light**				**Number of patient**	**V-beam**			
	4th week	**8th week**	**12th week**	**Mean**		**4th week**	**8th week**	**12th week**	**Mean**
1	3	3	2	2.67	1	6	6	6	6
2	4	3	4	3.67	2	5	4	3	4
3	2	3	2	2.33	3	5	3	3	3.67
4	3	5	3	3.67	4	4	3	5	4
5	4	3	3	3.33	5	4	4	4	4
6	3	3	3	3	6	5	6	5	5.33
7	2	2	1	1.67	7	5	6	6	5.67
8	2	3	2	2.33	8	5	6	5	5.33

Table 4.24 (continued)

Side effects: Time of post-treatment erythema (hr)									
Number of patient	**Intense pulsed light**				**Number of patient**	**V-beam**			
	4th week	**8th week**	**12th week**	**Mean**		**4th week**	**8th week**	**12th week**	**Mean**
9	2	4	3	3	9	5	5	3	4.33
10	8	5	6	6.33	10	3	3	4	3.33
11	3	3	3	3	11	5	5	6	5.33
12	4	3	3	3.33	12	6	6	5	5.67
13	6	5	5	5.33	13	3	3	3	3
14	4	5	6	5	14	4	3	3	3.33
15	4	3	4	3.67	15	3	4	3	3.33
16	3	5	4	4	16	3	5	5	4.33
17	4	5	5	4.67	17	5	5	4	4.67
18	3	4	3	3.33	18	3	3	3	3
19	5	4	3	4	19	3	3	3	3

Table 4.25 Comparison of side effects between the two treatment

Side Effects	**IPL (n=19)**	**V-beam (n=19)**	**Paired Difference**	**P-value**
	Mean ± S.D.	**Mean ± S.D.**		
Pain Score	4.36 ± 1.88	6.04 ± 1.34	-1.68 ± 1.39	0.001
Post-treatment edema (hrs.)	1.74 ± 0.73	2.33 ± 0.50	-0.60 ± 1.01	0.025
Post-treatment erythema (hrs.)	3.60 ± 1.13	4.28 ± 1.01	-0.68 ± 1.92	0.138

P-value compared between 2 groups: intense pulsed light and V-beam with Wilcoxon Signed Ranks test or paired t-test, Significant at $p < 0.05$

Based on Table 4.25, the mean of pain scores at the side of the face treated with intense pulsed light device was 4.36 ± 1.88, while at the side treated with pulsed dye laser: 595 nm (Vbeam) device was 6.04 ± 1.34. The pain score after treatment with pulsed dye laser: 595 nm (Vbeam) device was higher than with intense pulsed light

device = 1.68 ± 1.39, with statistical significance ($p < 0.05$). The duration of facial edema after treatment with intense pulsed light device was 1.74 ± 0.73 hrs, and with pulsed dye laser: 595 nm (Vbeam) device was 2.33 ± 0.50 hrs. The duration of facial edema after treatment with pulsed dye laser: 595 nm (Vbeam) device was higher than with intense pulsed light device = 0.60 ± 1.01, with statistical significance ($p < 0.05$) . The duration of facial erythema after treatment with intense pulsed light device was 3.60 ± 1.13 hrs, and with pulsed dye laser: 595 nm (Vbeam) device was 4.28 ± 1.01 hrs. There was no statistical significance in the mean difference between the two devices.There was one case (1/20= 5%) with skin type V who had first degree burn then turn to postinflammatory hyperpigmentation after the first treatment session with intense pulsed light device, at parameter; Filters: 560-nm, fluence 21 mJ/cm2, pulse duration 3.0 ms ,double light pulsed with 20 ms interval, 1 passes. The hyperpigmentation resolved at six weeks after being treated with bleaching agent (combination of 4% hydroquinone, 0.01% fluocinolone acetonide, and 0.05% Tretinoin; Triluma®). The other side of the face which was treated with pulsed dye laser: 595 nm (Vbeam) device did not have this side effect. Purpura was not observed in any patient. However, no other side effects such as infection, ulceration, scar formation were present in any subjects

Table 4.26 Comparison of side effects after each of treatment session

Groups of comparison	**Postinflammatory erythema lesion**	
	Intense pulsed light	**V-beam**
Pain Score (4^{th}, 8^{th} and 12^{th} week)	0.219	0.744
Post-treatment edema (4^{th}, 8^{th} and 12^{th} week)	0.819	0.330
Post-treatment erythema (4^{th}, 8^{th} and 12^{th} week)	0.395	0.567

Note. P-value compared 3 groups with Friedman 2-way ANOVA test, Significant at $p < 0.05$

Based on Table 4.26 shows pain score, duration of facial edema after treatment, duration of facial erythema after treatment was no statistical significance in the mean difference between each session in the same device.

CHAPTER 5

DISCUSSION AND CONCLUSION

Acne vulgaris is one of the most common skin diseases. Most inflammatory acne lesions can result in postinflammatory erythema because blood vessels may become permanently dilated as part of a wound healing response at the sites of focal inflammation. Some acne erythema lesions may improve with time, but the persistent erythema (Yoon et al., 2007). Target of treatment to reduce vascular such as topical vasoconstrict, lasers and light sources that used to reduce the red coloration of postinflammatory erythema include the pulsed dye laser (PDL), the potassium-titanylphosphate (KTP) laser, intense pulsed light (IPL), and the neodymium: yttrium-aluminum-garnet (Nd: YAG) laser. Usually, 3 to 4 or more treatments are required, at approximately 1-month intervals (Rao, 2011). There have been many studies about the efficacy of the pulsed dye laser: 585,595 nm for the treatment postinflammatory erythema (Dierickx et al., 1995; Alster & Mcmeekin, 1996; Yoon et al., 2008), based on the principle of selective photothermolysis ablation of the dilated capillaries. Intense pulsed light (IPL) systems are high-intensity pulsed sources that emit polychromatic light in broad wavelength spectrum. The IPL system acts on the principle of selective photothermolysis and has proved to be useful in treating many vascular lesions.

Superficial red vascular lesions have a high amount of oxyhemoglobin. The wavelength absorption peaks of oxyhemoglobin are: 418, 542 and 577 nm (Railan, Parlette, Uebelhoer, & Rohrer, 2006). IPL can improve postinflammatory erythema from acne vulgaris. One studies (Chang et al., 2007) shows improve postinflammatory erythema from acne vulgaris was observed in IPL groups with minimal down time or purpura. However, no controlled study comparing the efficacy of the pulsed dye laser: 595 nm (Vbeam) with that of the intense pulsed light has been done. This study therefore, was conducted to compare the clinical effectiveness and side effects of the intense pulsed light with those of the pulsed dye laser: 595 nm (Vbeam) for the treatment of

postinflammatory erythema from acne vulgaris in split-faced study. The study population consisted of the patients with Fitzpatrick skin type III-V who have postinflammatory erythema from acne vulgaris both side of cheeks.

The previous study showed that intense pulsed light device and pulsed dye laser: 595 nm (Vbeam) device were effective for treatment of postinflammatory erythema from acne vulgaris. The results of the present study also demonstrated the significant improvements in postinflammatory erythema from acne vulgaris and also decrease the erythema index after the treatment with both intense pulsed light device and pulsed dye laser: 595 nm (Vbeam) device.

Chang et al. (2007) investigated the efficacy of the intense pulsed light quipped with a 530- to750-nm filter (I2PL, Ellipse Flex, DDD, Horsholm, Denmark) in treatment of postinflammatory erythema from acne vulgaris. Topical anesthesia was not used; the energy fluence was 8.0 J/cm2 for skin type III (11 patients) and 7.5 J/cm2 for skin type IV (19 patients) using pulse durations of 2.5 ms and double light pulse with 10-ms interval. Resulting for postinflammatory erythema, 63% was good or excellent (by improvement scoring) on the IPL treated side compared to 33% on the untreated side. The results of colorimeter were compatible with clinical improvement of postinflammatory erythema. No side effects were seen except a few, mild postinflammatory hyperpigmented spots lasting for less than 2 weeks in three patients (10%). Papageorgiou et al. (2008) assessed the efficacy of an IPLdevice (QuantumSR , Lumenis, London, UK; lem=560–1200nm, double pulses of 2.4 and 4.0,5.0,or 6.0ms (depending on the skin type), fluence:24–32J/cm2) for the treatment (four treatments at three-weeks interval) of stage I rosacea (flushing, erythema, and telangiectasia) in34 patients. Photographic assessment showed significant improvement of erythema (46%) and telangiectasias (55%). Side effects were minimal and self-limiting.

In the present study, the researcher used The Quantum SR® (Lumenis Inc. San Jose, CA) applicator is intense pulsed light device for 1 passes at the parameter: Filters: 560 nm, pulse energy 20 J/-25 J/cm^2, pulse duration 2.4 ms - 4.0 ms, double light pulsed with 20-40 ms interval in the first, second and third treatment sessions. The independent dermatologists rated most of the postinflammatory erythema improvement grade as excellent (>75%) moderate (25-50%) and good (50-75%) improvement, some patients were rated as no improvement(0%) and mild (<25%) improvement. The mean of the

postinflammatory erythema improvement grade after treatment with intense pulsed light device (Quantum SR®) was 2.71 ± 1.21 .Ten patients (10/19= 52.6 %) evaluated themselves as most satisfied after treatment complete. The mean reduction of postinflammatory erythema lesion counts and the mean reduction of erythema index after completing the IPL treatments with statistical significance ($p < 0.001$).

Several studies have been conducted on the use of PDL in postinflammatory erythema from acne vulgaris. Alster et al. (1996) investigated the efficacy of the pulsed dye laser (585 nm flashlamp-pumped pulsed dye laser, average fluence, 6.5 J/cm2; range, 6.0 to 7.0 J/cm2; 7 mm spot size) in treating erythematous or hypertrophic acne scarring in twenty-two patients. Erythema measurements were much lower than those obtained at baseline after one or two laser treatments. Yoon et al. (2008) researched the ability of the pulsed dye laser with integrated dynamic cooling device (V-beam laser®; Candela Laser Corporation, Wayland, MA, USA) in treatment postinflammatory erythema from acne vulgaris and Fitzpatrick skin phototypes III–IV in twenty patients. Cryogenic cooling set at 30 ms with a 10-ms delay. Treatments were performed using the following parameters: wavelength 595 nm, spot size 7 mm, pulse duration10 ms and fluence 9.5–11 J/cm^2. Measurement erythema by Mexameter. All patients received two treatment sessions with 4-week intervals. A total of 90% of postinflammatory erythema patients achieved clinical improvements. Lesion counts decreased 24.9% after the first treatment and by 57.6% (versus baseline) after the second treatment. Significant improvements were also seen in erythema indexes after each treatment.

In the present study, the researcher used V-beam laser® (Candela Laser Corporation, Wayland, MA, USA) applicator is pulsed dye laser with the 595 nm wavelength for 1 passes at the parameter : non-overlapping single pulses , spot size 7 mm, pulse duration 10 ms and fluence 9.5–11 J/cm2 first ,second and third treatment session. The two independent dermatologists also rated most of the postinflammatory erythema improvement grade as excellent (>75%) and good (50-75%) improvement, few patients were rated as moderate (25-50%), mild (<25%) and no improvement (0%). The mean of the postinflammatory erythema improvement grade after treatment with pulsed dye laser: 595 nm device (V-beam laser®) was 3.28 ± 1.11. Eleven patients (11/19= 57.9%) evaluated themselves as most satisfied after with the treatment. The mean reduction of

postinflammatory erythema lesion counts and the mean reduction of erythema index after completing the PDL (595nm) treatments with statistical significance ($p < 0.001$).

Although the recent the pulsed dyelaser: 595 nm (Vbeam) was invented to reduce the postinflammatory erythema counts when compared with the intense pulsed light device, the present study found that there was no statistical significance in the difference between both devices in the mean reduction of postinflammatory erythema lesion counts evaluated by two independent dermatologists ($p = 0.102$), the mean of satisfaction ($p = 0.614$), and the mean reduction of erythema index evaluated from Mexameter ® ($p=0.780$), but against assignment by two independent dermatologists when comparing the mean of the postinflammatory erythema improvement grade from each device, the mean of improvement grade after treatment with Pulsed dyelaser: 595 nm device was better than the mean of improvement grade after treatment with intense pulsed light device. There was statistical significance in the difference between the mean of improvement grade after treatment with both devices ($p = 0.027$).

The adverse effects of both treatment devices in the present study were pain, transient facial edema and transient facial erythema. Since this study was the split-faced study, the adverse effects between the two devices can be compared without any influences from various characteristics of the patients, including skin types, and post-treatment care. The statistical significant difference of adverse effects after treatment with the intense pulsed light device and pulsed dyelaser: 595 nm (Vbeam), device were pain scores and the duration of facial edema. The pain score of pulsed dyelaser: 595 nm (Vbeam) device (6.04 ± 1.34) was higher than intense pulsed light device (4.36 ± 1.88) and the durational of facial edema in the pulsed

dyelaser: 595 nm (Vbeam) device (2.33 ± 0.50 hrs) was longer than the intense pulsed light device (1.74 ± 0.73 hrs). In the previous review study of. Tanghetti (2012), the pain score (scale of 0 -10) of the treatment with pulsed dye laser devices ranged from 2 to 8 with an average score of 4.5 ± 1.8 (SD).

In the present study there was one case (1/20 = 5%) with skin type V who had first degree burn then turn to postinflammatory hyperpigmentation after the first treatment session with intense pulsed light device, at parameter; Filters: 560-nm, fluence 21 mJ/cm2, pulse duration 3.0 ms, double light pulsed with 20 ms interval, 1 passes. The hyperpigmentation resolved at six weeks after being treated with bleaching agent

(combination of 4% hydroquinone, 0.01% fluocinolone acetonide, and 0.05% Tretinoin; Triluma®). The other side of the face which was treated with pulsed dye laser: 595 nm (Vbeam) device did not have this side effect. None of the patients reported any lasting post-treatment purpura which was treated with pulsed dye laser: 595 nm (Vbeam) device. In the previous study, Barikbin et al. (2011), reviewed article about the use of intense pulsed light (IPL) for the treatment of vascular lesions, side effects and complication. The main disadvantage of intense pulsed light is the lack of adequate skin cooling that can lead to a higher risk of complications in dark-skinned patients, if not used correctly. Other disadvantages of IPL can included inconsistence of emitted spectrum and fluence, the heavy weight of handpiece, large spot size, light cannot be focused, gel application required (hampers the observation of immediate local response) and direct contact of handpiece to the skin required .Pain and transient erythema are the most complications reported. Other rare complications included: blistering, purpura, crusting, hypopigmentation, hyperpigmentation, atrophia, scarring, hypertrophic scarring, or keloid formation, and infection.

A limitation of this study is that the numbers of patients and controls were relatively small. Further research is required to identify optimum treatment parameters, needed to compare the effectiveness parameter of the device.

In conclusion, both intense pulsed light device (Quantum SR®, Lumenis Inc. San Jose, CA), and the pulsed dye laser: 595 nm device (V-beam laser®; Candela Laser Corporation, Wayland, MA, USA) are safe and effective treatment modality for the treatment of postinflammatory erythema from acne vulgaris in patients with Fitzpatrick Skin Types III to V. Most of the patients were very satisfied with the result of treatment. Both devices have similar effectiveness for postinflammatory erythema from acne vulgaris treatment. Although there were some differences regarding side effects from both devices, they were mild and transient.

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APPENDICES

APPENDIX A

หนังสือยินยอมเข้าร่วมโครงการวิจัย (INFORMED CONSENT FORM)

หนังสือยินยอมเข้าร่วมโครงการวิจัย (Informed Consent Form)

วันที่……เดือน……พ.ศ. ……

ข้าพเจ้า (นาย /นาง /นางสาว)……นามสกุล…….....

อายุ…….ปี อยู่บ้าน/หมู่บ้าน/ คอนโดชื่อ.....

บ้านเลขที่……หมู่ที่…….....ซอย.....ตำบล/แขวง…….....

อำเภอ/เขต.....จังหวัด…….....รหัสไปรษณีย์.....

เบอร์โทรศัพท์.....

ขอทำหนังสือแสดงความยินยอมเข้าร่วมโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่า

1. ข้าพเจ้าได้รับทราบโครงการวิจัยของ แพทย์หญิง เมธารัตน์ ทัศนะเทพประเสริฐ และ อาจารย์ นายแพทย์ ไพศาล รัมณีย์ธร เรื่อง การศึกษาเปรียบเทียบประสิทธิภาพของการใช้เพาส์ดราย เลเซอร์:595 นาโนเมตร เทียบกับแสงความเข้มสูง ในการรักษา รอยแดงจากสิว COMPARISON OF A PULSED DYE LASER: 595 NM AND AN INTENSE PULSED LIGHT FOR THE TREATMENT OF POSTINFLAMMATORY ERYTHEMA FROM ACNE VULGARIS

2. ข้าพเจ้ายินยอมเข้าร่วมโครงการวิจัยนี้ด้วยความสมัครใจ โดยมิได้มีการบังคับ หลอกลวง แต่ประการใด และพร้อมจะให้ความร่วมมือในการวิจัย

3. ข้าพเจ้าได้รับการอธิบายและตอบข้อสงสัยจากผู้วิจัยเกี่ยวกับวัตถุประสงค์การวิจัย วิธีการวิจัย ความปลอดภัย อาการ หรืออันตรายที่อาจเกิดขึ้น รวมทั้งประโยชน์ที่จะได้รับจากการวิจัย โดยละเอียดแล้วตามเอกสารชี้แจงผู้เข้าร่วมการวิจัยแนบท้าย

4. ข้าพเจ้าได้รับการรับรองจากผู้วิจัยว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ จะเปิดเผยได้เฉพาะในรูปแบบของการสรุปผลการวิจัยเท่านั้น นอกเหนือจากจุดประสงค์ทางวิชาการแล้วจะไม่มีการเปิดเผยข้อมูลใดแก่บุคคลภายนอกโครงการวิจัย ยกเว้นได้รับคำสั่งศาลเท่านั้น

5. ข้าพเจ้าได้รับทราบจากผู้วิจัยแล้วว่า หากเกิดอันตรายใดๆ จากการวิจัย ข้าพเจ้าจะได้รับการรักษาพยาบาลจากคณะผู้วิจัยโดยไม่คิดค่าใช้จ่าย ตลอดจนมีสิทธิ์ได้รับค่าทดแทนความพิการที่อาจเกิดขึ้นจากการวิจัยตามสมควร

6. ข้าพเจ้าได้รับทราบว่า ข้าพเจ้ามีสิทธิที่จะถอนตัวออกจากการวิจัยครั้งนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบใดๆ ต่อการรักษาพยาบาลตามสิทธิ์ที่ข้าพเจ้าควรได้รับ

7. ข้าพเจ้าได้รับทราบในการติดต่อกับ แพทย์หญิง เมธารัตน์ ทัศนะเทพประเสริฐ หัวหน้าโครงการวิจัยด้วยหมายเลข 0815828101

8. เมื่อเข้าร่วมการวิจัยแล้ว ข้าพเจ้ามีความมุ่งหมายจะมาตามนัดการรักษา การติดตามผลทั้งหมด 4 ครั้งได้ทุกครั้ง ข้าพเจ้าจะให้ความร่วมมือกับผู้วิจัยด้วยดี และรับทราบว่าหากข้าพเจ้าไม่สามารถทำตามนั้นได้ ข้าพเจ้าไม่ควรจะเข้าร่วมงานวิจัยนี้ตั้งแต่ครั้งแรก

9. แพทย์หญิง เมธารัตน์ ทัศนะเทพประเสริฐ หัวหน้าโครงการวิจัยได้อธิบายเกี่ยวกับรายละเอียดต่างๆของโครงการตลอดจนประโยชน์ของการวิจัยรวมทั้งความเสี่ยงและอันตรายต่างๆที่อาจเกิดขึ้นในการเข้าร่วม โครงการนี้ให้ข้าพเจ้าทราบและตกลงและรับผิดชอบตามคำรับรองในข้อ 5 ทุกประการ

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้แล้ว จึงได้ลงลายมือชื่อไว้เป็นสำคัญ พร้อมกับหัวหน้าโครงการวิจัยและพยาน

ลงชื่อ..... ผู้ยินยอม/ผู้ปกครอง

(.....)

ลงชื่อ..... หัวหน้าโครงการวิจัย

(นางสาว เมธารัตน์ ทัศนะเทพประเสริฐ)

ลงชื่อ..... พยาน

(.....)

ลงชื่อ..... พยาน

(.....)

หมายเหตุ

กรณีผู้ยินยอมตนเข้าร่วมโครงการทำวิจัย ไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือให้ความยินยอมนี้แก่ผู้ยินยอมตนเข้าร่วมโครงการวิจัยฟังจนเข้าใจแล้ว และให้ผู้ยินยอมตนเข้าร่วมโครงการวิจัยลงนาม หรือพิมพ์ลายนิ้วหัวแม่มือรับทราบ ในการให้ความยินยอมดังกล่าวด้วย

ลงชื่อ.....

(นางสาว เมธารัตน์ ทัศนะเทพประเสริฐ)

หัวหน้าโครงการวิจัย

เอกสารคำอธิบาย/คำชี้แจง โครงการวิจัยแก่ผู้เข้าร่วมโครงการ (Information Sheet)

การวิจัยเรื่อง:การศึกษาเปรียบเทียบประสิทธิภาพของการใช้เพาส์ดรายเลเซอร์:595 นาโนเมตร เทียบกับแสงความเข้มสูงไอพีแอล ในการรักษา รอยแดงจากสิว (ข้อมูลทั้งหมดจะถูกปิดเป็นความลับ)

เรียนอาสาสมัครทุกท่าน

ท่านเป็นผู้ได้รับเชิญจากแพทย์ให้เข้าร่วมการศึกษาทางคลินิก เรื่อง การศึกษาเปรียบเทียบประสิทธิภาพของการใช้เพาส์ดรายเลเซอร์:595 นาโนเมตร เทียบกับแสงความเข้มสูงไอพีแอล ในการรักษา รอยแดงจากสิว ซึ่งเครื่องมือทั้งสองประเภทมีชื่อการค้าคือ V-beam Pecfecta laser® และ IPL Quantum SR® ก่อนที่ท่านจะตกลงเข้าร่วมการศึกษาดังกล่าว ขอเรียนให้ท่านทราบถึงข้อมูล ที่มาและรายละเอียดของการวิจัย ดังนี้

ชื่อโครงการ:การศึกษาเปรียบเทียบประสิทธิภาพของการใช้เพาส์ดรายเลเซอร์:595 นาโนเมตร เทียบกับแสงความเข้มสูงไอพีแอล ในการรักษา รอยแดงจากสิว(COMPARISON OF A PULSED DYE LASER :595 NM AND AN INTENSE PULSED LIGHT FOR THE TREATMENT OF POSTINFLAMMATORY ERYTHEMA FROM ACNE VULGARIS)

ผู้รับผิดชอบโครงการวิจัย

1. แพทย์หญิง เมธารัตน์ ทัศนะเทพประเสริฐ
2. อาจารย์ นายแพทย์ ไพศาล รัมณีย์ธร

วัตถุประสงค์การวิจัย

เพื่อศึกษาเปรียบเทียบประสิทธิภาพ ผลข้างเคียง และความพึงพอใจของอาสาสมัคร ของเครื่องเพ้าส์ดรายเลเซอร์:595 นาโนเมตร กับแสงความเข้มสูงไอพีแอล ในการรักษารอยแดงหลังจากสิว

สถานที่ทำวิจัย

โรงพยาบาล มหาวิทยาลัยแม่ฟ้าหลวง กรุงเทพฯ

ประโยชน์ของการวิจัย

1. สามารถนำผลการวิจัยนี้ไปใช้เป็นข้อมูลในการรักษารอยแดงสิว ด้วยเครื่อง เพ้าส์ดรายเลเซอร์: 595 นาโนเมตร และ แสงความเข้มสูงไอพีแอล โดยใช้พารามิเตอร์ที่เหมาะสมเพื่อให้เกิดประโยชน์สูงสุด และเกิดภาวะแทรกซ้อนน้อยที่สุด

2. สามารถใช้เป็นข้อมูลพื้นฐานเพื่ออ้างอิงในการศึกษาวิจัยต่อยอดในอนาคต

เกณฑ์การคัดเลือกเข้ามาศึกษา

1. ผู้หญิงหรือผู้ชายที่มีอายุตั้งแต่ 18-55 ปี สุขภาพแข็งแรงดีและไม่มีปัญหาทางจิต

2. ได้รับการวินิจฉัยจากแพทย์ว่าเป็น รอยแดงจากสิวบริเวณแก้มทั้งสองข้างที่ต้องการรักษา

3. ประเภทผิว (Fitzpatrick's skin type) III-V จากการวินิจฉัยของแพทย์ผู้เชี่ยวชาญทางด้านผิวหนัง

4. สามารถรับเข้าการตรวจติดตามที่ โรงพยาบาลมหาวิทยาลัย แม่ฟ้าหลวง กรุงเทพฯ

5. ยินยอมเข้าร่วมโครงการด้วยความสมัครใจ และลงลายลักษณ์อักษรในใบยินยอมรับการรักษา (Informed consent)

เกณฑ์คัดออกอาสาสมัครเข้าร่วมการศึกษาวิจัย

1. กำลังตั้งครรภ์หรือให้นมบุตร

2. มีประวัติเป็นโรคผิวหนังหรือกำลังเป็นโรคผิวหนังอยู่ เช่น โรคผื่นแพ้ โรคด่างขาว โรคสะเก็ดเงิน ฯลฯ หรือมีรอยสักบริเวณที่ต้องการทำเลเซอร์

3. มีประวัติการทำเลเซอร์ปรับสภาพผิวชนิดมีแผล (ablative), ชนิดมีแผลน้อย (Semi-ablative) ภายใน 3 เดือน

4. มีประวัติการฉีดสารโบทูลินั่ม ท๊อกซิน หรือสารเติมเต็ม ภายใน 6 เดือน หรือ สารเติมเต็มแบบถาวรในบริเวณที่จะทำการรักษา

5. มีประวัติการกรอหน้าหรือลอกหน้าด้วยสารเคมีแบบลึกภายใน 3 เดือน

6. มีประวัติใช้ยาในกลุ่มเรตินอยด์ (retinoid) ภายในระยะเวลา 6 เดือน,ใช้ยาละลายลิ่มเลือดหรือยาต้านการแข็งตัวของเลือดภายในระยะเวลา 6 เดือน

7. มีโรคประจำตัวที่ไวต่อแสง เช่น โรคลูปัส (SLE) โรคลมชัก ฯลฯ และโรคประจำตัวอื่น ๆ เช่น โรคภูมิคุ้มกันทำลายตัวเอง โรคเบาหวานที่ยังควบคุมไม่ได้ ฯลฯ

8. มีประวัติรอยโรคเป็นมะเร็งผิวหนัง หรือเนื้องอกที่มีโอกาสเป็นมะเร็งสูงในบริเวณที่จะทำการรักษา

9. มีประวัติเป็นโรคเริมภายในระยะเวลา 6 เดือน หรือกำลังเป็นอยู่

เกณฑ์การให้อาสาสมัครเลิกจากการศึกษาวิจัย

1. ผู้เข้าร่วมวิจัยต้องการออกจากการวิจัย

2. ผู้เข้าร่วมวิจัยเกิดอาการแทรกซ้อนอย่างรุนแรงจากการรักษา

3. ผู้เข้าร่วมวิจัยได้รับการรักษาอื่นนอกเหนือจากที่ผู้วิจัยจัดให้ระหว่างการวิจัย

4. ตั้งครรภ์ ,มีโรคร้ายแรง หรือ ตายระหว่างการวิจัย

5. ไม่สามารถมาติดตามผลการรักษาได้

ข้อมูลและวิธีการศึกษา

รอยแดงจากสิว (Postinflammatory erythema) เกิดหลังการอักเสบของสิวและมีเส้นเลือดฝอยใต้ผิวหนังขยายตัวซึ่งเป็นส่วนหนึ่งในการหายของแผล จากการตอบสนองต่อการที่มีชั้นหนังกำพร้าบาดเจ็บ รอยแดงจากสิวอาจหายได้เองในบ้างรอยโรคแต่ใช้ระยะเวลาเป็นเดือน ถึงปี โดยผิวหนังด้านบนมีลักษณะเรียบเสมอกับผิวหนังข้างเคียง

การรักษารอยแดงสิวในปัจจุบัน มีหลายวิธีตั้งแต่ ยาทา ,เลเซอร์ ที่มีเส้นเลือดเป็นเป้าหมาย และ แสงความเข้มสูง

เลเซอร์ที่มีเส้นเลือดเป้าหมาย มีความสำคัญในการรักษารอยแดงจากสิว โดยเฉพาะ เพาส์ดรายเลเซอร์: 595 (PULSED DYE LASER: 595 NM) นาโนเมตรซึ่งในหลักการของ Selective photothermolysis คือ การใช้พลังงานเลเซอร์เปลี่ยนเป็นความร้อนให้เส้นเลือดสลาย รอยแดงจากเส้นเลือดขยายจะจางลง ส่วนแสงความเข้มสูง (INTENSE PULSED LIGHT) เป็นแสงความยาวคลื่น ใช้หลักการเดียวกับเลเซอร์ (Selective photothermolysis) และมีช่วงแสง 515-1200 นาโนเมตร ซึ่งสามารถเปลี่ยนพลังงานแสงเป็นพลังงานความร้อนได้เช่นกัน รอยแดงสิวจะจางลงได้เนื่องจากพลังงานความร้อนทำให้เส้นเลือดสลายตัว

การศึกษาของเราเป็นการเปรียบเทียบเครื่องมือ เพาส์ดรายเลเซอร์: 595 นาโนเมตร (PULSED DYE LASER: 595 NM) และแสงความเข้มสูง (INTENSE PULSED LIGHT)

หากท่านมีข้อสงสัยเกี่ยวกับวิธีการศึกษาวิจัย ท่านสามารถสอบถามแพทย์ได้ แพทย์ยินดีตอบคำถามละแจ้งให้ท่านทราบโดยละเอียด

ทางโครงการวิจัยมีข้อมูลแจ้งให้ท่านทราบดังต่อไปนี้ ก่อนที่ท่านจะตกลงเข้าร่วมการศึกษาวิจัยนี้

1. การรักษารอยแดงสิวโดย V-beam Pecfecta laser® และ IPL Quantum SR® โดยปรกติ ทั้งคอรส์ไม่ต่ำกว่า 6000-10000 บาท อ้างอิงตามราคาคลินิกความงามในปัจจุบัน

2. ในโครงการวิจัยนี้ผู้วิจัยไม่ได้รับประโยชน์ เชิงพาณิชย์ กล่าวคือไม่ได้รับค่าแรง เงินเดือน หรือการสนับสนุนเงินทุนจากบริษัท/ห้าง/ร้าน รวมทั้งการตอบแทนในเชิงวัตถุ สิ่งของใดใด

3. เมื่อท่านได้รับการประเมิณจากแพทย์แล้วเหมาะสมแก่การเข้าร่วมการวิจัย ท่านจะได้รับการรักษาโดยเครื่องทั้งสองตัว คือ V-beam Pecfecta laser® และ IPL Quantum SR® โดยแบ่งครึ่งหน้าในการรักษา เครื่องมือทั้งสองตัวต่างมีประสิทธิภาพ ในการรักษารอยแดงจากสิวและผ่านการรับรองจากองค์กรอาหารและยาแล้วว่าเป็นเครื่องมือที่ปลอดภัย

4. ท่านจำเป็นต้องหยุดการรักษารอยแดงสิวด้วยวิธีอื่น และใช้ผลิตภัณฑ์ สบู่ล้างหน้าแบบอ่อนโยนและกันแดด จากผู้วิจัยที่จัดเตรียมไว้ โดยท่านไม่ต้องเสียค่าใช้จ่ายแต่อย่างใด

5. ท่านสามารถมารักษาและติดตามผล ตามที่แพทย์นัดทุกครั้ง จำนวน 4ครั้ง แบ่งเป็นรับการรักษาและประเมิณผิวหน้า ทั้งหมด 3ครั้ง ทุกๆ 4อาทิตย์ และตรวจติดตามผล อีก 1 ครั้ง หลังรับการรักษาครั้งสุดท้าย 4 อาทิตย์

6. คำแนะนำ สำหรับอาสาสมัคร

6.1 หลังการรักษาแต่ละครั้งสามารถใช้ผลิตภัณฑ์ดูแลผิวหน้า ที่ผู้วิจัยมอบให้ ได้แก่ ผลิตภัณฑ์ ทำความสะอาดผิวหน้า เช้า เย็น, ใช้ผลิตภัณฑ์กันแดดทุกเช้า

6.2 งดให้ผิวหน้าถูกแสงแดดในช่วง 1-2 สัปดาห์หลังการรักษาแต่ละครั้ง

7. ท่านจะได้รับการบันทึกผลข้างเคียง ทั้งใบหน้าด้านซ้ายและด้านขวา หากเกิดผลข้างเคียงจากการรักษา ระหว่างการศึกษาวิจัย ให้รีบแจ้งผู้วิจัยทันที ติดต่อแพทย์หญิง เมธารัตน์ ทัศนะเทพประเสริฐที่เบอร์โทร 0815828101 หรือมาพบที่ รพ.มหาวิทยาลัยแม่ฟ้าหลวง กรุงเทพฯ โดยทันที เมื่อผู้วิจัยประเมิณว่าผลข้างเคียงที่เกิดจำเป็นต้องรับการรักษาเพิ่มเติม ท่านจะได้รับการรักษาโดยไม่เสียค่าใช้จ่ายใดๆ

8. ความเสี่ยงหรือผลข้างเคียงที่จะเกิดขึ้นต่ออาสาสมัคร

8.1 ผลข้างเคียงที่มักพบบ่อยหลังจากทำการรักษาด้วยแสงความเข้มสูง (IPL)

1) ความรู้สึกเหมือนถูกหนังยางดีดเบาๆบริเวณที่ทำการรักษา,อุ่นหรือร้อนบริเวณที่ทำการรักษา

2) รอยแดง (erythema) และบวม (edema)

ผลข้างเคียงที่พบได้น้อยหลังจากทำการรักษาด้วยแสงความเข้มสูง (IPL)โดยเฉพาะทำการรักษาในผิวสีเข้ม

1) แสบ มีแผล ถลอก หากเกิดขึ้นจะรักษาด้วยการ ดูแลแผลด้วยยาฆ่าเชื้อแบบทา และ แบบรับประทาน (topical and systemic antibiotics) จนกว่าแผลจะดีขึ้น

2) รอยไหม้ (burn) หากเกิดขึ้นจะรักษาด้วยการดูแลแผลด้วยยาฆ่าเชื้อแบบทา และ แบบรับประทาน (topical and systemic antibiotics) จนกว่าแผลจะดีขึ้น

3) สีผิวไม่สม่ำเสมอ รอยคล้ำ หากเกิดขึ้นจะรักษาด้วยการ ให้ยาทาปรับผิวขาว (whitening agents) จนกว่าสีผิวจะดูสม่ำเสมอ หรือรอยด่างขาว เนื่องจากมีวิธีรักษาที่จำกัด หากเกิดขึ้นจะรักษาด้วยการ ใช้ยาทาที่มีส่วนประกอบของ tar แสงหรือ เลเซอร์

4) แผลผุพอง หากเกิดขึ้นจะรักษาด้วยการดูแลแผลด้วยยาฆ่าเชื้อแบบทา และ แบบรับประทาน (topical and systemic antibiotics) จนกว่าแผลจะดีขึ้น

5) รอยช้ำ (purpura) สามารถหายเองได้ 10-14 วัน

6) แผลเป็นหลุม หากเกิดขึ้นจะรักษาด้วยการทำ subcision หรือใช้เลเซอร์ในการรักษาแผลเป็นจนกว่าจะดีขึ้น หรือแผลเป็นนูนสาเหตุจากรอยไหม้ หากเกิดขึ้นจะรักษาด้วยการฉีดยา triamcinolone เข้าไปในรอยโรค (intralesional triamcinolone)

8.2 ผลข้างเคียงที่มักพบบ่อยหลังจากทำการรักษาด้วยเพาส์ดรายเลเซอร์ (PDL:595 nm)

1) รอยช้ำ (purpura)สามารถหายเองได้ 10-14 วัน

2) รอยแดง (erythema) และบวม (edema) สามารถหายเองได้ 2-5 วัน

ผลข้างเคียงที่พบได้น้อยหลังจากทำการรักษาด้วยเพาส์ดรายเลเซอร์

1) รอยคล้ำ (hyperpigmentation) หากเกิดขึ้นจะรักษาด้วยการ ให้ยาทาปรับผิวขาว (whitening agents) จนกว่าสีผิวจะดูสม่ำเสมอ หรือรอยด่างขาว เนื่องจากมีวิธีรักษาที่จำกัด หากเกิดขึ้นจะรักษาด้วยการ ใช้ยาทาที่มีส่วนประกอบของ tar แสงหรือ เลเซอร์

2) แผลถลอก (abrasion) หากเกิดขึ้นจะรักษาด้วยการ ดูแลแผลด้วยยาฆ่าเชื้อแบบทาและ แบบรับประทาน (topical and systemic antibiotics) จนกว่าแผลจะดีขึ้น

9. หากมีผลข้างเคียงเกิดขึ้นในระหว่างวิจัย แพทย์ผู้ทำวิจัยจะให้การรักษาตามมาตรฐานวิชาชีพแพทย์ โดยไม่เสียค่าใช้จ่ายใดๆ และอาสาสมัครสามารถถอนตัวออกจากโครงการวิจัยได้ตลอดเวลา ถ้าผลข้างเคียงรุนแรงจนไม่สามารถใช้ชีวิตประจำวันได้ แพทย์ผู้ทำวิจัยจะให้ค่าตอบแทนวันละ 500 บาท

10. หลังให้การรักษาแล้ว แพทย์จะให้ใบประเมินผลการรักษากับท่าน กรุณากรอกใบประเมินตามความเป็นจริง เพื่อจะนำข้อมูลไปวิเคราะห์ต่อไป

11. ข้อมูลต่างๆของท่านจะถูกเก็บเป็นความลับ และจะเปิดเผยเฉพาะข้อมูลที่ได้สรุปผลหลังเสร็จสิ้นโครงการวิจัยเท่านั้น

12. การเข้าร่วมโครงการวิจัยนี้เป็นไปโดยสมัครใจ ท่านอาจปฏิเสธที่จะเข้าร่วมหรือถอนตัวจากการศึกษานี้ได้ตลอดเวลา โดยไม่กระทบต่อการดูแลรักษาที่ท่านจะได้รับการแพทย์

ประการสำคัญที่ท่านควรทราบคือ ผลการศึกษานี้ใช้สำหรับวัตถุประสงค์ทางวิชาการเท่านั้น โดยข้อมูลส่วนบุคคลต่างๆจะถูกเก็บไว้เป็นอย่างดีและไม่มีการเผยแพร่สู่สาธารณชน

ขอขอบคุณในความร่วมมือมา ณ ที่นี้

APPENDIX B

RESEARCH RECORD DATA SHEET

แบบบันทึกข้อมูลโครงการวิจัย

การศึกษาเปรียบเทียบประสิทธิภาพของการใช้เพาส์ดรายเลเซอร์ :595นาโนเมตร เทียบกับแสงความเข้มสูงในการรักษารอยแดงสิว

Record number.....

ข้อมูลทั่วไปของผู้ป่วย (Patient demographic information)

เฉพาะเจ้าหน้าที่

1. วัน เดือน ปีที่เก็บข้อมูล..... Date

2. ชื่อ นามสกุล..... Name

3. ที่อยู่..... Address

เบอร์โทรศัพท์.....E-mail..... Tel

4. เพศ ……..1.ชาย .....2. หญิง Sex

5. อายุ .....ปี Age

6. อาชีพ .....1. ข้าราชการ .....2. พนักงานบริษัท Occupation

.....3. แม่บ้าน .....4. นักเรียน/นักศึกษา

.....5. กิจการส่วนตัว .....6. อื่นๆ…….

7. FitzpatrickSkin type ….I,….II,….III,….IV

8. โรคประจำตัว.....มี.....ไม่มี Underlying disease

ถ้ามี ยาที่ทานอยู่..... Drug use

9. ประวัติการทานอาหารเสริม..... Supplement use

10. สูบบุหรี่ หรือไม่ ……สูบ ……ไม่สูบ Smoking

11. ดื่มเครื่องดื่มที่มีแอลกอฮอล์หรือไม่ .....ดื่ม .....ไม่ดื่ม Alcohol drinking

12. ประวัติการรักษาที่เคยได้รับมาก่อน .....1.เคย .....2.ไม่เคย Previous Treatment

ถ้าเคย ชื่อวิธี..... ระยะห่างก่อนมาทำการรักษาครั้งนี้..... If yes: Method and time

Experiment record data sheet

1. Post inflammatory erythema lesion counts evaluation

Patients

name……

Name of evaluator……

	Duration of treatments							
	Baseline		**After 1st treatment (Weeks 4)**		**After 2nd treatment (Weeks 8)**		**After 3rd treatmnent (Weeks 12)**	
	Left	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**
Post								
inflammatory								
erythema								
lesion counts								

2. Clinical post inflammatory erythema improvement grade evaluation

score	**Mean**
0	no improvement
1	<25% (mild) improvement
2	25-50% (moderate) improvement
3	51-75% (good) improvement
4	>75%(excellent)

Patients

name……

Name of evaluator……

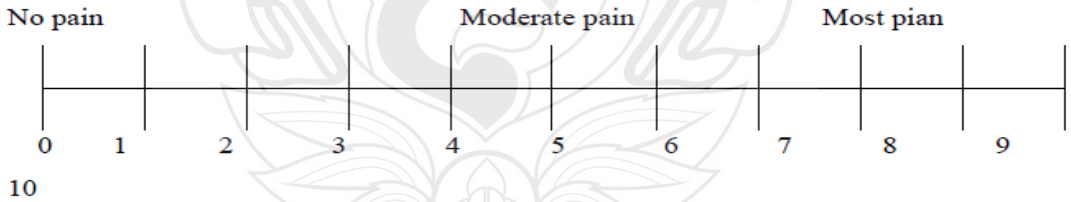
	At weeks 12 (after treatment)	
	Left	**Right**
Post inflammatory erythema improvement score (0 - 4)		

3. Erythema index scores(mean) by mexameter MH 18

	Duration of treatments							
	Baseline		**After 1st treatment (Weeks 4)**		**After 2nd treatment (Weeks 8)**		**After 3rd treatmnent (Weeks 12)**	
	Left	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**
Erythema index (mean)								

4. Pain score during the procedure

Pain score: Please circle by the real data



5. Clinical evaluation by patient

การประเมิณคะแนนพึงพอใจของผู้เข้าร่วมงานวิจัยหลังรับการรักษารอยแดงจากสิว

ชื่อ.....

	dissatisfied น้อยที่สุด (scale=0)	Less satisfied น้อย (scale=1)	moderately satisfied ปานกลาง (scale=2)	very satisfied มาก (scale=3)	most satisfied มากที่สุด (scale=4)
Face's Left side หน้าด้านซ้าย					
Face's Right side หน้าด้านขวา					

Side effect record data sheet

1. การประเมินผลข้างเคียงโดยผู้ป่วย

สัปดาห์ที่……..

….. 1. มี ..... 2. ไม่มี

ผลข้างเคียง	**After 1st treatments**		**After 2nd treatments**		**After 3rd treatments**	
	Left	**Right**	**Left**	**Right**	**Left**	**Right**
แดง (ชม)						
บวม (ชม)						
รอยช้ำ (ชม)						

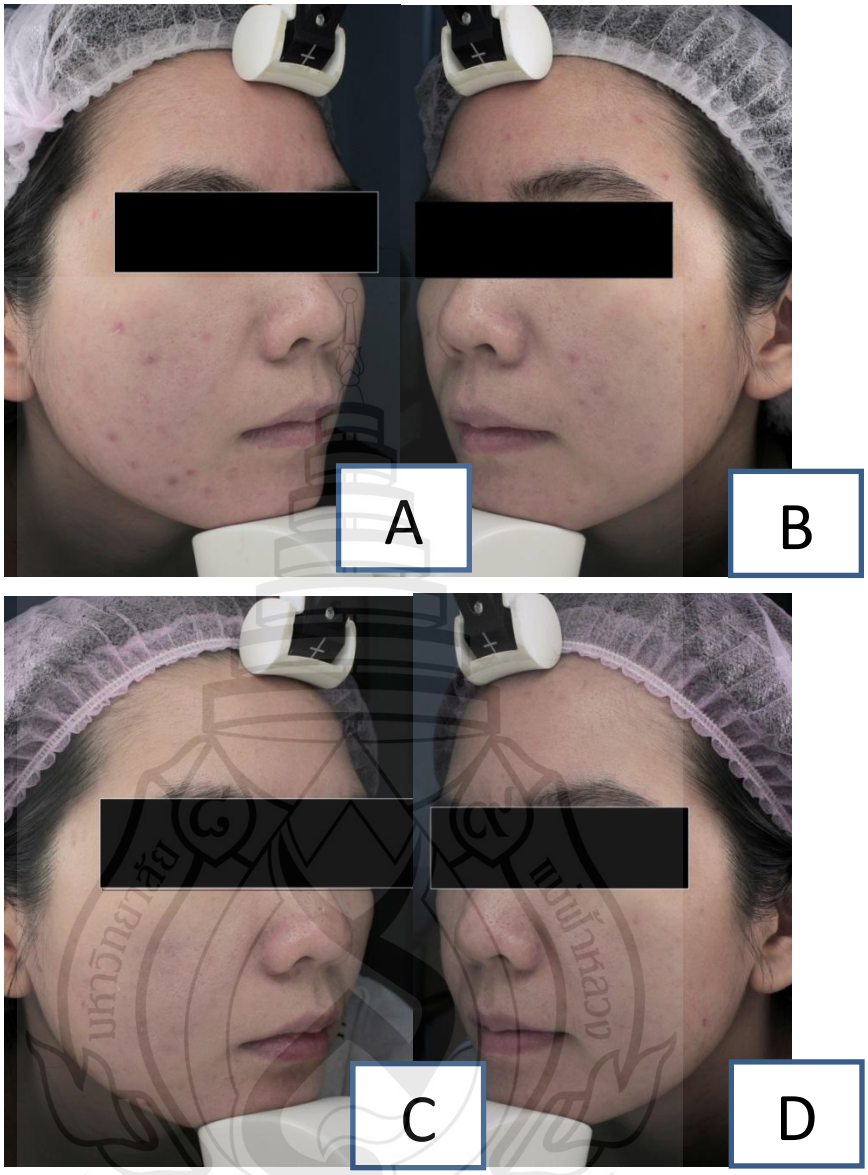


Figure B1 (A) before treatment, (C) one month after 3 treatment sessions of the intense pulsed light device. (B) before treatment, (D) one month after 3 treatment sessions of the pulsed dyelaser:595 nm device

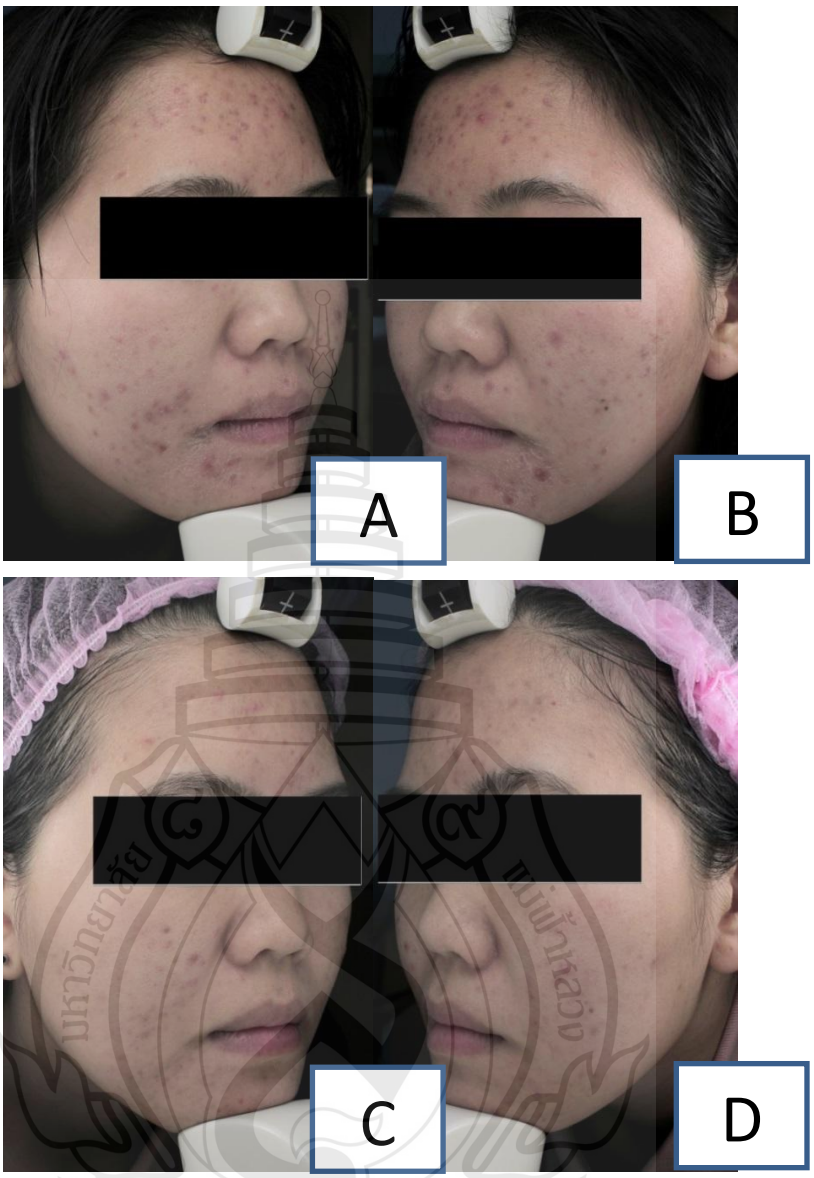


Figure B2 (A) before treatment, (C) one month after 3 treatment sessions of the pulsed dyelaser: 595 nm device. (B) before treatment, (D) one month after 3 treatment sessions of the intense pulsed light device .

CURRICULUM VITAE

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