

Randomized, Investigator-Blinded Study to Compare the Efficacy and Tolerance of a 650-microsecond, 1064-nm YAG Laser to a 308-nm Excimer Laser for the Treatment of Mild to Moderate Psoriasis Vulgaris

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ABSTRACT

Background: Phototherapy is a safe and effective modality for the treatment of mild to moderate psoriasis.

Objectives: To compare the efficacy and safety of the 650-microsecond, 1064-nm pulsed YAG laser with the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs.

Methods: Eligible subjects (n=15) aged 54.3 ± 11.7 years enrolled in a randomized, investigator-blinded study. Psoriatic plaques on one side of the body were treated with the 650-microsecond laser and plaques on the other side were treated with the 308-nm excimer laser. Subjects made up to 15 visits, twice weekly, or fewer if full clearance was achieved. Efficacy and tolerance were evaluated by the mPASI scores and local skin reactions, respectively.

Results: Both devices showed efficacy in treating psoriatic plaques. Differences between the two devices were not significant for redness, thickness, scaliness, mPASI scores for arms and legs, and overall mPASI scores for the treated psoriatic plaques on each side of the body. The investigator-assessed scores for erosion/ulceration, vesicles, erythema, scaling, edema, and atrophy were low and identical for both sides of the body.

Conclusion: The efficacy and tolerance of the 650-microsecond laser is equivalent to that of the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs.

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INTRODUCTION

Current options for the treatment of psoriasis include systemic and topical modalities. Systemic therapies include immune inhibitors, immune modulators and, for moderate to severe disease, biological agents.¹ Primarily, for mild to moderate psoriasis, topical treatments comprise ointments, medicated bath with diastase or herbal extracts, and phototherapy. Phototherapy is safe, effective, and does not incur the side effects of systemic medications.²

The 308-nm excimer laser is considered first-line phototherapy for topical plaque psoriasis.² The efficacy and safety of this laser has been extensively evaluated for the treatment of psoriasis.³⁻⁹ The advantage of the excimer laser is its ability to treat psoriatic lesions with high doses of monochromatic radiation while sparing unaffected skin.² Three protocols have been developed to optimize treatment: the minimal erythema dose, the induration, and the minimal blistering dose.⁷

A novel 650-microsecond 1064-nm Nd: YAG laser was intro-

duced in 2009 by Khatri and colleagues who used the laser to remove unwanted hair.¹⁰ Since then, other investigators have used the 650-microsecond laser to treat skin of color,^{11,12} onychomycosis,¹³ facial telangiectasias,¹⁴ and acne.¹⁵ The advantage of the 650-microsecond laser is that treatment does not require cooling or anesthesia because the pulse duration is shorter than or equal to the thermal relaxation time of the therapeutic target. This feature minimizes scarring, pigmentary changes, thermal damage to surrounding tissues, and discomfort during or after treatment.¹⁵ The 650-microsecond laser has received FDA approval for the treatment of psoriasis.

The primary objective of this study was to compare the ability of the 650-microsecond, 1064-nm pulsed YAG laser (LightPod Neo®, Aerolase Corp., Tarrytown, NY) to clear psoriatic plaques with that of the 308-nm excimer laser (XTRAC Velocity 400®, PhotoMedex, Inc., Montgomeryville, PA). Plaques were located on the limbs of subjects with mild-to-moderate psoriasis vulgaris.

The secondary objective was to compare the tolerance and safety of the two lasers during treatment.

METHODS

Subjects

Eligible subjects (n=15) were healthy and included 11 males and 4 females aged 54.3 ± 11.7 (mean \pm SD) years. Subjects were Caucasian (n = 10), black or African American (n = 5), and Fitzpatrick skin types II through VI (II = 1, III = 4, IV = 5, V = 3, VI = 2).

Inclusion Criteria

Eligible subjects had a clinical diagnosis of mild to moderate plaque psoriasis (psoriasis vulgaris) of at least 6 months duration. The disease involved the limbs, was amenable to phototherapy, and comprised 4 or more psoriatic plaques. The modified Psoriasis Area and Severity Index (mPASI) score was at least 2 and the defined treatment area was confined to only 2% to 30% of the body surface area (BSA). Women of child-bearing potential tested negative for pregnancy, were not breast feeding, and were willing to practice a reliable method of contraception during the study.

Exclusion Criteria

Subjects not eligible for the study had an unstable form of psoriasis (eg, guttate, erythrodermic, pustular); other inflammatory skin disease that could confound the evaluation of psoriasis vulgaris; pigmentation, scarring, pigmented lesions, or sunburn in the treatment area. Other grounds for exclusion were planned prolonged exposure to natural or artificial sunlight; history of hypersensitivity to any component of the test product; history of hypercalcemia, vitamin D toxicity, severe renal insufficiency, or severe hepatic disorder; undergoing systemic treatment with biological therapies 4 to 16 weeks prior to randomization; use of systemic immunosuppressant therapies within 4 weeks prior to Visit 1/baseline and during the trial; use of phototherapy (psoralen + ultraviolet A radiation [PUVA] and ultraviolet B radiation [UVB]) within 4 weeks prior to Visit 1/baseline and during the trial; use of topical treatments (eg, corticosteroids, vitamin D analogs, retinoids, salicylic acid, pimecrolimus, tacrolimus, anthralin, tar) with a possible effect on psoriasis within 2 weeks prior to Visit 1/baseline; clinical signs of skin infection with bacteria, viruses, or fungi; HIV infection; chronic or acute medical condition which, in the opinion of the investigator, may have posed a risk to the safety of the subject, or may have interfered with the assessment of safety or efficacy in the trial; required the use of any concomitant medication, which, in the opinion of the investigator, had the potential to cause an adverse effect when given with the investigational product or would interfere with the interpretation of trial results; initiation of, or expected changes to, concomitant medication that may affect psoriasis; or participation in another clinical trial; or received an investigational product or non-marketed drug substances within 30 days prior to screening.

Study Design

In this investigator-blinded study, psoriatic plaques were randomized to receive one of the two laser treatments. The study was IRB- approved and all subjects provided signed informed consent. Target areas on the right and left sides of the body were thoroughly cleaned before laser therapy with either the 650-microsecond laser on one side or the 308-nm excimer laser on the other side. A non-blinded individual treated each psoriatic plaque according to the randomization scheme. Subjects made up to 15 treatment visits, twice weekly, or fewer if full clearance was achieved. Subjects were photographed at visits shown in the Table 1.

Treatment Parameters

The 650-microsecond laser settings were the following: lens type 5 to 6 mm, energy mode 7 to 8, and pulse width 650 microseconds. Fluence ranged from 24 to 41 J/cm². Each subject received multiple passes per treatment session. For the excimer laser, median dose (fluence) ranged from 0.60 to 0.96 J/cm² and median body surface area treated ranged from 800 to 1410 cm². Multiple passes were not required.

Assessments

The Physician's Global Assessment (PGA) was performed on each subject by the investigator at the screening visit to determine the severity of disease. The investigator also determined the Body Surface Area (BSA) involvement at baseline and the end-of-study visits. Adverse events and concomitant medications were monitored at each visit. Subjects completed the Itch by Numerical Rating Scale (NRS) at visits 2, 5, 8, 11, 14, 16, and 17 and the investigator completed the modified Psoriasis Area and Severity Index (mPASI) and Local Skin Reaction (LSR) with a Visual Analog Scale (VAS) at study visits 2, 5, 8, 11, 14, 16, and 17.

Physician's Global Assessment

The PGA (Table 2) is the investigator's or designee's impression of the disease at a single time point using a defined, 5-point, static scale (clear, almost clear, mild, moderate, or severe). The PGA represents the average lesion severity on the limbs. The assessment is based on the condition of the disease at the time of evaluation (eg, during the baseline visit), and not in relation to the condition at a previous visit.

Body Surface Area (BSA) Involvement

For each subject, the investigator assessed the extent of psoriatic involvement on the limbs at visits specific to the Schedule (Table 1). The total psoriatic involvement on the limbs (excluding genital and intertriginous areas) was recorded as a percentage of the total BSA, assuming that the surface of the subject's full, flat palm (including the five digits) is approximately 1% of the total BSA. This information was used to estimate the area on the limbs to be treated with the lasers.

TABLE 1.

Schedule of Visits, Treatments, and Assessments																	
Procedure	Visit																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Screen	x																
Define Tx area	x	x															
LaserTx		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
PGA	x																
Itch		x			x			x			x			x		x	x
BSA		x															x
mPASI		x			x			x			x			x		x	x
Photography	x	x			x			x			x			x		x	x
LSR (VAS)		x			x			x			x			x		x	x
Adverse events		x			x			x			x			x		x	x
Concomitant medications	x	x			x			x			x			x		x	x

Tx = treatment; PGA = Physicians Global Assessment; BSA = Body Surface Area; mPASI = Modified Psoriasis Area and Severity Index; LSR = local skin reaction; VAS = Visual Analogue Scale.

TABLE 2.

Characteristics of the Physician Global Assessment (PGA) Scores	
Score	Description
0 (clear)	Plaque thickening = no elevation or thickening of normal skin Scaling = no evidence of scaling Erythema = none (no residual red coloration but post-inflammatory hypo or hyperpigmentation may be present)
1 (almost clear)	Plaque thickening = none or possible thickening but difficult to ascertain whether there is a slight elevation above normal skin level Scaling = none or residual surface dryness and scaling Erythema = light pink coloration
2 (mild)	Plaque thickening = slight but definite elevation Scaling = fine thin scales partially or mostly covering lesions Erythema = light red coloration
3 (moderate)	Plaque thickening = moderate elevation with rounded or sloped edges Scaling = coarse scale layer at least partially covering most lesions Erythema = definite red coloration
4 (severe)	Plaque thickening = marked and very marked elevation typically with hard or sharp edges Scaling = non-tenacious or thick tenacious scale predominates, covering most or all of the lesions Erythema = very bright red coloration, extreme red coloration; deep red coloration

TABLE 3.

Scale for the Severity of Psoriatic Lesions			
Score	Redness	Thickness	Scaliness
0 (none)	no erythema	no plaque elevation	no scaling
1 (mild)	faint erythema, pink to very light red	slight, barely perceptible elevation	sparse, fine-scale lesions, only partially covered
2 (moderate)	definite light red erythema	definite elevation but not thick	coarser scales, most of lesions covered
3 (severe)	dark red erythema	definite elevation, thick plaque with sharp edge	entire lesion covered with coarse scales
4 (very severe)	very dark red erythema	very thick plaque with sharp edge	very thick coarse scales, possibly fissured

Modified Psoriasis Area and Severity Index (mPASI)

The severity of the psoriatic lesions on the arms and legs was recorded for redness, thickness, and scaliness (Table 3). For each clinical sign, a single score reflected the average severity of all psoriatic lesions on the arms or the legs.

The extent of psoriatic involvement was recorded for the arms and legs using the following scale:

Parameter	Arms	Legs
Redness	3	1
Thickness	2	1
Scaling	2	1
Subtotal	7	3
Weighting factor	0.2	0.4
Weighted intensity	1.4	1.2
No. of handprints/body region	1	1
Area affected (%)	5	1.2
PASI area score/extent	1	1
Weighted intensity x area score	1.4	1.2
mPASI score	1.4 + 1.2 = 2.6	

Calculation of mPASI score

Redness, thickness, and scaling were all graded according to the scale 0 = none; 1 = mild; 2 = moderate; 3 = severe; 4 = very severe. The weighting factor for the arms was 20% (0.2) and for the legs was 40% (0.4). In all cases the median number of handprints per arm and per leg was 1. The extent of involvement was 0% to 10%, so the area score was 1 in all cases.

An example is shown below.

Average of arms* and legs†	Involvement (%)
0	0
1	< 10
2	10-20
3	30-49
4	50-69
5	70-89
6	90-100

*includes back of hands.

†includes buttocks and top of feet.

Local Skin Reaction (LSR) Assessment With Visual Analog Scale (VAS)

The LSR involved signs assessed by the investigator and symptoms reported by the subject. The investigator assessed the treatment and immediate surrounding areas for perilesional erosion/ulceration, vesicles, erythema, scaling, edema, and atrophy. The most severe intensity of each LSR category was graded according to the scale in Table 4. The subjects assessed burning and pain after application.

Itch by Numerical Rating Scale (NRS)

The intensity of psoriatic itch within the previous 24 hours was graded by the subject according to a 10-point numerical rating scale (NRS) in which 0 = no itch at all and 10 = the worst itch one can imagine.

Statistics

Since much of the data consisted of small whole numbers, data were analyzed using non-parametric statistics with $P=0.05$ as the cutoff value for significance. Differences were evaluated for significance by the Wilcoxon Signed Rank test.

RESULTS

Twelve subjects (80%) completed the study. One subject withdrew because of a change in work schedule that interfered with study visits. Two other subjects were lost to follow-up.

Body Surface Area

The median BSA at baseline ($n=15$) was 2.00, ranging from 2.0 to 4.0. At the end of the study ($n=12$), the median BSA was 2.25 and values ranged from 2.0 to 4.0. The median BSA at the end of study did not differ significantly from baseline.

mPASI Scores

The median mPASI scores of the arms and legs are shown in Tables 5 and 6. Differences between the 650-microsecond and excimer lasers were not significant for redness, thickness, scaliness, mPASI scores for arms and legs, and mPASI scores. Overall mPASI scores for 650-microsecond vs. excimer lasers throughout the study period are shown in the Figure 1. Values decreased rapidly until visit 10 when they leveled off at 1.3 and decreased to 1.2 at the end of the study.

TABLE 4.**Local Skin Reaction Categories (Lesional and Peri-Lesional Areas)**

Score	Erosion/ Ulceration	Vesicles	Erythema	Scaling	Edema	Atrophy (thinning)
0 (absent)	none	none	none	none	none	none
1 (mild)	barely visible	barely visible	barely visible	barely visible	barely palpable	barely visible
2 (moderate)	distinct	distinct	distinct	distinct	easily palpable	distinct
3 (severe)	ulceration	bullae	dark red	coarse	gross	striae

TABLE 6.

The mPASI Parameters and Scores for Legs										
Visit	Redness		Thickness		Scaliness		mPASI		Overall mPASI	
	650-mcs	Excimer	650-mcs	Excimer	650-mcs	Excimer	650-mcs	Excimer	650-mcs	Excimer
(Baseline)	2.0	2.0	2.0	2.0	2.0	2.0	2.4	2.4	2.8	2.8
5	1.5	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.3	2.5
8	1.5	1.5	1.5	2.0	1.5	2.0	2.0	2.2	1.6	1.6
11	1.5	1.5	1.5	2.0	1.0	1.5	1.8	2.0	1.3	1.3
14	1.5	2.0	1.5	2.0	1.5	1.0	2.0	2.0	1.3	1.3
16	1.5	2.0	1.5	2.0	1.5	1.5	2.0	2.0	1.3	1.3
17 (EOS)	1.5	1.0	1.5	1.0	1.5	1.0	1.8	1.6	1.2	1.2
P value	0.650 (ns)		0.3125 (ns)		1.000 (ns)		0.7500 (ns)		1.000 (ns)	

*Wilcoxon signed rank test.

TABLE 5.

The mPASI Median Scores for Arms									
Visit	Redness		Thickness		Scaliness		mPASI		
	650-mcs	Excimer	650-mcs	Excimer	650-mcs	Excimer	650-mcs	Excimer	
(Baseline)	2.0	2.0	2.0	2.0	2.0	2.0	1.2	1.2	
5	2.0	2.0	2.0	2.0	2.0	2.0	1.1	1.0	
8	2.0	1.5	2.0	2.0	2.0	2.0	1.1	1.0	
11	2.0	1.5	2.0	2.0	2.0	2.0	1.0	1.0	
14	2.0	2.0	2.0	2.0	2.0	1.0	1.1	1.0	
16	2.0	1.5	2.0	1.0	2.0	1.0	1.1	0.8	
17 (EOS)	1.5	1.0	1.5	1.5	1.5	1.5	0.9	0.9	
P value*	0.1250 (ns)		1.000 (ns)		0.500 (ns)		0.1250 (ns)		

*Wilcoxon signed rank test.

TABLE 7.

Median Local Skin Reactions (Maximum Value) for the Lesional and Perilesional Areas on Both Sides of the Body								
Visit	Lesional Area		Perilesional Area					
	Erosion/ Ulceration	Vesiculation	Erythema	Scaling	Edema	Atrophy	Vesiculation	Erosion/ Ulceration
Baseline	0.0 (0)	0.0 (0)	0.0 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
5	0.0 (1)	0.0 (0)	0.0 (2)	0.0 (3)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
8	0.0 (2)	0.0 (0)	0.0 (0)	0.0 (3)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
11	0.0 (2)	0.0 (0)	0.0 (2)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
14	0.0 (2)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
16	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)

Local Skin Reactions

Median local skin reactions for the lesional and perilesional areas are shown in Table 7. Since visual inspection revealed that median reaction scores were identical on both sides of the body, values are not separated according to the laser. Median reaction scores were zero for each reaction parameter. Maximum values ranged from 0 to 2 for erosion/ulceration and erythema and from 0 to 3 for scaling. One subject was burned during

treatment with the excimer laser. The subject had erythema and tenderness at the treated lesions.

Although pain during or after treatment was significantly greater for the 650-microsecond laser ($P=0.0002$), no subject withdrew from the study for this reason.

Itch Scores

Median itch scores are shown in Figure 2. Since visual inspection revealed that median values were identical for both lasers, values are not separated according to the laser. Values varied from 2 to 4 during the initial visits and decreased to 2 by the end of the study. The median itch score at the end of the study was significantly lower than the baseline value ($P=0.0156$).

DISCUSSION

The efficacy of the 650-microsecond laser has been shown to be equivalent to that of the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs. Differences were not significant for redness, thickness, scaliness, mPASI scores for arms and legs, and overall mPASI scores. As shown in Figure 1, the median overall mPASI scores for both lasers were identical for all except treatment 4. As expected, the values decreased rapidly until visit 10 when they leveled off at 1.3 and decreased 1.2 at the end of the study.

TABLE 8.

Pain Assessments		
Visit	Pain VAS (Median, IQR)	
	650-mcs	Excimer
Baseline	39.5 (58.4)	0.0 (1.1)
5	59.0 (62.7)	1.0 (3.0)
8	56.0 (46.7)	1.0 (2.2)
11	17.5 (59.5)	2.0 (7.3)
14	74.0 (81.0)	1.5 (6.6)
16	36.5 (77.6)	2.0 (2.0)

VAS = Visual Analog Scale; IQR = interquartile range (75th percentile – 25th percentile).

Tolerance of both laser treatments was excellent as shown by the Table 7 data. Erosion/ulceration and erythema were 1 or 2 and scaling was 3 in some cases. Although pain during and after treatment was greater with the 650-microsecond laser than with the excimer laser (Table 8), this did not discourage any subject from completing the study.

A recent roundtable discussion¹² includes the experience of one author (Dr. Nazanin Saedi) on the use of the 650-microsecond laser for treating plaque psoriasis. The author states, "I've had really good experience with plaque psoriasis patients who have either failed topical therapy, have hard-to-treat areas, or been sick or non-compliant with topicals. We see improvement shortly after initial treatment. For example, I had a woman, skin type II, with it (psoriasis) on the ear. I used the 6-mm spot at level six and four passes. A week after her first treatment there's barely anything left." This preliminary finding agrees with the results of the present study.

The 650-microsecond Nd:YAG 1064nm laser offers unique features not available in other devices. Its 650-microsecond pulse duration causes minimal pain during treatment of skin of color without anesthetic or skin cooling. Since the pulse duration is shorter than the thermal relaxation time of both the skin and blood vessels, the therapeutic target is heated more rapidly than the rate heat is conducted to the surrounding skin, thus reducing damage and lowering the risk of pigmentary alterations.¹⁴ The 650-microsecond laser also delivers energy in a collimated beam, so the operator may vary handpiece-to-skin distance without changing the fluence. This enhances both efficacy and safety during treatment and renders treatment less dependent on operator technique.¹⁶ Clinical examples of the treatment of psoriasis with the 650-microsecond laser are shown in Figures 3 through 5.

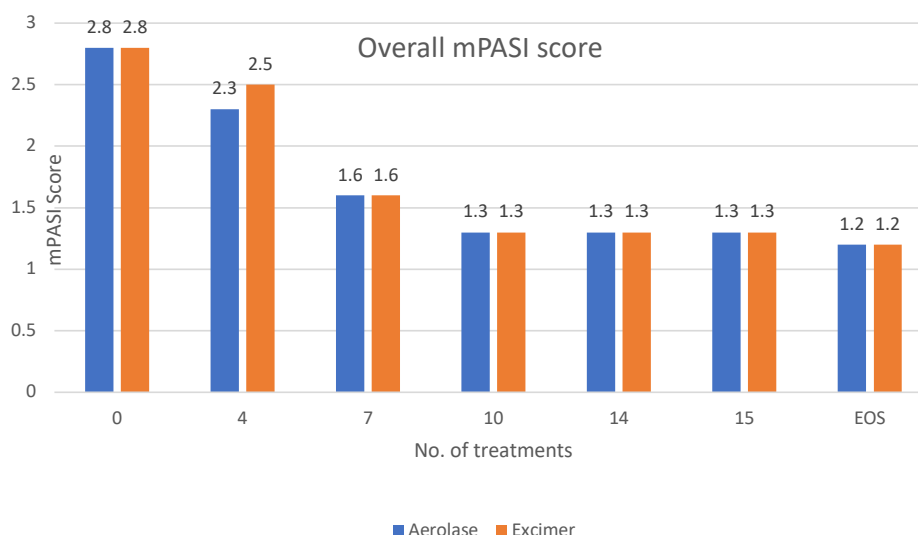
FIGURE 1. Overall mPASI scores for 650-microsecond vs. excimer lasers after the indicated treatments. EOS = end of study.

FIGURE 2. Itch scores (median) by Numerical Rating Scale (0 = no itch; 10 = worst possible itch) at each treatment visit. A trend toward reduction in subject-rated itch with continued treatment is apparent.

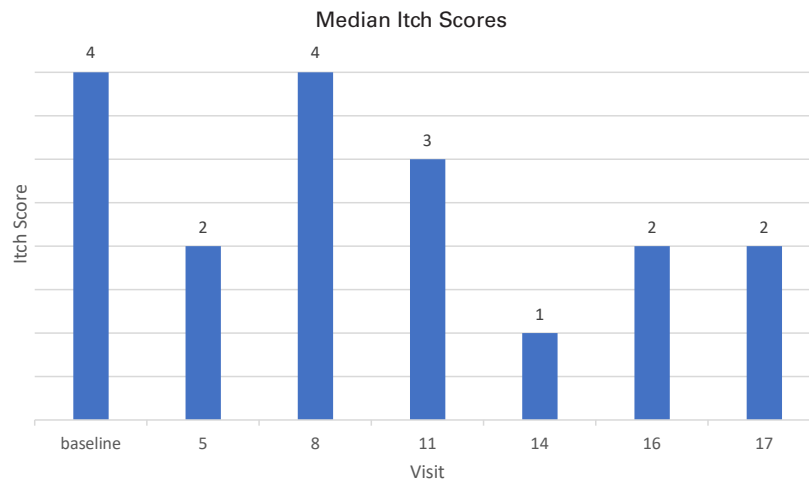


FIGURE 3. Left knee of a 65-year-old black male before (left) and after (right) 15 treatments (24 J/cm², multiple passes) with the 650-microsecond, 1064-nm pulsed YAG laser.

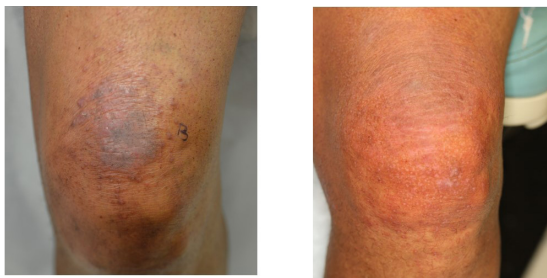


FIGURE 4. Left elbow of a 57-year-old white male before (left) and after (right) 15 treatments (28 J/cm², multiple passes) with the 650-microsecond, 1064-nm pulsed YAG laser.



FIGURE 5. Left hand of a 60-year-old white male before (left) and after (right) 15 treatments (28 J/cm², multiple passes) with the 650-microsecond, 1064-nm pulsed YAG laser.



The strength of the present study is its comparison with the excimer laser, the current first-line phototherapy for the treatment of mild to moderate psoriasis vulgaris. Results are nearly identical throughout the study and treatment-related adverse events were not observed. Limitations are the small number of patients and the short follow-up time. The encouraging results justify additional studies with more patients and longer follow-up time.

CONCLUSION

The efficacy and tolerance of the 650-microsecond laser has been shown to be equivalent to that of the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs.

DISCLOSURES

Dr. Nestor has received research grants from Aerolase and is a consultant to Aerolase. Drs. Fischer and Arnold have no disclosures.

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