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Clinical Outcome of 1064-nm Picosecond Neodymium-Doped Yttrium Aluminium Garnet Laser for the Treatment of Hypertrophic Scars

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ABSTRACT

Background: Currently no study has evaluated the effect of the novel 1064-nm picosecond neodymium-doped:yttrium aluminium garnet laser (ps-Nd:YAG) for reducing Hypertrophic scarring (HS). **Objective:** The aim of this study was to verify the efficacy and safety of a 1064-nm ps-Nd:YAG in the management of HS. **Materials and Methods:** A retrospective chart review and photographic analysis were conducted on patients treated with a low-fluence 1064-nm ps-Nd:YAG for HS improvement. The Vancouver Scar Scale (VSS), 5-point Global Assessment Score (GAS), and patient satisfaction score were used to determine the effect of scar improvement. **Results:** A total of 24 Korean patients (9 males and 15 females; mean age of 33.25 ± 15.50 years) were retrospectively evaluated. Mean treatment settings were 1064-nm wavelength, 750 ps pulse duration, 7.94 mm spot size, 0.93 J/cm^2 fluence, and 9.69 Hz frequency. The average VSS score decreased significantly (from 5.33 to 2.71) after laser treatment ($p < 0.001$). The average GAS (3.02 ± 0.93) showed fair cosmetic improvement, and patient satisfaction scores (6.88 ± 2.66) indicated moderate satisfaction. **Conclusion:** The novel low-fluence 1064-nm ps-Nd:YAG could be considered as an effective and safe optional modality for the treatment of HS in Asian skin.

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hypertrophic scars; laser treatment; neodymium-doped:yttrium aluminium garnet; picosecond

Introduction

Hypertrophic scarring (HS) is a fibroproliferative disorder that occurs during abnormal healing of damaged skin. Common causes of HS include inflammation, trauma, surgical procedures, burns, skin piercing, and vaccination (1,2). Unlike normal scars, HSs show increased collagen synthesis and inflammatory cytokines (including TGF- β expression), and collagen breakdown is reduced by decreased collagenase activity (3). HS often has negative cosmetic and psychosocial impacts on patients, which has been demonstrated in previous studies by the influence of HS on the quality of life (QOL) of affected patients. Therefore, there has been a continuing effort to manage patients with HS in an appropriate way to improve patients' QOL (4,5).

The pathophysiology of keloids and HS has not yet been fully elucidated. In particular, keloids and HS are troublesome conditions in the Asian population. Asians have a genetic susceptibility to HS, and differential susceptible loci expression is associated with keloids and HS in Asians (6,7).

Treatment of HS is a particular challenge to dermatologists. Intralesional corticosteroid injection has been used as a first-line treatment for keloids and HS. However, corticosteroid injection therapy can cause considerable pain for patients. Dermal atrophy, telangiectasia, and other side effects are also problematic. In addition, topical steroids, silicone sheeting, cryotherapy, 5-fluorouracil, bleomycin, mitomycin C, radiation therapy, and surgical excision have been used to revise abnormal scars (8,9).

Laser and light-based therapies have recently been applied to patients with keloids and HS. According to a recently published meta-analysis, pulsed-dye laser (PDL) treatment using the 585-nm or 595-nm wavelength was the most effective in both prevention and treatment of HS (10). However, PDL requires periodic dye replacement. Because this process is expensive, there is a need for other laser equipment to use in patients with HS in Asia. In addition to the PDL, many reports described the clinical efficacy of various laser devices. Ablative lasers such as 10,600-nm carbon dioxide and 2940-nm erbium-doped:YAG, and non-ablative lasers such as 532-nm Nd:Vanadate, 532-nm potassium-titanyl-phosphate (KTP), 980-nm diode, 1064-nm long-pulsed neodymium-doped:yttrium aluminium garnet (Nd:YAG), and 1550-nm fractional erbium-glass laser have been used to prevent and treat HS (8–12).

The therapeutic effect of low-fluence 1064-nm Q-switched (QS) Nd:YAG laser for keloids and HS has been demonstrated in Asian skin (13). The inhibitory effect of the 1064-nm Nd:YAG laser against collagen formation in the dermis has previously been shown (14), and this laser has been successfully applied to keloids in several clinical trials (15–17). A picosecond domain Nd:YAG laser (ps-Nd:YAG) has recently been introduced. Compared to the conventional nanosecond domain QS Nd:YAG laser, the ps-Nd:YAG can produce significantly higher peak powers at the same energy level thereby reducing the photothermal effect while increasing the photo-mechanical effect. For these reasons, ps-Nd:YAG lasers are

expected to have fewer adverse events than the QS Nd:YAG. So far, there is a paucity of clinical data on the ps-Nd:YAG.

We evaluated the efficacy and safety of a novel 1064-nm ps-Nd:YAG laser treatment on patients with HS, and compared results to those treated with the conventional 1064-nm QS Nd:YAG laser.

Materials and methods

Study design

This was a single-center, retrospective, clinical study of the efficacy and safety of a 1064-nm ps-Nd:YAG for treatment of HS in Asian skin. The Institutional Review Board of Kangbuk Samsung Hospital approved this study (approval No.: KBSMC 2017-01-017). A retrospective review was conducted on patients treated with a 1064-nm ps-Nd:YAG for treatment of HS between December 2015 and August 2016. Electronic medical records including patient age, sex, total duration of laser treatment, total number of treatment sessions, laser treatment records, and adverse events were reviewed along with clinical photographs.

Inclusion criteria

This study was conducted on ethnic Korean patients with Fitzpatrick skin type III to V who were diagnosed as having HS. Any patient who received any other treatment on the scar lesion including cryotherapy, intralesional corticosteroid injection, silicone gel sheet, and other laser devices in the three months prior to the trial was excluded. For HS patients other than postoperative HS, patients who did not wish a silicone formulation to be prescribed but only wanted laser treatment alone, and who were actually laser-treated, were enrolled in our study.

Exclusion criteria

Any patient who received any other treatment on the scar lesion including cryotherapy, intralesional corticosteroid injection, silicone gel sheet, and other laser devices in the three months prior to the trial was excluded. Also, patients with grossly visible infection on the affected HS lesion were also excluded.

Laser treatment protocol

Participants were treated with a low-fluence, 1064-nm ps-Nd:YAG laser (PICO⁺4*, Lutronic Co., Ltd, Seoul, Korea) at intervals of several weeks. No topical anesthesia or pre-procedure processes were used. The treatment area included about 1 cm on each side of the scar. Laser fluence was adjusted based on each patient's response to the previous treatment. Laser settings were as follows: fixed pulse duration of 750 ps, 4–8 mm spot size, 0.4–2.0 J/cm², and a 2–10 Hz pulse rate. Appropriate overlapping (approximately 3 to 5 passes) was performed until mild erythema developed in the scar area and surrounding normal skin.

Post-laser care

All patients were instructed not to use silicone gel sheets or topical bleaching agents during the follow-up period. Patients with treated scars located on UV-exposed areas were advised to use a UVA/B sunscreen of SPF 30 or higher.

Photographic analysis

Clinical photographs were taken before each treatment using a handheld digital camera (Canon EOS 750D, Canon Inc., Tokyo, Japan) under the same conditions. Two blinded dermatologists assessed clinical improvement using these photographs.

Efficacy measurements

Clinical assessments were evaluated with two different modalities. First, the Vancouver Scar Scale (VSS) was used to make objective clinical assessments. The VSS is composed of four parameters, including lesion pigmentation (rating 0–2), vascularity (0–3), pliability (0–5), and height (0–3) (18). The score for each parameter was assessed separately and then summed.

Second, the 5-point Global Assessment Score (GAS) was estimated by two blinded dermatologists using clinical photographs taken at each visit. The 5-point GAS consists of the following scales; Excellent: 75–100% lesion clearance, score 5; Good: 50–74% lesion clearance, score 4; Fair: 25–49% lesion clearance, score 3; Poor: <25% lesion clearance, score 2; Worse: results worse than pretreatment status, score 1.

Patient satisfaction

Subjective satisfaction scores (dissatisfied, score 0; somewhat dissatisfied, score 1–4; neutral, score 5; moderately satisfied, score 6–9; and very satisfied, score 10) were assessed with a cellphone survey after treatment.

Safety assessment

All cutaneous adverse events were recorded to assess the safety of the ps-Nd:YAG; these included hyper-/hypopigmentation, erythema, edema, petechia, purpura, and pain.

Statistical analysis

Scores were expressed as averages and ranges. Considering the limited sample size, the Wilcoxon signed-rank test analysis with Statistical Package for the Social Sciences version 11.0 (SPSS Inc., Chicago, IL, USA) was used to compare VSS between pre- and posttreatment states. Statistical significance was defined as $p < 0.05$.

Results

Clinical characteristics of patients

A total of 24 patients were evaluated and photographically reviewed. The participants were composed of 9 men (37.5%)

and 15 women (62.5%), with a mean age of 33.25 ± 15.49 years (range: 6–80). Fitzpatrick skin type was III to V for all patients; 12 patients (50%) were type III, 9 patients (37.5%) were type IV, and 3 patients (12.5%) were type V. In descending order of frequency, causes of HS were postoperative (62.5%), trauma (20.8%), hypertrophic acne (4.1%), chemical burn (4.1%), hidradenitis suppurativa (4.1%), and post-laser (4.1%). The distribution of scars included the face (37.5%), trunk (20.8%), upper extremity (12.5%), and lower extremity (12.5%) (Table 1). In total, scars less than 6 months old accounted for 17 out of 24 patients (70.83%), and the remaining 7 scars had a duration exceeding 6 months (29.17%). The mean duration of the scars was 15.4 months and the average number of months was increased due to the presence of one patient who was treated with 17 years of traumatic mature HS (Table 2).

Picosecond Nd:Yag treatment

All 24 patients were treated with a ps-Nd:YAG at the wavelength of 1064-nm, pulse duration of 750 ps, mean spot size of 7.94 mm (range 4–8 mm), mean fluence of 0.93 J/cm^2 (range $0.4\text{--}2.0 \text{ J/cm}^2$), and mean pulse rate of 9.69 Hz (range 2–10 Hz). The mean number of treatments was 3.29 ± 1.31 (range: 1–7), and mean total duration of treatment was 21.28 ± 15.46 weeks (range: 4–26) (Table 2). The mean interval of laser treatment was 5.77 weeks (range: 3–13 weeks).

Vancouver scar scale

The four-component VSS as described above was measured before and after laser treatment. The mean pre- and posttreatment VSS scores were 5.33 ± 1.37 and 2.71 ± 1.27 , respectively ($p < 0.001$). All four VSS components showed statistically significant improvement when compared before and after treatment. The average percentage change in scores after treatment for the total VSS was 49.2% (Figure 1A). The average percentage change in scores after treatment for each component of the VSS was 57.8% for vascularity, 38.6% for

pigmentation, 56.5% for pliability, and 43.8% for height (Figure 1B). The VSS score representing the sum of the individual component scores significantly decreased after treatment with the 1064-nm ps-Nd:YAG (Figs. 2–4).

Efficacy assessment using the 5-point GAS

Two blinded dermatologists compared the pre- and posttreatment photographs and evaluated them using the 5-point GAS described above. The average GAS (3.02 ± 0.93) showed fair cosmetic improvement. Dermatologist 1 scored excellent in 1 patient (4.2%), good in 6 patients (25%), fair in 13 patients (54.2%), and poor in 4 patients (16.7%). Dermatologist 2 scored excellent in 1 patient (4.2%), good in 7 patients (29.2%), fair in 6 patients (25%), poor in 8 patients (33.3%), and worse progression in 2 patients (8.3%) (Fig. 4). Dermatologist 1 identified 83.3% patients as fair or higher, while dermatologist 2 scored 58.3% patients as fair or higher, with an average of 70.8%.

Patient satisfaction score

The subjective satisfaction with the treatment outcome was 6.88 ± 2.66 using a score of 0–10 points (Table 3). This corresponds to moderate satisfaction. Overall, patients were satisfied with ps-Nd:YAG treatment.

Safety

Anticipated side effects were transient complications such as erythema, petechiae, and purpura. There was mild pain in five patients (20.8%) and mild erythema in one patient (4.2%). However, all transient complications improved spontaneously within a week. There was no persistent or serious adverse events such as aggravation of scars or hyper-/hypopigmentation after ps-Nd:YAG treatment.

Discussion

Various interventions have been applied to prevent and treat HS. The treatments for HS and keloids are somewhat different, and HS has a tendency to respond better to therapy than keloids. Therefore, safer and more effective treatment techniques have been developed for HS reduction. Intralesional injection of triamcinolone acetonide has been used as the first-line treatment for HS since it was reported by Hollander in 1961 (19). However, this treatment requires more than three years and more than 20–30 injections. It can induce local side effects such as atrophy, hypopigmentation, and telangiectasia, and it may cause systemic side effects when used long-term (20). When side effects such as depigmentation are observed in darker skin types, such as Asian skin types, even if the scar appearance improves, patients may report cosmetic dissatisfaction.

Unlike keloids, HS tends to respond well to surgical excision as an initial treatment. Keloids and HS respond differently to surgical excision and laser surgery. A large number of previous studies have verified that the PDL based on the 585-nm or 595-nm wavelengths is effective in preventing and

Table 1. Clinical characteristics of the study population.

Demographic information	Measurement
Gender, <i>n</i> (%)	24 (100)
Male	9 (37.5)
Female	15 (62.5)
Age (years), mean \pm SD	33.25 ± 15.50
Fitzpatrick skin types, <i>n</i> (%)	24 (100)
III	12 (50.0)
IV	9 (37.5)
V	3 (12.5)
Cause, <i>n</i> (%)	24 (100)
Post-operative scar	15 (62.5)
Trauma	5 (20.8)
Acne scar (hypertrophic)	1 (4.1)
Chemical burn	1 (4.1)
Hidradenitis suppurativa	1 (4.1)
Post-laser scar (melanocytic nevus)	1 (4.1)
Scar location, <i>n</i> (%)	24 (100)
Face	9 (37.5)
Neck	4 (16.7)
Trunk	5 (20.8)
Upper extremities	3 (12.5)
Lower extremities	3 (12.5)

Table 2. Overall results of patients treated with the 1064-nm picosecond Nd:YAG laser.

Patient number	Sex	Age	Fitzpatrick skin type	Cause	Scar location	Duration of scar (months)	Total number of treatment sessions	Total duration of the treatment (weeks)	Mean energy fluence (J/cm ²)	Mean GAS	VSS Pre/Post	Patient satisfaction score	Adverse events
1	F	35	IV	Hypertrophic acne scars	Face	6	5	26	0.7	4.5	6/2	9	Mild pain
2	F	43	III	Thyroidectomy (post-operation)	Neck	1	7	24	0.76	3	5/2	9	None
3	F	34	III	Lipoma (post-operation)	Trunk	0.5	4	16	0.85	2	6/4	6	None
4	M	8	IV	Nevus (post-operation)	Chin	72	3	26	1.95	2	5/4	3	None
5	M	34	IV	Epidermal cyst (post-operation)	Shoulder	1	2	9	0.7	3.5	6/3	10	Mild pain
6	M	18	III	Trauma	Cheek	192	3	8	0.7	3.5	5/2	6	None
7	F	32	III	Epidermal cyst (post-operation)	Trunk	0	2	8	1.4	2.5	6/4	7	None
8	M	28	V	Hidradenitis suppurativa	Buttock	7	2	5	1.1	2.5	9/5	5	Mild pain
9	F	21	III	Trauma	Trunk	4	3	9	0.8	3	3/1	9	None
10	F	37	III	Trauma	Shin	12	4	16	1.05	1.5	8/5	7	Mild pain
11	F	41	III	Trauma	Lower leg	24	4	18	1.3	3.5	5/2	8	None
12	F	28	III	Epidermal cyst (post-operation)	Nape	2	5	24	0.82	1.5	4/3	8	None
13	M	47	IV	Hemangioma (post-operation)	Philtrum	1	4	18	1.08	3.5	5/3	8	None
14	M	63	V	Epidermal cyst (post-operation)	Philtrum	1	2	6	0.75	3	4/1	10	None
15	M	39	IV	Epidermal cyst (post-operation)	Cheek	1	4	12	0.88	2.5	5/2	0	None
16	M	39	IV	Thyroidectomy (post-operation)	Neck	3	2	11	0.9	3	5/2	7	None
17	F	31	III	Lipoma (post-operation)	Arm	1	3	8	0.87	3.5	5/2	9	None
18	F	18	III	Chemical burn	Dorsum of foot	1	5	24	1.12	4	4/1	6	None
19	M	31	V	Dermatofibroma (post-operation)	Forehead	1	3	6	0.97	4.5	5/2	5	None
20	F	29	III	Epidermal cyst (post-operation)	Buttock	5	3	8	0.97	2.5	6/4	10	Mild erythema
21	F	80	IV	Basal cell carcinoma (post-operation)	Nose	1	1	4	1	3.5	7/4	1	None
22	F	6	III	Trauma	Chin	3	3	6	0.7	2.5	3/2	9	None
23	F	36	IV	Thyroidectomy (post-operation)	Neck	18	2	5	1.55	4	5/1	6	Mild pain
24	F	20	IV	Melanocytic nevus (post-laser)	Elbow	12	3	8	0.8	3	6/4	7	None

GAS: Global Assessment Scale; VSS: Vancouver Scar Scale.

treating keloid scars (8,9). According to recently published reports, however, HS showed a better response to the long-pulsed 1064-nm Nd:YAG laser than keloids (16,17). Furthermore, the long-pulsed 1064-nm Nd:YAG was found to exceed the efficacy of conventional PDL (17). Keloids tend to become avascular as they mature, resulting in thick hyalinized collagen bundles called keloidal collagen. PDL is thought to have less effect on this structure.

According to the Updated International Clinical Recommendations on Scar Management, the PDL is the most preferred laser for the treatment and prevention of HS, but the fractional laser is also equally recommended. In particular, the fractional laser can be considered as an alternative treatment, if there is no response to PDL treatment in the management of immature and linear HS. Furthermore, in the treatment of wide-spread burn HS, the fractional laser may be preferentially selected as the laser treatment to be recommended (21). Especially in recent years, nonablative and ablative fractional lasers have been

demonstrated to have an efficacy close to that of the PDL in the treatment of early postoperative scars (22,23).

Recently, keloids and HS have been conceptualized as dysfunctions of vascular endothelial cells caused by damage to the reticular dermis and a persistent inflammatory reaction (1,16). Lasers are capable of reducing angiogenesis, continuous inflammation, and abnormally increased collagen tissues of the reticular dermis and may be effective at treating HS in the long term. The long-pulsed 1064-nm Nd:YAG laser penetrates into the reticular dermis and is superior to the PDL, which causes blood vessels to penetrate through the skin at a depth of about 2 mm to the papillary dermis (16,24). If individuals have a history of HS or keloids, early application of appropriate laser treatment after scar formation or trauma may produce good results.

We are particularly interested in the prevention of HS and have published several prospective-controlled studies on this topic. Prophylaxis against HS after thyroidectomy using the

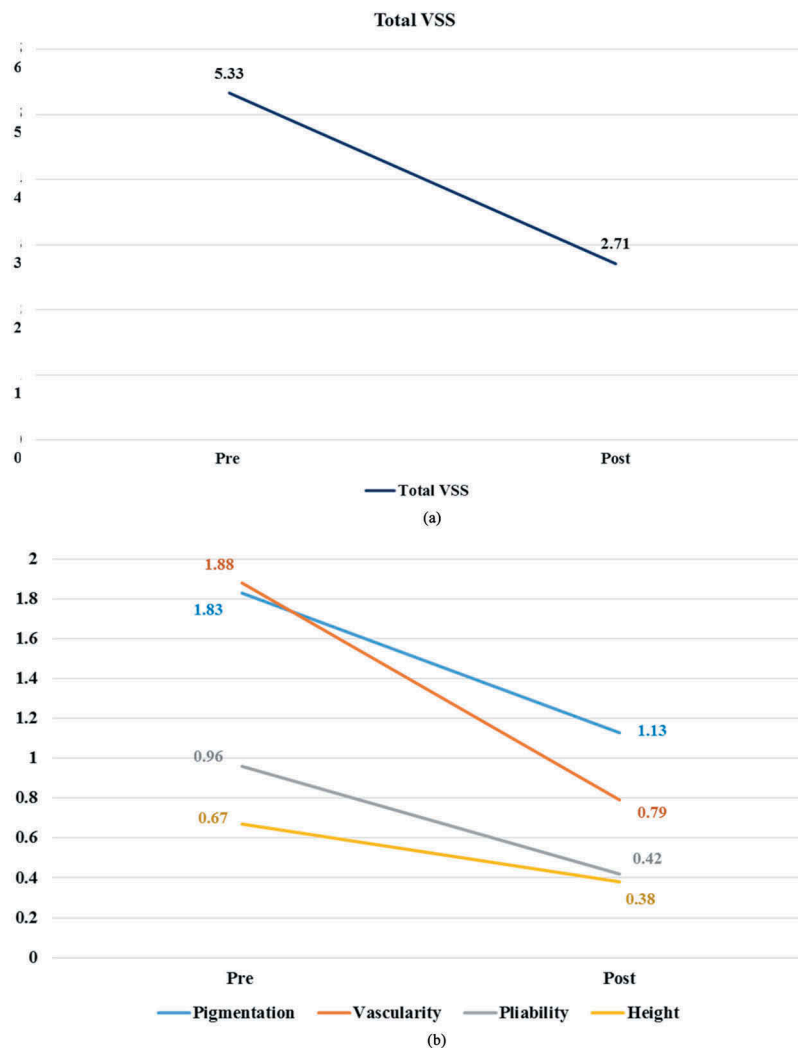


Figure 1. Changes in the Vancouver Scar Scale (VSS) scores. (a) Changes in the total VSS ($p < 0.001$). (b) Changes in each component of VSS.

1550-nm fractional erbium-glass laser was reported in 2009, and a study on the prevention of HS using the 532-nm KTP laser was reported in 2011. In these studies, laser treatments were mainly applied to recent surgical scars in which the sutures had just been removed (11,12). Hence, we emphasize that prevention of early HS is more important than treatment after HS develops.

One intraoperative split-scar study using fractional carbon dioxide laser showed significant improvements in the appearance and texture of surgical scars. Although our previous studies have begun to initiate scar prevention on the suture removal day, there has been an attempt to more aggressively minimize scarring by intraoperative wound edge ablation (25,26).

The QS 1064-nm Nd:YAG laser is mainly used to clear nevus of Ota, melasma, café-au-lait macules, and tattoo pigments in Asian skin. This device is used in a variety of pigmentary disorders because of its short downtime, reasonable price, minimal pain that does not require anesthetic cream, and few adverse events. Although there are not yet established principles for the prevention and treatment of HS, a variety of vascular lasers (e.g., PDL, 532-nm KTP, and long-pulsed 1064-nm Nd:YAG) have

been used for the early stage of scarring, as has 830-nm light-emitting diode low-level light therapy (27). The formation of new blood vessels plays an essential role in the production of collagen fibers and other extracellular matrices, primarily in the formation of HS (28). The 1064-nm wavelength has deep penetration ability and is reasonably well absorbed in both oxyhemoglobin and water. It can cause coagulation necrosis of vessels in the dermis and induce photothermal effects, leading to collagen breakdown. Melanosome absorption at 1064-nm also contributes to the treatment. HS treatment with the QS 1064-nm Nd:YAG laser involves clearance of dermal pigmentation without significant epidermal damage, coagulation necrosis of dermal capillaries by selective photothermolysis, laser heating-induced dermal remodeling, and collagen breakdown by repetitive microscopic damage (13,16,17,29).

The recently introduced 1064-nm ps-Nd:YAG laser provides a rationale to support these hypotheses. About 20 years ago, Ross et al. confirmed that a very short laser pulse in the picosecond domain was more efficient than longer pulse nanosecond domain counterparts in tattoo pigment clearance (30). To date, the efficacy and safety of

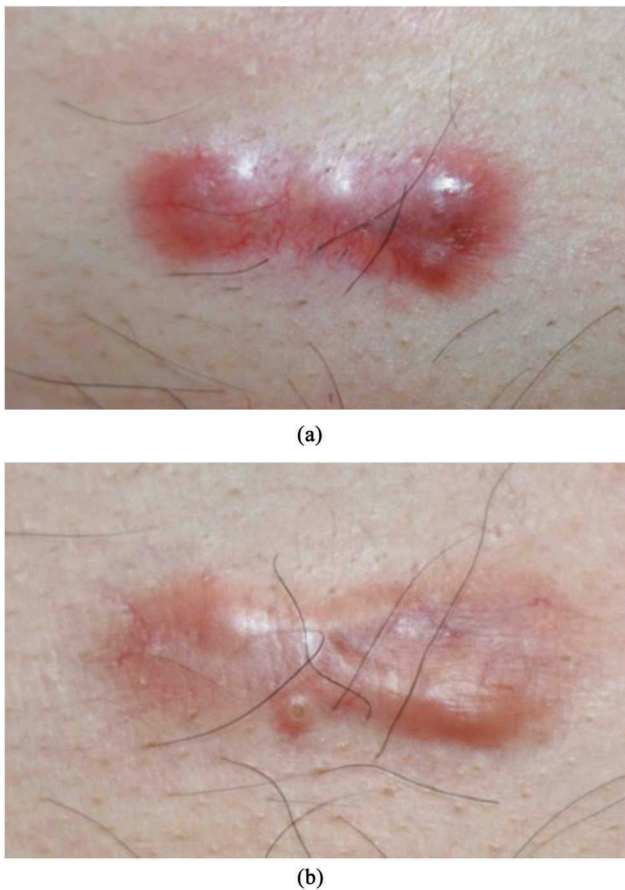


Figure 2. Clinical images of (a) before treatment and (b) after two treatments on a hypertrophic scar on the shoulder of a 34-year-old patient. The total Vancouver Scar Scale score was improved by 50% (from 6 to 3).

the ps-Nd:YAG has been verified only in tattoo removal and lentigines (31,32). The ps-Nd:YAG has the same treatment principle as the nanosecond laser, but with a pulse width one thousand times shorter. It produces much higher peak powers than the QS Nd:YAG with the same energy, enabling reduction of the photothermal effect while increasing the photomechanical effect (photoosmosis) (30). Previous studies using QS 532-nm and 1064-nm Nd:YAG lasers to treat HS have focused on the role of postinflammatory hyperpigmentation induced by melanocytes and melanosomes in the formation of HS (13,33). The authors thought that the ps-Nd:YAG laser could treat HS more effectively and safely while reducing side effects by using lower energy fluence than the previous QS Nd:YAG.

This study evaluated the treatment outcome of VSS and found significant clearance of pigmentation (38.6%) and improved vascularity (57.8%) for HS treated with the 1064-nm ps-Nd:YAG. Pliability improved by 56.5% after treatment and by 43.8% in height compared to before treatment. The results of the 1064-nm ps-Nd:YAG on HS were consistent with our hypothesis.

Compared with the previous study by Cho et al. using a conventional nanosecond 1064-nm QS Nd:YAG (13), the mean energy fluence (J/cm^2) was significantly lower for the ps-Nd:YAG (range: 1.8–2.2 vs. 0.4–2.0, mean: 0.93 ± 0.25), and the mean number of treatment sessions was less (7.8 vs.

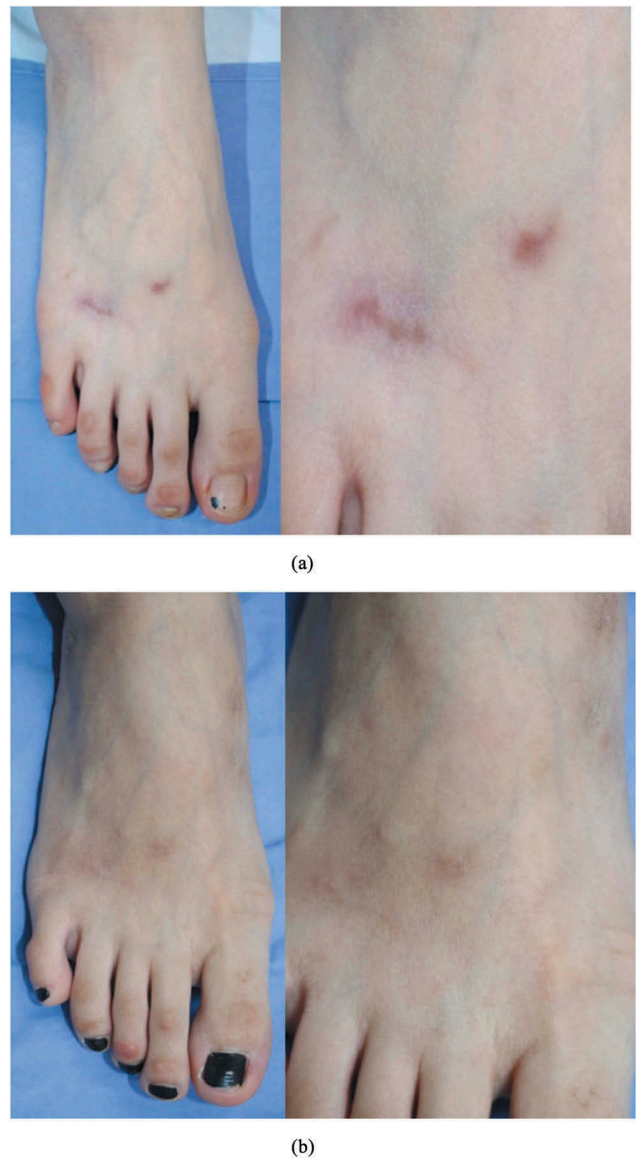


Figure 3. Clinical images of (a) before treatment, and (b) after three treatments on a hypertrophic scar (chemical burn) on the dorsum of the foot of an 18-year-old patient. The total Vancouver Scar Scale score was improved by 75% (from 4 to 1).

3.29) in this study. This is consistent with the hypothesis that pigmentation can be treated more efficiently using lower fluences by increasing the photomechanical effect associated with the 1064-nm ps-Nd:YAG while decreasing the photothermal effect.

The satisfaction score assessment showed more than moderate satisfaction (6.88 ± 2.66). During the study period, there were no persistent or serious adverse events associated with the ps-Nd:YAG laser treatment.

A retrospective setting, small sample size, lack of control group, and single-center analysis are important limitations in this study. More than half of the patients (15/24, 62.5%) were treated with the ps-Nd:YAG due to post-operative HS, and most of these cases were thought to be early surgical HS occurring within six months after surgery. Therefore, a relatively short follow-up period (mean 21.28 ± 15.46 weeks) was also a limitation. Additionally, the primary efficacy measures (VSS and GAS) assessed by blinded dermatologists were relatively subjective.

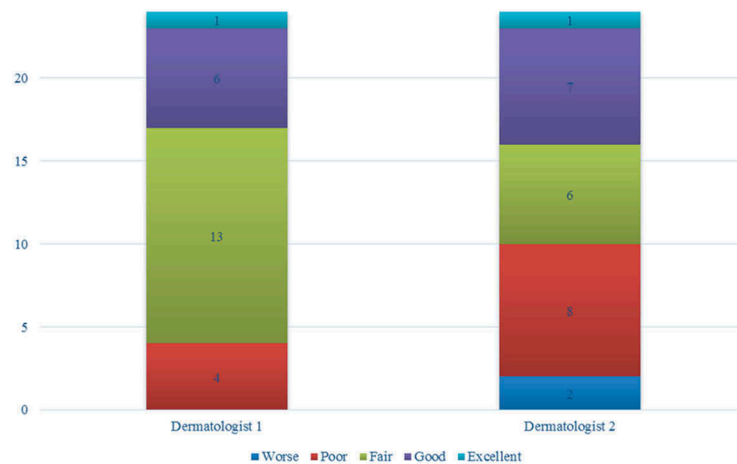


Figure 4. The 5-point global assessment score evaluation.

Table 3. Patient satisfaction scores.

Patient satisfaction scores	n (%)
Very satisfied (10)	3 (12.5)
Moderately satisfied (6–9)	16 (66.7)
Neutral (5)	2 (8.3)
Somewhat dissatisfied (1–4)	2 (8.3)
Dissatisfied (0)	1 (4.1)

In conclusion, the efficacy and safety of a new 1064-nm ps-Nd:YAG laser for treatment of HS in skin of color was demonstrated. Compared to the conventional 1064-nm QS Nd:YAG, this new device reduced the mean energy fluence and could therefore be used more safely. It also shortened the total treatment period, which may increase patient compliance. The 1064-nm ps-Nd:YAG can therefore be recommended to manage early-stage HS without severe hypertrophy and to treat pigmented HS.

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Conflict of Interest

The authors have no significant interest with commercial supporters.

Financial Disclosures

None.

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