

Nordlys™

Clinical Evidence Compendium



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Clinical Evidence Compendium

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Introduction

The Nordlys™ multi-application device by Candela is one of the most versatile platforms on the market, offering 4 distinct technologies to treat in-demand conditions including epidermal pigmented and vascular lesions, skin resurfacing, and hair removal. Nordlys system technologies comprise Selective Waveband Technology (SWT®) narrowband Intense Pulsed Light (IPL), non-ablative fractional 1550 nm and 1940 nm lasers and the Nd:YAG laser for a platform that addresses 24 clinical indications.*

SWT is a unique narrowband state-of-the-art IPL with an advanced dual-filter technology engineered to cut off potentially harmful wavelengths on both sides of the spectrum, along with an exceptional ability to deliver true sub-millisecond pulses that redefine IPL treatment. The system offers a variety of SWT applicators with wavelength ranges of 400-720 nm, 530-750 nm, 555-950 nm, 600-950 nm, and 645-950 nm, providing a solution to a wide range of aesthetic conditions.

The non-ablative, fractional 1550 nm and 1940 nm diode lasers allow for dual-depth skin resurfacing and treatment of benign pigmented lesions (1940 nm laser). These laser applicators deliver energy to the skin, as arrays of micro thermal zones (MTZs) that can penetrate the skin to coagulate confined structures of the epidermis and dermis, while preserving the stratum corneum. This initiates a controlled wound healing response of the treated areas that assists with tissue regeneration and reduced patient downtime compared to ablative resurfacing. The additional Nd:YAG laser further expands treatment opportunities. An integrated SoftCool™ system allows for skin cooling for patient comfort and safety during treatment.

This compendium includes a selection of studies and results that capture the breadth of clinical evidence and versatility of using the Nordlys multi-application system.

* Nordlys™, CE marked for 24 indications in EMEA.

Clinical Bulletins

Clinical Bulletins

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* Photorejuvenation is defined as treatment of benign pigmented lesions and benign vascular lesions in photodamaged/photoaged skin.

Treatment of photodamaged/photoaged skin is commonly referred to in the scientific literature as "photorejuvenation" or "skin rejuvenation".

Dual-wavelength non-ablative fractional resurfacing of photoaged skin with the Frax 1550™ and Frax 1940™ handpieces

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Nicolle Dest MSN, RN; Raylene Piretti, LE**

Introduction

Photoaging induced by chronic exposure to sunlight produces dramatic changes in the skin that are of cosmetic concern to many individuals.¹ Although some manifestations of photoaging are more prominently displayed in certain racial groups, pigmentary alterations are a major component of photoaged skin in all skin types.¹ Light-based treatments can be appealing to patients seeking gradual improvement for the clinical characteristics of photoaged skin, without prolonged downtime and with fewer risks compared to more invasive procedures.²

Non-ablative lasers, with wavelengths in the near to mid-infrared (IR) spectrum that are selectively absorbed by water within the skin, have been used successfully to address the clinical aspects of photoaging, such as pigmentary and vascular changes, as well as changes to skin texture.³ The heat produced by the laser coagulates structures of the epidermis and dermis, initiates a controlled wound healing response and stimulates collagen growth within the inner dermal layer.⁴ Delivering energy to the skin, as arrays of micro thermal zones (MTZs), preserves the stratum corneum and precisely targets confined epidermal and dermal coagulations.⁴ Due to skin physiology and laser-tissue interaction in Asian and ethnic skin, laser therapy can be challenging. Nevertheless, non-ablative technologies have also been used successfully in skin of color⁵, and available evidence strongly suggests that fractional lasers are a favorable treatment option for photorejuvenation in darker skin types.⁶

The 1940 nm wavelength is the closest match to one of the water-absorption peaks in the mid-IR band (at ~1935 nm) and can achieve controlled superficial depths of focal damage, extending about 200 µm deep to the surface, to thermally denature the epidermis without ablating it.⁷ The 1550 nm wavelength, with a penetration depth up to 800 µm, causes thermal coagulation deeper in the dermis and stimulates production of collagen.⁸ Intense pulsed light (IPL) devices deliver a wavelength spectrum of light to tissue, which can be filtered to target hemoglobin, melanin and water in the skin.⁹

A combination approach to treating the clinical characteristics of photoaging is often required to ensure patient satisfaction.¹⁰ Combination treatment with IPL and non-ablative fractional photothermolysis in a single session achieved results statistically superior to treatment with either modality alone.¹¹ Treatment of photodamaged skin, using the Nordlys SWT® (Selective Waveband Technology) handpieces to treat pigmentary and vascular dyschromia and a fractional 1550 nm laser handpiece (Frax 1550™) to treat skin texture irregularities by resurfacing (Light & Bright™ treatment), resulted in significant improvement in Fitzpatrick Skin Types II–IV.¹²

In this IRB-approved clinical study*, the original Light & Bright™ treatment protocol was expanded to include the clinical practice of overlapping non-ablative laser passes to photodamaged skin, with combined 1940 nm and 1550 nm

wavelengths, to address both shallow (epidermal) and deeper (dermal) resurfacing needs. Following the series of resurfacing treatments, the Nordlys SWT treatment was offered for improvement in underlying vascular lesions that were possibly masked by pigmentation at baseline.

The Nordlys SWT technology was designed with dual-filtering technology to filter out the shorter and longer infrared wavelengths and to correspond with the absorption spectrum of a specific skin chromophore, while minimizing heating to the surrounding tissues. Restricting the wavelength band from 530 - 750 nm covers the two absorption peaks of oxyhemoglobin (542 and 577 nm) and reduces the fluence and number of treatments needed, compared to broadband IPL, for treatment of visible telangiectasias and diffuse erythema.¹³

Methods

Subjects

Healthy male and female subjects presenting with clinically visible signs of photoaged skin were eligible to participate in the study. Subjects underwent up to three monthly skin resurfacing treatments to the face and/or body (i.e. chest) with the Frax 1940™ and Frax 1550™ handpieces. At 2 - 3 weeks after the series of resurfacing treatments, an optional SWT treatment was offered for improvement in underlying vascular lesions (i.e. diffuse redness, linear telangiectasias).

Dual-Wavelength Resurfacing Treatments

The Frax 1940 and Frax 1550 handpieces, available on the Nordlys™ and Frax Pro™ systems, are both CE marked for general skin resurfacing procedures.** The handpieces are equipped with a replaceable roller tip and motion sensor, controlling the rate at which the laser delivers the MTZ arrays to the skin, as determined by the speed at which the user advances the roller across the targeted area and the number of passes. The treating operator has control over a wide range of scan widths (4 to 12 mm), energy per MTZ, and percent of coverage, while the system independently calculates the number of MTZs / scan width and the number of passes in Guided Mode. As a safety feature to prevent multiple MTZ arrays being overlaid, the laser can only deliver energy while the roller is in motion. A low power < 1 mW red aiming beam at 650 nm helps to show the user where the treatment laser pulses will be delivered. An integrated cold air delivery system provides patient comfort. The ergonomic handpieces and adjustable scan widths (4 to 12 mm) enable treatment of larger areas or smaller nasolabial and periorbital areas.

Various SWT handpieces can be used to treat benign pigmented lesions and benign vascular lesions**, such as the diffuse redness and linear telangiectasias that may be visible after the resurfacing treatments.

Assessments

Digital clinical photography with standardized conditions was performed at all laser treatments and follow-up visits. Photoaged skin on the face was assessed for elastosis severity (ES), using the Fitzpatrick Wrinkle and Elastosis Scale (1-9). Photoaged skin on the body was assessed for severity of texture irregularities, using a 5-point scale (0=None to 4=Extreme). All treated sites were assessed for improvement in pigmentation severity, using a 5-point scale (0=No improvement to 4= Excellent response: Most or all lesions much lighter or gone). Investigator assessment of overall cosmetic improvement after treatment was reported, using the Global Aesthetic Improvement Score (GAIS) scale (1= Very Much Improved - Optimal cosmetic result to 5= Worse - The appearance is worse than the original condition).

Immediately following the treatment sessions, subjects reported on discomfort associated with Frax 1550, Frax 1940 and SWT treatments, using a scale of 0=no pain to 10=severe pain. At all visits post the first treatment, subjects reported on satisfaction with treatment outcome, using a 5-point Likert scale (1= Not satisfied to 5= Very satisfied), and overall cosmetic improvement, using the GAIS scale.

Results

Subjects

A total of 24 female participants were enrolled in the study. Two subjects withdrew informed consent and are not included in the study analysis. Currently, 22 female subjects (21 Caucasians, 1 Hispanic) with Fitzpatrick Skin Type II (n=11), III (n=10) and IV (n=1) and mean age of 51 ± 12 years (range 27-67) underwent skin resurfacing treatments to the face (n=16) or chest (n=6). One of the subjects treated on the face was also treated on the hands.

Dual-Wavelength Resurfacing Treatments

A total of 62 resurfacing treatment sessions were performed to the 23 treatment areas. Most subjects (81%, 18/22) underwent three treatments (1 subject had 1 treatment only and 3 subjects had 2 treatments). Topical anesthetic cream was applied 30 to 60 minutes prior to treatment, using a Lidocaine 23%/Tetracaine 7% compound.

Treatment parameters were set according to physician discretion taking into consideration location of treatment, skin type and clinical indication. Generally, 2 - 3 passes with the Frax 1550 handpiece were administered and followed by 2 - 3 passes with the Frax 1940 handpiece. Focal (spot) treatments to areas with textural irregularities were applied with the Frax 1550 handpiece. This was performed by decreasing the scan width and performing additional passes over areas of deeper textural irregularities. Skin areas with dense pigmentation

underwent additional passes with the Frax 1940 handpiece, with a decreased scan width and increased coverage of 35-50%. Treatment parameters for the face and off-face (chest and hands) areas are summarized in Table 1.

Immediate treatment responses to resurfacing were limited to mild to moderate Micro-Epidermal Necrotic Debris (MENDS), edema, erythema and blanching. Mean pain score was 5.3 ± 1.7 for both

Frax 1550 and Frax 1940 treatments, with no significant difference between treatment modalities ($p = 0.8403$). There were no adverse events reported during the study.

SWT Treatments

Following the resurfacing treatment series (~1 to 3 months post final treatment), 14 subjects received Nordlys SWT treatments for vascularity and/or pigmentation on the face (n=10) or chest (n=4). Single or double pulses with the PR 530 handpiece, fluence of $5.8 - 9.4 \text{ J/cm}^2$ and pulse durations of 1.5, 2.5, 5 or 10 msec, were used to treat 13 subjects. One subject was treated with the PL 400 handpiece, fluence of 7.4 J/cm^2 and 35 single pulses for benign pigmented lesions on the face.

Investigator Assessments

Mean baseline ES score for the subjects treated on the face was 6 ± 2 (range 3 - 9). There was significant improvement at the final follow-up visit after the series of resurfacing and SWT treatments ($p < 0.05$, Wilcoxon Signed Rank test for paired data), with mean ES scores of 5 ± 3 (range 2 - 9) and 4 ± 3 (range 2 - 8), respectively. Typical examples of visible improvement after the treatment series are shown in Figures 1 and 2.



Photos Courtesy of Candela Institute of Excellence. Konika Patel Schallen, MD.
All photos are unretouched. Individual results may vary.

Figure 1. A 67-year-old woman with Fitzpatrick Skin Type II. Visible improvement in photoaged skin after 2 skin resurfacing treatments to the face with the Frax 1940 and Frax 1550 handpieces.

Mean baseline Texture Irregularity Severity score for the subjects treated on the chest and hands was 2 ± 1 (range 1 - 3). There was significant improvement after the second and third resurfacing treatments ($p < 0.05$, Wilcoxon Signed Rank test for paired data), with mean severity scores of 1 ± 1 (range 1 - 2) and 1 ± 1 (range 0 - 2), respectively.

Laser Type	Frax 1550	Frax 1940
Laser Parameters (Face)	Mean (range)	Mean (range)
Energy/MTZ (mJ)	44 (15 - 70)	15 (10 - 20)
Coverage (%)	25 (19 - 30)	37 (23 - 53)
Pulse Time (ms)	3 (3 - 5)	4 (2 - 6)
Scan Width (mm)	4, 8, 10 or 12	4, 10 or 12
Passes	3 (1 - 6)	3 (2 - 6)
Est. Depth (μm)	779 (500 - 850)	220 (170 - 270)
Est. Width (μm)	374 (240 - 420)	450 (400 - 500)
Max. Velocity (cm/s)	3 (2 - 5)	3 (2 - 5)
MTZ/Pass	72 (44 - 130)	93 (39 - 173)

Laser Parameters (Chest / Hands)	Mean (range)	Mean (range)
Energy/MTZ (mJ)	41 (34 - 51)	15 (12 - 20)
Coverage (%)	25 (21 - 30)	38 (16 - 50)
Pulse Time (ms)	3 (3 - 4)	5 (4 - 9)
Scan Width (mm)	4, 8, 10 or 12	4, 6, 10 or 12
Passes	3 (1 - 4)	3 (2 - 6)
Est. Depth (μm)	787 (750 - 810)	218 (190 - 270)
Est. Width (μm)	368 (350 - 390)	449 (420 - 500)
Max. Velocity (cm/s)	3 (2 - 4)	3 (1 - 4)
MTZ/Pass	67 (52 - 120)	88 (41 - 157)

Table 1. Summary of Resurfacing Treatment Parameters



Photos Courtesy of Candela Institute of Excellence. Konika Patel Schallen, MD. All photos are unretouched. Individual results may vary.

Figure 2. A 56-year-old woman with Fitzpatrick Skin Type III. Visible improvement in photoaged skin at the 1-month follow-up, after 3 skin resurfacing treatments to the face, with the Frax 1940 and Frax 1550 handpieces.

Of note, skin assessments were sometimes worse prior to the second treatment than at baseline, due to sun exposure during the summer months. Initial treatments performed in the spring, prior to the Covid-19 pandemic, often had a lengthy treatment interval of 5 - 8 months between the first and second treatments. Resurfacing treatments can be customized for not only Fitzpatrick Skin Type, but also degree of sun exposure. Figure 3 demonstrates an example of this progression in treatment outcome with very visible improvement after treatment to suntanned skin.



Photos Courtesy of Candela Institute of Excellence. Konika Patel Schallen, MD.
All photos are unretouched. Individual results may vary.

Figure 3. A 53-year-old woman with Fitzpatrick Skin Type II. Suntanned skin shows more visible photodamage at 8 months after 1 resurfacing treatment than baseline. Visible improvement in photoaged skin at the 1-month follow-up, after 3 skin resurfacing treatments, with the Frax 1940 and Frax 1550 handpieces.

Global Aesthetic Improvement Score (GAIS) & Pigmentation Assessments

Investigator and subject GAIS assessments for overall improvement of photoaged skin (Figure 4) were reported after one treatment (n=21 subjects), after two treatments (n=18 subjects) and at the final follow-up (before the SWT treatment or at the 1-month follow-up after resurfacing) for 16 subjects. Investigator assessments of photoaged skin improved with treatment, with 93% of subjects demonstrating improvement by the final follow-up.

Subject assessments were slightly better than the investigator assessments. All subjects experienced overall improvement of photoaged skin and indicated some degree of satisfaction with treatment outcome by the final follow-up, with 88% of subjects (14/16) 'Very much improved' or 'Much improved' and 69% (11/16) 'Very satisfied'.

Investigator assessments of pigmentation severity also improved with treatment. At final follow-up, all assessed subjects showed some improvement, with 79% having a good to excellent response.

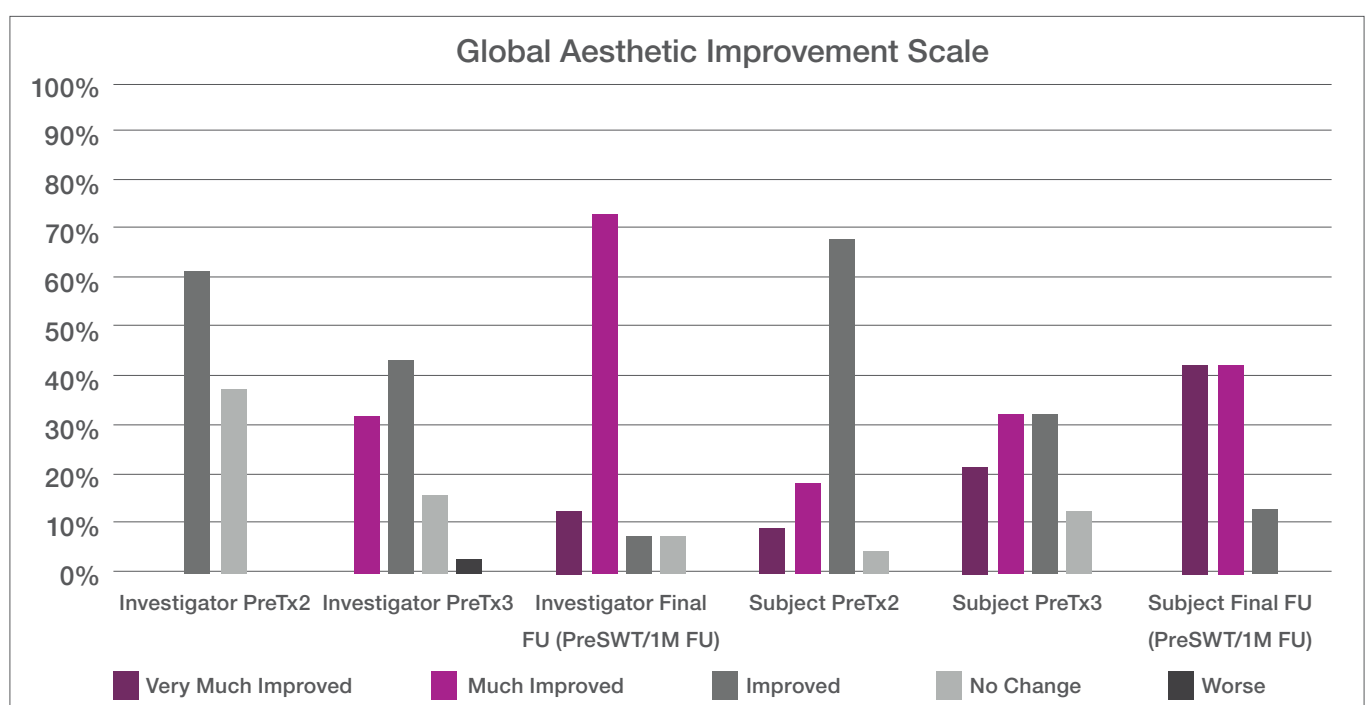


Figure 4. Investigator and subject GAIS scores by study visit.

Conclusion

In this study, a dual-wavelength non-ablative fractional laser system was used to resurface photoaged skin with the Frax 1940 and Frax 1550 handpieces. Investigator assessments demonstrated significant improvement following two or three treatments. Subjects reported high satisfaction and improvement with treatment outcome.

With the versatility of dual wavelengths for resurfacing at different depths and dual-filtering SWT handpieces, the treatment protocol can be customized to the patient, based upon Fitzpatrick Skin Type, degree of suntan, and baseline treatment condition.

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**Nordlys CE mark, October 2019

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Non-invasive Lip and Perioral Rejuvenation* with the 1550 nm Non-ablative Fractional Laser on the Nordlys™ Multi-Application System

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Introduction

Lips play a significant role in our facial aesthetics and are often considered a focal point of beauty and sensuality.^{1,2} Over time, factors like aging, sun exposure, and lifestyle choices can take a toll on the appearance and condition of our lips. As we age, collagen, a protein responsible for maintaining the elasticity and firmness of the skin, gradually diminishes. This leads to the formation of fine lines and wrinkles, including those around the lips. Therefore, aging is commonly associated with perioral fine lines, marionette lines, and flattening of the cupid's bow. In addition, the philtrum becomes longer, indirectly contributing to a vermilion involution and thinner upper lip.³ Aging processes are also associated with a prominent decrease in hyaluronic acid and collagenous fibers in the dermis, as well as a decrease of muscle fiber in the vermilion.⁴

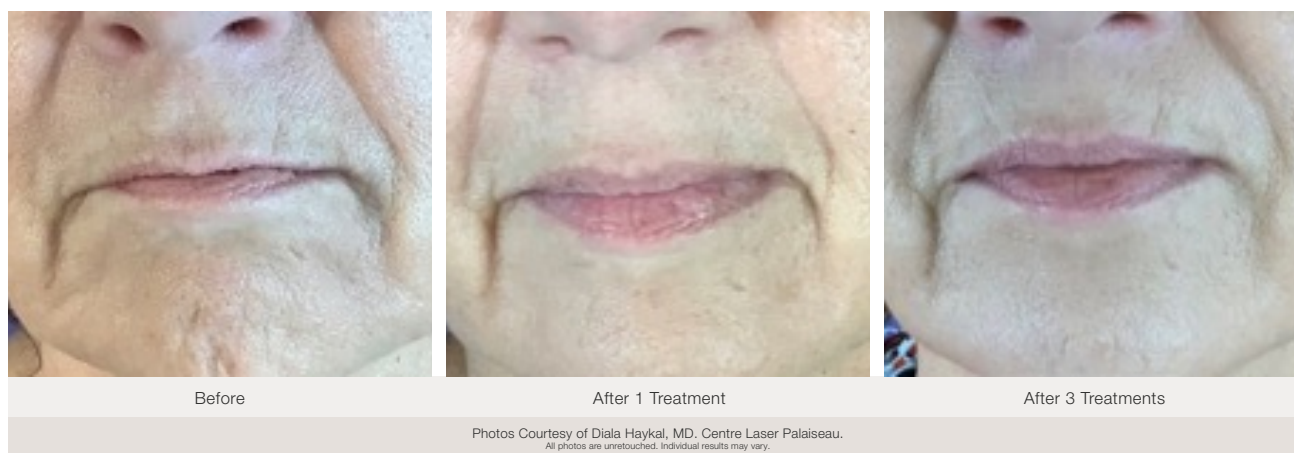
Advances in aesthetic procedures have introduced innovative non-surgical lip rejuvenation treatments with lasers to enhance the natural beauty of lips by stimulating collagen production within the lip tissue. Laser treatment is non-invasive and is not associated with the undesired complications of injectables, such as allergic or hypersensitivity reactions to the injected material.⁵ In addition, lasers can break down

excess pigments and reduce hyperpigmentation.⁶ Therefore, dark spots or uneven pigmentation on the lips that can be caused by factors such as sun exposure, smoking, or hormonal changes may also be addressed with laser treatment.⁷

The Nordlys multi-application platform by Candela® incorporates timeless technologies, including Selective Waveband Technology (SWT®) narrowband IPL applicators, non-ablative fractional laser NAFL applicators (1550 nm and 1940 nm), and a Nd:YAG laser.** The 1550 nm NAFL applicator is designed for deep tissue resurfacing treatment, such as needed for lip rejuvenation treatment. The 1550 nm wavelength can penetrate the skin tissue with depths up to 800 µm, creating an array of thermal coagulation zones in the deep dermis. Therefore, treatment initiates a tissue wound healing response, which results in the production of collagen.⁷ Since the treated zones are separated by healthy untreated tissue, the treatment is associated with low downtime and a relatively low risk of complications.

In the case presented here, we showcase laser-based lip and perioral rejuvenation using the Nordlys system with the 1550 nm laser.

Lip and Perioral Rejuvenation* using Non-ablative Fractional 1550 nm Laser Treatment



Applicator	Area	Number of Passes	Energy	Coverage	Penetration Depth	Scan Width	Pulse Duration
1550 nm	Lips	2	34-36 mJ	25%	750-770 µm	4 mm	2.7 ms
1550 nm	Perioral	4	37-39 mJ	25%	770-780 µm	10 mm	2.7 ms

A 52-year-old woman visited my clinic with concerns regarding the appearance of her lips. Over the years, she had noticed the development of fine lines and wrinkles on her lips, making them appear less plump and less youthful. She also had some uneven pigmentation on her right upper lip and noticed some wrinkles around her lips as well. She expressed her desire to have laser treatment to naturally rejuvenate her lips and restore a more youthful appearance. The patient declined injections, stating that she would prefer laser treatment instead. After clinical examination, it was evident that she had moderate signs of aging, with visible fine lines and a loss of volume in her lips along with the presence of hyperpigmentation, particularly on the upper right lip. It was decided that optimal treatment was likely to be achieved using the 1550 nm laser because it addresses deeper skin resurfacing needs with short downtime and minimal side effects.

The subject underwent three treatments at one month apart. Based on the lip color, the laser parameters were selected as: 2 passes with 25% coverage, energy ranging between 34-36 mJ, 750-770 µm (tissue depth), 2.7 ms pulse duration and 4 mm scan width. Her perioral area was also treated using

the following treatment parameters: 4 passes with 25% coverage, energy ranging between 37-39 mJ, 770-780 µm (tissue depth), 2.7 ms pulse duration and 10 mm scan width. One hour before each procedure, a topical numbing cream (EMLA) was applied to ensure patient comfort during the treatment. Each treatment lasted only a few minutes and treatment was associated with a mild warming sensation and minimal discomfort. Post-treatment care included the use of soothing lip balms and avoiding exposure to direct sunlight. The patient experienced temporary redness and mild swelling on her lips for around three days after her treatment. Three months after the third treatment, the subject returned for a follow-up appointment.

After treatment the patient noted that her lips appeared volumized, plump, and more vivid. The hyperpigmentation on her upper right lip had also improved, resulting in a more even and balanced lip color. The patient also experienced noticeable improvements in perioral wrinkles or “smoker’s lines” and the marionette lines that had given her a sad appearance. The subject expressed her satisfaction with the results and her increased self-confidence.

Conclusion

In the case presented here, resurfacing treatment with the non-ablative fractional 1550 nm laser improved lip structure and texture irregularities. An additional observation post treatment was improvement in the tone and appearance of hyperpigmentation of the surrounding skin. The treatment not only enhanced the appearance of her lips and perioral region, but also contributed to her overall self-confidence and satisfaction.

The procedure itself is relatively quick, and from my experience, most individuals describe the sensation as a mild tingling or warming sensation, with no downtime and only temporary side effects. Following the procedure, it is common to experience some temporary redness, swelling, or mild bruising, which typically resolves within a few days. It is important to follow the post-treatment care instructions provided by the laser specialist to ensure optimal results and minimize any potential side effects.

The results of lip and perioral rejuvenation with the 1550 nm laser treatment are gradual and improve over time as collagen production increases. Depending on the desired outcome, multiple treatment sessions may be recommended for optimal results. In my practice experience, the effects of the treatment can last for several months to a year, and periodic touch-up sessions can help maintain the rejuvenated appearance of lips and perioral skin.

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* Skin rejuvenation by skin resurfacing of sun-damaged (photodamaged) or aging skin.

** Frax 1940 for Nordlys & Frax Pro Systems, CE mark.



Frax 1940™ non-ablative fractional laser handpiece for skin resurfacing

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Introduction

The development of laser-based aesthetic devices has provided patients with an appealing nonsurgical treatment alternative to address clinical aspects of photoaging skin.¹ Many treatments include skin resurfacing of the uppermost skin layers to initiate a skin regeneration process with fewer risks and complications and with a faster recovery time than conventional invasive procedures.¹

Non-ablative lasers have been developed with wavelengths in the near to mid-infrared (IR) spectrum that are selectively absorbed by water within the skin to raise the skin temperature. The heat produced by the laser coagulates structures of the epidermis and dermis, initiates a controlled wound healing response and stimulates collagen growth within the inner dermal layer.² Nonablative fractional lasers allow the delivery of energy to the skin as arrays of microscopic treatment zones (MTZs), preserving the stratum corneum and precisely targeting confined epidermal and dermal coagulations. Healing is associated with Micro-Epidermal Necrotic Debris (MENDS) located at the MTZ margins.² Therefore, clinical results are less associated with postoperative morbidity as compared to traditional flat-beam laser treatments.³

The 1940 nm wavelength matches one of the water absorption peaks in the mid-IR band, and the tissue water absorption coefficient for this wavelength is within the range to vaporize skin tissue, but below the ablation threshold.⁴ Unlike non-ablative lasers with wavelengths in the 1320-1550 nm range or lasers used for ablative resurfacing (i.e. CO₂ and Er:YAG), the 1940 nm wavelength achieves controlled superficial depths of focal damage to thermally denature the epidermis without ablating it.⁴ Histological analysis

of photoaged skin treated with a fractional 1940 nm laser has shown focal damage that extended to about 200 µm in depth.⁴ Penetration depths were greater following treatment of photoaged skin with a fractional 1550 nm laser, with histological analysis showing 800 µm penetration depth at a treatment level of 88 mJ and 400 µm at 44 mJ.⁵ Clinical improvement was significant for reduction in diffuse pigmentation, rhytides and elastosis following treatment with the 1940 nm laser.⁴

The Frax 1940 non-ablative solid-state diode laser handpiece was developed for the Nordlys™ and the Frax Pro™ multi-application systems. The Frax 1940 non-ablative fractional laser handpiece was recently CE-marked for coagulation of soft tissue.* Treatment of the skin using the Frax 1940 handpiece leads to skin resurfacing via ablation and coagulation of soft tissue. The handpiece is equipped with a replaceable roller tip and motion sensor, controlling the rate at which the laser delivers the MTZ arrays to the skin, as determined by the speed at which the user advances the roller across the targeted area. The treating operator has control over the scan width, energy per MTZ, and percent of coverage, while the system independently calculates the number of MTZs / scan width and the number of passes. As a safety feature to prevent multiple MTZ arrays being overlaid, the laser can only deliver energy while the roller is in motion. A low power < 1 mW red aiming beam at 650 nm helps to show the user where the treatment laser pulses will be delivered. An integrated cold air delivery system provides patient comfort.

During the second phase of an IRB-approved clinical trial**, 18 female subjects at our clinic underwent a series of 2-3 skin resurfacing treatments to photoaged skin with the Frax 1940 handpiece. Preliminary findings are described below.

Methods

Healthy male and female subjects presenting with clinically visible signs of photoaged skin were eligible to participate in the study. Subjects underwent up to three monthly skin resurfacing treatments to the face and/or body (i.e. chest) with the Frax 1940 handpiece. Digital clinical photography with standardized conditions was performed at all study visits. Subjects reported on their satisfaction and graded their overall cosmetic improvement at the 1-month and 3-month follow-ups using a 5-point Likert scale (1= Not satisfied to 5= Very satisfied) and Global Aesthetic Improvement Score (GAIS) scale, from 1= Very Much Improved - Optimal cosmetic result to 5= Worse - The appearance is worse than the original condition, respectively.

Results

Subjects

A total of 18 female participants (12 Caucasians, 6 Asian) with Fitzpatrick skin type II (n=3), III (n=9) and IV (n=6) and mean age of 51±9 years (range 37-64) participated in the second part of the study for full resurfacing treatments. These subjects underwent a series of 2-3 skin resurfacing treatments to the face with the Frax 1940 handpiece. Seven of the subjects were also treated in off-face areas of the chest (n=5), arms (n=1) and hands (n=1).

Treatments

Prior to full resurfacing treatment, several test spots were performed on other anatomical locations. Test spots were monitored for up to 28±7 days in order to evaluate treatment parameters for patient safety.

Topical anesthetic cream was generally applied prior to treatment using a Lidocaine 23%/Tetracaine 7% compound, EMLA™ (Lidocaine/Prilocaine) or BLT (Benzocaine/Lidocaine/Tetracaine). Full treatment parameters were set according to physician discretion taking into consideration: test spot outcome, location of treatment, skin type and clinical indication. In general, the scan width was decreased, and the coverage increased to 30-40% when focusing on areas with discrete lesions. Face and off-face treatment parameters are summarized in Table 1.

Treatment complications were minimal, and discomfort associated with treatment was generally mild to moderate.

Laser Parameters (Face)	Mean ± Standard Deviation
Energy/MTZ (mJ)	15.8±3.1
Coverage (%)	35.5±10.3
Pulse Time (ms)	4.7±0.9
Scan Width (mm)	9.0±3.8
Passes	3.5±0.8
Est. Depth (µm)	226.6±30.8
Est. Width (µm)	455.9±30.0
Max. Velocity (cm/s)	2.8±0.6
MTZ/Pass	72.7±34.7
Laser Parameters (Off-Face)	Mean ± Standard Deviation
Energy/MTZ (mJ)	14.2±2.3
Coverage (%)	38±10.0
Pulse Time (ms)	4.4±0.8
Scan Width (mm)	8.5±4.0
Passes	3.7±1.0
Est. Depth (µm)	210.7±23.6
Est. Width (µm)	440.1±23.6
Max. Velocity (cm/s)	2.9±0.6
MTZ/Pass	82.3±34.3

Satisfaction and Global Assessment Improvement

According to the study protocol, clinical photography was performed for a blinded assessment evaluation at the final follow-up. Subjects were to report on satisfaction and Global Aesthetic Improvement Score (GAIS) at the 1-month and 3-month follow-up visits. Two subjects dropped from the study prior to the third treatment. At the 1-month follow-up, a total of 20 assessments (15 for full face, 4 for chest and 1 for hands) were reported for the 16 subjects. All subjects reported satisfaction with their treatment outcome with 50% (10/20) of assessments reported as “Very satisfied”. Most assessments (90%, 18/20)

indicated improvement with 65% (13/20) of the GAIS assessments showing marked improvement to optimal cosmetic result (“Very much improved”). Due to clinic closure for the coronavirus (COVID-19) pandemic, 3-month follow-up data is available for only four of the treated subjects at this time.

Visible reduction in pigmentation associated with photoaged skin was observed at the 1-month follow-up (Figures 1 – 3) but varied by severity at baseline and treatment location. For example, some subjects showed better clinical outcomes after treatments to the face than to the chest.



Photos courtesy of K. Patel Schallen, MD, USA
All photos are unretouched. Individual results may vary.

Figure 1. A 51-year-old woman with Fitzpatrick skin type III underwent 3 skin resurfacing treatments to the face with the Frax 1940 handpiece. Subject reported ‘Very Much Improved’ and ‘Very Satisfied’ for 1-month follow-up assessments.

Tx #	Treatment Area	Energy / MTZ	% Coverage	Pulse Duration	Scan Width	# of Passes	Est. Depth	Est. Width	Max Velocity	MTZ / Pass	Delivered Energy
1	Face	14.3	30	4.1	12	4	210	440	2.6	48.98	0.75
2	Face	16.2	35	4.7	12	4	230	460	2.3	52.64	0.91
2	Pigmented Areas	18.3	40	5.3	4	2	250	480	2.9	110.5	0.04
3	Face	18.6	40	5.4	12	5	250	480	2.7	43.6	0.98
3	Pigmented Areas	20	50	5.8	4	2	270	500	2.5	129	0.03



Photos courtesy of K. Patel Schallen, MD, USA
All photos are unretouched. Individual results may vary.

Figure 2. A 55-year-old woman with Fitzpatrick skin type III underwent 2 skin resurfacing treatments to the face with the Frax 1940 handpiece. Visible improvement was observed at the 1-month follow-up.

Tx #	Treatment Area	Energy / MTZ	% Coverage	Pulse Duration	Scan Width	# of Passes	Est. Depth	Est. Width	Max Velocity	MTZ / Pass	Delivered Energy
1	Face	12.3	30	3.6	12	4	190	420	2.7	53.25	0.73
2	Face	15.9	40	5.2	12	4	230	460	2.3	48.77	0.68
2	Pigmented Areas	17.9	50	5.2	4	3	250	480	2.6	140.3	0.13



Photos courtesy of K. Patel Schallen, MD, USA
All photos are unretouched. Individual results may vary.

Figure 3. A 51-year-old woman with Fitzpatrick skin type III underwent 3 skin resurfacing treatments to the chest with the Frax 1940 handpiece. Visible improvement was observed at the 1-month follow-up.

Tx #	Treatment Area	Energy / MTZ	% Coverage	Pulse Duration	Scan Width	# of Passes	Est. Depth	Est. Width	Max Velocity	MTZ / Pass	Delivered Energy
1	Chest	11.5	35	3.3	12	4	180	410	2.3	64.79	0.78
1	Pigmented Areas	11.8	35	3.4	4	3	190	420	3.5	127.5	0.03
2	Chest	13	35	3.9	12	4	200	430	60.5	2.2	0.92
2	Pigmented Areas	15	35	4.3	4	2	220	450	3.3	110.8	0.03
3	Chest	15	35	4.3	12	4	220	450	2.4	55.41	0.72
3	Pigmented Areas	20	50	5.8	4	2	270	500	2.5	129	0.08

Discussion

In this study, the Frax 1940 handpiece was used to resurface photoaged skin. Clinical photography demonstrated visible improvement following two or three treatments, noted particularly in areas of pigmentation. Subjects reported satisfaction and improvement with treatment outcome.

In clinical practice, if patients presenting with photoaged skin have visible linear telangiectasias or diffuse redness at baseline, then the vascular dyschromia can be addressed after a series of skin resurfacing treatments. Intense pulsed light (IPL) treatment, using the Ellipse SWT® handpieces available with the Nordlys system, demonstrated significant improvement in diffuse redness and linear telangiectasias in a previous clinical study.⁶ The IPL treatment should be performed after the MENDs from the skin resurfacing procedure have cleared (2-3 weeks).

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* Frax 1940 for Nordlys and Ydun [Frax Pro] CE Mark.

** IRB-approved study protocol: "FRX19004-Clinical Evaluation of a Nonablative Fractional 1940nm Diode Laser for Facial Skin Resurfacing".

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Advanced Superficial Resurfacing With A Novel Fractional Handpiece: Frax 1940

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Introduction

Facial rejuvenation treatments have become increasingly popular with the advent of various interventions with shorter downtime and faster recovery, including the non-ablative fractional laser technology. This technology is based on the fractional delivery of beams of light in columns in a wavelength that is absorbed by tissue water but below the vaporising threshold and typically in the near infrared range of 1200 and 1600 nm¹. The resultant tissue interaction leads to thermal coagulation of the epidermis and dermis (depth related to wavelength and fluence used) with ultimately a wound healing process that translates into visible clinical improvements in aspects of photoaging and photodamage such as texture, fine lines and wrinkles.

There are currently several devices in the market with wavelengths in this range with various specifications including the Candela handpiece of Frax 1550 nm with unique features such as the in-built cooling system and an adjustable scanner width². The 1550 nm treatment has largely become one of the most sought after non-ablative fractional laser treatments.

The new Frax 1940 nm handpiece

Candela's newest handpiece device, the Frax 1940, is a major advancement in the field of non-ablative fractional laser technology with very little matched technology available to date. The technology relies on a solid state diode emitting a 1940 nm wavelength in a scanning mode with in-built cooling (Softcool).

This wavelength is unique since it lies very close to the peak of the water absorption wavelength in the non-ablative range just below the ablative threshold (1935 nm). This results in a unique avid light-tissue interaction with water with a superficially-located biological interaction manifesting as coagulation and epidermal and superficial papillary dermal injury³. Microscopic Epidermal Necrotic Debris (also known as MENDs) lead to epidermal renewal and pigment clearance, and together with the superficial nature of the injury this leads to clinically visible improvements in tone, texture and superficial pigment clearance. There are currently very few available technologies aside from ablative lasers that have such a marked impact on the epidermis giving clinical results described by patients as: "glowing skin", "smoother skin", and a "porcelain feel" of the treated skin.

Features of the Frax 1940 nm handpiece:

The handpiece is relatively light and ergonomically friendly with an aiming beam and a disposable roller with in-built Softcool technology for comfort. The device allows for energy adjustment from 6 to 20 mj, giving an estimated depth of 200 micron. The density is adjustable between 20 and 50%, and the scanner width has the choices of 4, 6, 8, 10, and 12 mm. The latter is particularly a huge advantage as it allows for a customised treatment in smaller areas, as well as targeting with precision and maximum impact smaller lesions, such as lentigos and flat seborrheic keratoses.

Case 1

A 56 year-old woman with evidence of photodamage and dull, rough facial skin was treated with the Frax 1940 handpiece, using the following parameters: Energy of 10 mj, density of 35%, scanner width of 10 mm, 4 passes over the entire face with 2 additional passes on the large individual lentigos using a 4 mm scanner width, 50% density and 7 mj fluence. The clinical endpoint is erythema and post care consisted of a light-based moisturizer regularly with strict sun protection. The downtime is around 4 to 5 days with erythema and darkening of the lentigos, and a total of 2 treatments were performed with significant improvement in pigment reduction, smoothening of the skin and the “glow” described by the patient that continued for weeks post treatment.



Case 2

A 46 year-old woman with Fitzpatrick Skin Type 2 and evidence of photodamage, as well as what she described as a “dull and lifeless facial skin” underwent a single treatment session using the following parameters: Fluence of 8 mj, 40% density, scanner width 12 mm, 4 passes and with softcool technology. Immediately post treatment topical vitamin C serum and non-cross-linked hyaluronic acid serum was applied to the skin. Downtime was 5 days of erythema with darkening of the superficial pigmented lesions. One month post treatment the patient reported significant improvement in the “feel of the skin”, texture and marked reduction in signs of photodamage. She particularly explained that her make-up simply sits much nicer on the skin and her facial skin is radiant with a glow.



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Treatment of Chrono and Photoaging with Combined Light Sources on the Nordlys™ Platform

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Introduction

Skin aging depends on various intrinsic (chronological) and extrinsic (ambiental) factors: chrono and photoaging changes include wrinkles, abnormal pigmentation, skin laxity, and telangiectasia.

Advanced skin aging has been treated primarily via ablative procedures that led to replacing the epidermis and superficial dermis, but at the price of high patient discomfort, prolonged social downtime and, potentially, serious adverse events.

Alternative treatments using non-ablative sources for facial resurfacing are increasingly preferred. ⁽⁴⁾

Intense Pulsed Light (IPL) is a type of light treatment using pulses of light to treat and improve various skin conditions, with a lower side effect profile compared to other devices. It targets a wide range of cutaneous structures, EBD devices. Including IPL targets a deeper pigmentation and increased vascularity. ^(1,2,3)

The Candela Selective Waveband Technology (SWT®) is a new and unique technology, defined by patented dual filter, as well as sub-millisecond pulses. Unlike other IPL devices, the pioneering SWT® delivers precisely filtered narrowband wavelengths, filtering out potentially harmful ones and only using those that are beneficial for the treatment. ⁽¹⁾

Non-ablative fractional laser therapy is a new concept of treatment, in which precise arrays of microscopic treatment zones (MTZ) are produced in the dermis, stimulating a therapeutic response around them. Surrounding normal intact epidermis enables accelerated healing after treatments. Many studies have proven that this treatment modality can achieve desirable clinical results without serious adverse effects or longer downtime, which was the major limitation of ablative laser resurfacing. ⁽⁴⁾

The Nordlys™ system is a multi-application platform that incorporates dual-filtering SWT® and two fractional, non-ablative laser resurfacing technologies with submillisecond pulse – addressing both shallow (Frax 1940™) and deeper (Frax 1550™) resurfacing needs, as well as Nd:YAG 1064.

Non-ablative fractional laser therapy with Frax 1550 nm is CE-marked for clinical conditions that require dermal remodeling, like skin resurfacing, stretch marks, acne and surgical scars ⁽⁶⁾.

With the Nordlys™, one can easily manage chrono and photoaging using the Light and Bright protocol: combining the narrowband, dual filter SWT PR530 or VL555 handpieces with the Frax 1550 fractional non-ablative technology to treat vascular and pigmented lesions, textural irregularities, and at the same time, improve the overall appearance of the skin. ^(6,7)

Case 1

A 46-year-old Caucasian female presented with a severe chrono and photoaging, manifesting hyperpigmentation, vascular lesions and wrinkles (Fig.1 A, B).

Patient was treated with the Nordlys SWT using a 555nm filter and a double-pulse technique with 4,5ms pulse duration, 10ms delay, and a fluence of 12 J/cm². Immediately post SWT session, patient was also treated by Frax 1550 (3 passes, 40mJ, 25%). No topical anesthetic cream was applied.

One month after the first session, a second combined treatment was performed, using the same sources and parameters.

She was examined 30 days after the second treatment: clinical improvement was amazing and the patient was very satisfied. (Fig.2 A, B).

No further treatments were required, the sessions went well, according to both the physician's and patient's satisfaction.



Figure 1 - A, B



Figure 2 - A, B

Case 2

A patient, 57-year-old Caucasian female, presented with severe photoaging, revealing intense hyperpigmentation, skin irregularities and wrinkles (Fig.3 A).

We performed two different monthly sessions, each using the Nordlys SWT (555nm filter, double-pulse technique with 4,5ms pulse duration, 10ms delay, and a fluence of 12 J/cm²) combined with Frax 1550nm (3 passes, 40mJ, 25%) at the same time. No topical anesthetic cream was applied.

30 days after the last combined session skin quality significantly improved and hyperpigmentation has almost disappeared (Fig.4 B), revealing a brighter, smoother-looking skin.

Patient is now in follow-up care: she is using daily topical treatment, and we have also planned an additional Light and Bright session, possibly an annual one.



Figure 3 - A

Figure 4 - B

Conclusions

Skin aging is influenced by multiple genetic and environmental factors that can manifest in the form of wrinkles, abnormal pigmentation, skin laxity, and telangiectasia. Non-ablative fractionated laser facial resurfacing treatments are increasingly preferred to treat skin aging. With this approach, selective dermal injury is caused by infrared light, leading to the production of new collagen, while the overlying epidermis remains intact.

In the clinical cases presented above, both patients were treated by combined sources, SWT and Frax 1550, and reported amazing results on skin quality after just two sessions, without any serious adverse effects or long downtime.

In conclusion, using the Light and Bright protocol, combined treatments with SWT (555nm or 530nm filters) and Frax 1550, both available on the Nordlys platform, can lead to impressive results on all components of skin aging, with reduced downtime and a lower incidence of complications adding to its popularity.

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Nordlys™ Hair Removal for Men

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Hady Hamade is a highly experienced Cosmetic Laser Specialist with over 8 years' experience in laser skin solutions. He is currently the Director of The Laserologist INC, a clinic in Hamilton, ON, Canada. The Laserologist has treated over a thousand patients, which led him to master his personalized combination of rejuvenating and anti-aging techniques to achieve remarkable patient-specific results.

Introduction

This Case Spotlight showcases the effectiveness of utilizing the Nordlys™ multi-application platform by Candela® for hair removal of large body areas in men, as well as beard definition. Nordlys is a multi-modality system offering a range of Selective Waveband Technology (SWT®) narrowband IPL applicators with wavelength ranges of 530-750 nm, 555-950 nm, 400-720 nm, 645-950 nm and 600-950 nm to address a variety of skin conditions.* The SWT applicators incorporate unique dual-filter technology and sub-millisecond pulses for highly targeted treatments.¹ The HRL 600 (600-950 nm) and HRD 645 (645-950 nm) applicators produce short bursts of light that target melanin in the follicles, designed to remove unwanted hair.² The advantages of SWT IPL treatment for hair removal are gentle light-based energy and no external cooling needed for patient comfort, a large treatment footprint, as well as no consumables.

Case Study 1: Back Hair Removal



A 34-year-old male with Fitzpatrick Skin Type III presented with undesired hair on the back. He received a series of treatments using the HRL 600 applicator (600-950 nm) with average fluence of 13.2 J/cm². Following each treatment, perifollicular edema was experienced for about 15-30 minutes. Mild erythema was also noticeable for 24-48 hours. As shown above, at 3 months after the 4th treatment, a clearly visible reduction in hair density was observed.

Treatment Parameters

Applicator	Average Fluence (J/cm ²)	Pulse Duration Range (ms)	Number of Pulses per Treatment (Range)
HRL 600	13.2	15-20	300-500

Case Study 2: Leg Hair Removal



A 31-year-old male with Fitzpatrick Skin Type IV presented to our clinic seeking hair removal treatment on his legs. He received a series of treatments using the HRL 600 applicator (600-950 nm) with average fluence of 12 J/cm². Perifollicular edema was experienced after each treatment for about 15-30 minutes. Mild erythema was also noticeable for 24-48 hours. As shown above, at 5 months after the 6th treatment, a clearly visible reduction in hair density was observed.

Treatment Parameters

Applicator	Average Fluence (J/cm ²)	Pulse Duration (ms)	Number of Pulses per Treatment (Range)
HRL 600	12	20	200-400

Case Study 3: Beard Definition



A 42-year-old male with Fitzpatrick Skin Type III presented with a thick black beard. In order to shape and define the beard, he underwent a series of treatment sessions using the HRL 600 applicator (600-950 nm) with average fluence of 13.4 J/cm². Following each treatment, perifollicular edema was experienced for about 15-30 minutes. Mild erythema also lasted for 24-48 hours. As shown above, at 6 weeks after the 5th treatment, the stubble surrounding the beard and on the neck was cleared, the density of the thick black hair was reduced, and a clean and well-defined beard was achieved.

Treatment Parameters

Applicator	Average Fluence (J/cm ²)	Pulse Duration Range (ms)	Number of Pulses per Treatment (Range)
HRL 600	13.4	15-20	40-80

Case Study 4: Beard Definition



A 31-year-old male with Fitzpatrick Skin Type II presented with a thick blackish brown beard. In order to thin out and define the beard, he underwent a series of treatments using the HRL 600 applicator (600-950 nm) with average fluence of 13.5 J/cm². Following each treatment, perifollicular edema was experienced for about 15-30 minutes. Mild erythema was also noticeable for 24-48 hours. As shown above, at 6 weeks after the 4th treatment, the stubble surrounding the beard and on the neck was reduced and definition of the beard was evident.

Treatment Parameters

Applicator	Average Fluence (J/cm ²)	Pulse Duration (ms)	Number of Pulses per Treatment (Range)
HRL 600	13.5	20	40-80

Summary

The four case studies presented here describe body and face hair removal treatments for men who were successfully treated with Nordlys SWT narrowband IPL applicators. In all cases, the immediate post-treatment endpoint was achieved with minimal discomfort for the patients. Although hair removal is successful after one treatment, multiple treatments are recommended to capture new hair growth occurring across the hair follicle life cycle. The number of treatments can be customized for the patient, according to hair removal needs and body location.

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* Nordlys and Frax Pro Systems U.S. FDA 510(k) clearance [K212492], Dec. 2021; Nordlys Health Canada Medical Device License (108788), Jan. 2023; Frax 1550 for Nordlys and Ydun [Frax Pro] CE Mark.

Selective Waveband Technology (SWT®) for Laser Hair Removal Treatment with the Nordlys™ System

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Introduction

Photoepilation devices, both intense pulsed light (IPL) and laser, have been used for decades for successful permanent hair reduction. Based on the principle of selective photothermolysis¹, light at a particular wavelength can selectively target melanin localized in the hair shaft, follicular epithelium, and hair matrix. IPL devices use polychromatic light wavelengths, ranging from 600 to 1400 nm, which are selectively absorbed by melanin.² By choosing different cut-off filters, wavelength ranges can be selected to treat a wide range of skin types. When using lasers, skin type factors into the selection of an appropriate wavelength for treatment. Subjects with pigmented skin are more prone to laser-related adverse events due to epidermal melanin absorption.³

Comparing Treatment Modalities

IPL devices and alexandrite, diode, and Nd:YAG lasers can be used effectively for long-term reduction of unwanted hair.⁴ A randomized controlled study demonstrated significant hair reduction at the 6- and 18-month follow-ups for both IPL and Nd:YAG-treated sides.⁵ However, pain scores were lower and fewer side effects were associated with IPL treatment. Furthermore, patient satisfaction scores were higher for IPL-treated sides. In another study, hair in the axillae was significantly reduced on both the diode laser and IPL-treated sides, but the diode laser was more painful.⁶

Evolution of IPL to a Narrowband Approach

Although IPL systems typically include wavelengths up to 1200 nm, selective waveband technology (STW®) offers more precisely filtered narrowband wavelengths, using only those wavelengths that have a beneficial treatment effect.* This is more than simply excluding wavelengths that mainly heat up water in the skin; the Nordlys™ and Sirius™ systems allow cut-off filters to be applied at any suitable wavelength.* With water filters in each handpiece and light filtered on both ends of the spectrum, the dual-filtering (water and light) technology eliminates wavelengths above 950 nm.⁷

Photoepilation of Asian skin in the axilla region, using the selective waveband technology (SWT®) source with a 645–950 nm filter (HRD handpiece) achieved 83.4% hair reduction, at the 8-month follow-up after four treatments.⁸ Furthermore, no significant adverse effects were reported after HRD treatment in these dark-skinned patients. Bikini hair in females with Fitzpatrick Skin Types II-IV showed hair reduction of 80.2%, at the 8-month follow-up after four treatments, using the Ellipse SWT® source with a 600–950 nm filter (HR handpiece).⁹

At our clinic in Israel, we evaluated hair reduction and patient satisfaction at three months following a series of four treatments with the Nordlys system for its CE-Marked intended use of hair removal.**

Methods

Male or female subjects with Fitzpatrick Skin Type I to V and unwanted body hair were eligible for a series of four monthly treatments. Hair removal treatments were done using the HR IPL family of handpieces, including the HR 600, HRL 600 and HRD 645. The HR 600 and HRL 600 handpieces emit light within the narrowband wavelengths of 600 nm – 950 nm. The penetration depth of these wavelengths is enough to reach even the deeper hair follicles.* Large areas were treated with the HRL 600 handpiece, with a spot size of 48mm X 18 mm to allow faster treatments with less overlapping. For dark skinned patients with a higher skin concentration of melanin, the HRD 645 handpiece was

used to emit light with wavelength 645 nm – 950 nm.

Treated areas were shaved prior to the SWT® treatment to avoid absorption of IPL energy by the exposed hair. Topical anesthesia (e.g. EMLA) was offered to minimize discomfort during treatment. The pulse duration was automatically designated by the system once the operator selected the thickness of the hair (thin, medium, or thick). Thin hair needs less energy to heat up, so relatively low energy is used. Thick hair needs more energy to heat up, so higher energy is used.

Results

Subjects and Treatments

Currently, 11 subjects (4 males, 7 females) with mean age of 42.5 ± 14.0 years (range 24 to 65 years) and Fitzpatrick Skin Types II (n=2), III (n=3), IV (n=5), and V (n=1) received a total of 40 treatments on 13 body areas: 6 lower legs, 2 backs, 2 chest, 2 abdomens and 1 set of arms. At baseline, the mean hair count was 68 ± 37 per treated area, and the hair was mostly black (12/13 black, 1/13 light brown), with medium hair thickness.

Handpiece (# of treatments)	Wavelength range (nm)	Fluence range (J/cm ²)	Pulse duration (ms)	Mean # of pulses per treated area	Mean treat- ment time (min)
HR 600 (n=17)	600-950	8.5-15.1	15-40	425±236	32±18
HRL 600 (n=14)	600-950	8.5-16	15-20	525±185	32±15
HRD 645 (n=9)	645-950	6.1-16.1	15-55	494±203	29±10

Table 1. Hair removal treatment parameters (n=40 treatments)

Treatment parameters are shown in Table 1.

The treatments were considered as comfortable to very comfortable, with a mean score of $1.61.6 \pm 0.7$ (5-point scale of -2 Very uncomfortable to 2 Very comfortable). Mild to moderate erythema and edema were common skin responses immediately after treatment (88% and 86%, respectively). There were no treatment complications or adverse events.

Hair Reduction Assessments

Preliminary data assessment of hair counts at baseline compared with hair counts after the treatment series demonstrated 86% and 79% hair reduction at the 1- and 3-month follow-ups, respectively. Overall mean percentage hair reduction and hair reduction percentages by handpiece are shown in Figure 1. Examples of hair reduction, at the 3-month follow-up, on large body areas are shown in Figures 2 and 3.

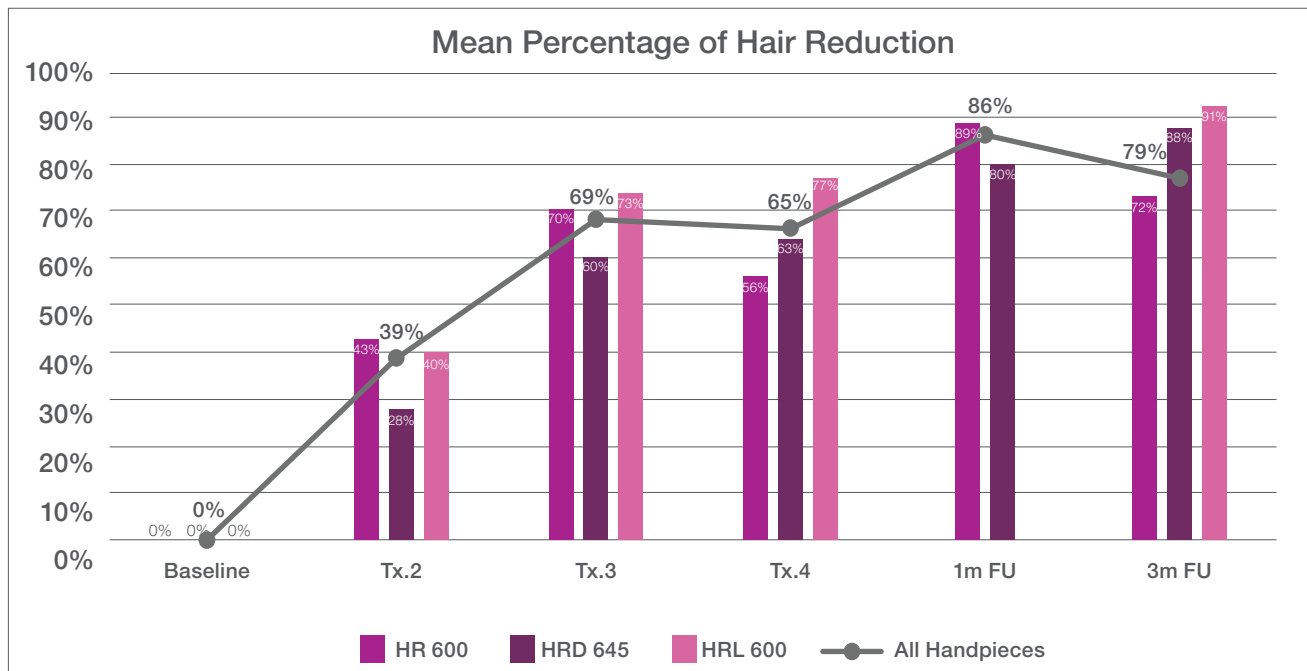


Figure 1. Mean Percentage of Hair Reduction.



Photos Courtesy of Candela Medical. David Friedman, MD.
All photos are unretouched. Individual results may vary.

Figure 2. 53-year-old male with Fitzpatrick Skin Type III and black hair of medium thickness on the upper and lower back. Hair reduction of 91% after 4 treatments with the HRL 600 handpiece: 13.2 – 16.0 J/cm² and 15 or 20-ms pulse durations.



Photos Courtesy of Candela Medical. David Friedman, MD.
All photos are unretouched. Individual results may vary.

Figure 3. 65-year-old male with Fitzpatrick Skin Type IV and black hair of medium thickness on the abdomen and thick hair on the chest. Hair reduction of 97% (abdomen) and 80% (chest) after 4 treatments with the HR 600 handpiece: 8.5 – 14.1 J/cm² and 15.5, 20 and 40-ms pulse durations.

Subject Assessments

Subject satisfaction was high (100% and 80% at the 1- and 3-month follow-up visits, respectively), and most subjects would recommend the treatment to others. Subjects reported that their skin was smoother and softer after treatment and that the treatment was more effective than waxing or shaving.

Conclusion

The Nordlys system offers three different selective waveband technology (SWT®) hair removal handpieces to customize treatment for various skin types and body areas. The handpieces were used at our clinic for hair removal treatments on various body areas in subjects with Fitzpatrick Skin Types II-V. Preliminary data supports that Nordlys treatment of large body areas and various skin types is successful in reducing hair counts, with overall percentage clearance like reported in the literature for Nd:YAG, alexandrite and narrowband IPL devices.^{6,8-10} Subject satisfaction was high. No adverse events or treatment complications were reported. The Nordlys system is a versatile platform for use in practices focusing on hair removal treatments, but also has the advantage of multiple handpiece technologies for other intended uses, such as skin resurfacing and treating vascular and pigmented lesions.

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* Nordlys™ and Sirius™ User Manuals (2020).

** Nordlys CE mark, October 2019.



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Scar Reduction with Combined Non-Ablative Fractional 1550 nm Laser and Selective Waveband Technology (SWT®) Intense Pulsed Light on the Nordlys™ Multi-application Platform

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Introduction

Scars are the normal result of the cutaneous wound healing process that leads to fibrosis and altered skin morphology.¹ Scars can have significant cosmetic, physical, and psychological impacts on patients, prompting many to seek treatment.^{1,2} Scars within the head and neck may be particularly physically disfiguring and associated with profound psychosocial implications.³ Various non-invasive light-based therapies, such as laser and intense pulsed light (IPL), may induce scar remodeling and reduce its appearance.

Non-ablative fractional lasers are commonly used for skin resurfacing, as well as a wide range of scar types, including acne scars, surgical scars, and traumatic scars.⁴ The non-ablative laser device emits microscopic laser beams into the tissue, creating tiny areas of coagulated tissue surrounded by intact tissue. This controlled damage triggers the body's natural healing response, as well as stimulating collagen production, and tissue regeneration.⁵ As the tissue heals, it is replaced with new, healthier tissue, resulting in improved skin texture. Treatment is regarded as gentle and associated with relatively low risk of complications and social downtime.

IPL is another light-based modality that may improve scars. IPL utilizes a spectrum of light wavelengths to target specific skin concerns, including hyperpigmented scars, and reddened or vascular

scars. IPL works by delivering short bursts of high-intensity light onto the scarred tissue. The light energy is absorbed by the pigmented or vascular components of the scar, such as melanin or blood vessels. This selective absorption helps break down excessive pigmentation or reduce the discoloration associated with scars, leading to a more even skin tone.⁶

The Nordlys™ multi-application platform by Candela® is a multi-modality system offering a range of Selective Waveband Technology (SWT®) narrowband IPL applicators with wavelength ranges of 400-720 nm, 530-750 nm, 555-950 nm and 600-950 nm, as well as non-ablative fractional 1550 nm and 1940 nm laser applicators and a Nd:YAG (1064 nm) applicator to address a variety of skin conditions.* The 1940 nm applicator produces controlled superficial depths of focal damage, while the 1550 nm applicator causes thermal coagulation deeper in the dermis. The SWT applicators incorporate unique dual-filter technology and sub-millisecond pulses to target vascularity and epidermal pigment.⁷

A new treatment modality was recently introduced to address photoaged skin by combining 1550 nm laser resurfacing with SWT IPL treatment.⁸ In our clinic, we use the 1550 nm laser to resurface scar tissue combined with the 530-750 nm (PR 530) SWT applicator.

Case Study

A 24-year-old female patient presented with a visible scar on her upper left eyebrow. The scar resulted from a recent accident when she fell and hit her eyebrow area on a sharp object. Despite trying various topical creams and ointments, the scar had not improved over time. The subject was concerned about the scar's appearance, which affected her self-esteem and daily life activities. The 2-cm scar was slightly deep, with a pinkish hue, and was surrounded by normal skin with no signs of active infection (Figure 1).



Figure 1. A 24-year-old woman, before (Left) and after 2 sessions (Right) with SWT treatment with the PR 530 IPL applicator combined with 1550 nm laser resurfacing.

To optimally address vascularity (redness) and overall skin texture, the subject underwent two sessions of combined SWT treatment (PR 530 applicator) and 1550 nm laser treatment, spaced 6 weeks apart to allow adequate time for skin healing and rejuvenation. The selected SWT applicator and treatment parameters were based on skin type, texture, and color. At each treatment session, a single pass was administered with the PR 530 applicator with 7 J/cm² fluence and 2.5-ms pulse duration and three passes with the 1550 nm laser with 6-mm scan width, 30 mJ energy, 20% coverage, 2.7-ms pulse duration and 730 µm penetration depth.

Prior to the treatment sessions, the patient was advised to avoid sun exposure and use broad-spectrum sunscreen with a high SPF to protect the skin. She was also instructed to discontinue any topical products containing retinoids or exfoliating agents for several days prior to treatment. To ensure patient comfort during laser procedure, a topical numbing cream (EMLA) was applied to the treatment area approximately 30 minutes before the session commenced.

Following each treatment, the patient applied a gentle, fragrance-free moisturizer to keep the treated area hydrated and protected. She was advised to avoid excessive sun exposure, use sunscreen daily, and refrain from picking or scratching the treated area. The patient experienced mild redness and swelling for a few days following each treatment session. After treatment the patient experienced remarkable results (Figure 1, Right), and she expressed immense satisfaction and gained a newfound sense of happiness and confidence in her appearance.

Conclusion

In our experience, combining PR 530 SWT treatment to target the vascular component of scar redness and 1550 nm laser treatment to resurface the scar tissue is highly effective in improving the appearance of the skin tissue. This combination treatment approach offers a comprehensive solution for scar management, addressing both the discoloration and texture of the scar tissue. It is important to manage patient expectations, as complete scar removal may not be possible, although significant improvement in scar appearance and texture can be achieved.

Individual results may vary depending on factors such as scar type, scar severity, and patient response to treatment. Timepoint of treatment initiation after injury may also be of importance to treatment outcome.⁸ The number of sessions required depends on the scar's response and the desired outcome.

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*Frax 1550 for Nordlys and Ydun [Frax Pro] CE Mark; Nordlys Health Canada Medical Device License (108788), January 2023.

Non-Ablative Laser Treatment of Surgical Scars and Acne-Induced Scars

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Introduction

Scars tell stories of life - almost everyone has at least one. They are caused in many different ways - by accidents, burns or surgical procedures that are medically necessary or motivated by aesthetic reasons. And there are scars that result from deep inflammations of the skin, as is the case with acne. What all scars have in common is the previous injury to the skin down into the dermis and the effort to repair it as best as possible. This repair succeeds with varying degrees of satisfaction depending on the individual predisposition, localisation and depth of the scar.

The disappearance of post-operative scars is important to many of our patients looking for aesthetic perfection. Accordingly, in all our dermatosurgical procedures (30-40 nevus and skin cancer excisions per week), we understand the importance of postoperative scar treatment in addition to intraoperative incision guidance, suture material, suture technique and freedom from tension. This is particularly indicated for aesthetically important areas such as the face, neck, décolleté and mammary, but also where there is a known tendency to hypertrophic scar formation as well as scars that heal under tension (at joints). Nowadays, it is considered standard to start laser therapy of scars at an early stage instead of waiting for the scars to heal. In the early stages we have the optimal chance to perfectly influence the appearance of scars.

The Nordlys™ multifunctional platform from Candela with its modular SWT® handpieces, the Nd:YAG laser and the fractional, non-ablative Frax 1550™ allows safe and effective scar therapy.

In the case of fresh, red-livid scars, we start treatment two weeks after surgery with the SWT PR 530 handpiece at intervals of 4 weeks. An accelerated fading of the redness is achieved. Teleangiectasias in the course of the scar, which are particularly typical of scars that tend to hypertrophy, are closed. We observe a reduced scar activity with a lower risk of keloid tendency.

In the same session following the SWT treatment, we treat the scar and its surroundings with a circumference of approx. 1 cm with the Frax 1550. Depending on the length of the scar and the sensitivity to pain, we perform this under topical anaesthetic cream. Thanks to the thermal columns applied in fractional mode, improved vascularisation is achieved in the scar area and dermal remodelling is supported. Depending on the type of scar, these treatments are carried out with the Frax 1550 alone or in combination with the PR 530 at intervals of four where the PR 530 targets the vascular component of the scar, while the Frax 1550 treats the scar tissue, leading to a smoother skin. In our experience, silicone gels that patients apply daily between intervals and consistent sun protection are additionally supportive.

In the case of rather coarse to hypertrophic scars, we additionally combine with intralesional triamcinolone injections, which support rapid flattening and flexibility of the scar. Thanks to the rapid visible improvement in the appearance of the scars, patient satisfaction is very high.

In our practice, we treat many teenagers with severe inflammatory acne on the face, which has often already left scarred residues on the cheeks, chin and forehead. In addition to the systemic isotretinoin therapy, laser treatment is part of our standard treatment from the beginning. Here we make use of various effects. The treatment of the inflammatory lesions with PR 530 causes them to „melt away“ quickly. The effect is not only anti-erythematous, but also antibacterial and anti-inflammatory. Because of the deep inflammation, the skin around them often looks very loose, sunken and bowl-shaped scarred. And this is exactly what the Frax 1550 is excellent for, to induce collagen remodelling and to work on the skin texture. Contrary to the former doctrine of waiting until the acne has stopped before treating the scars, we treat all affected areas from the beginning and achieve sensational results in the skin texture.

The compliance of our young acne patients is very high despite discomfort of the treatment, which is reduced with topical anaesthetic cream. Inflammatory lesions melt and disappear within a few days and the skin's appearance improves rapidly.

The Nordlys not only accelerates the healing of acne, but also provides a beautiful, smooth, firm skin appearance after the end of the therapy.

Case 1

A 59-year-old female patient presented with a pale, slightly shiny, rather inconspicuous thickening in the left medial cheek area, which had already been excised 20 years ago and had recently enlarged somewhat (Figure 1). Surgical excision confirmed the suspicion of a sclerodermiform basal cell carcinoma with perineural growth, tumour thickness 1.5mm (Figure 2). The tumour was completely excised and the histological control of the incision margin confirmed that the area was free of tumour (Figure 3).

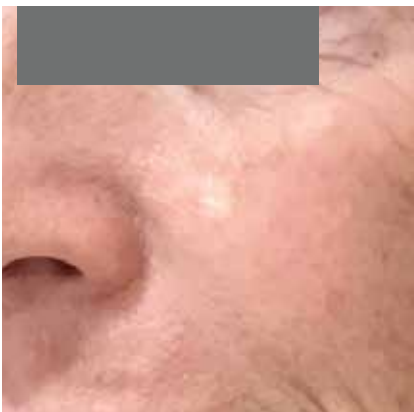


Figure 1: Basal Cell Carcinoma left cheek (BCC)



Figure 2: After Excision of the tumour, basal and lateral margins still affected



Figure 3: After Re-Excision, tumour free margins reached

10 days after the surgery we already initiated the scar treatment with Frax 1550 (Figure 4), 50mJ, 4mm 2 passes, scar surrounding with 50mJ, 10mm, 1 pass. Figure 5: Condition 4 weeks after 3 Frax 1550 treatments.

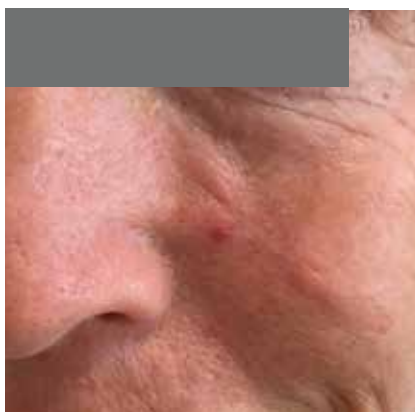


Figure 4: 3 sessions Frax 1550, 2 passes 4 mm, 50mJ, then one pass 10mm



Figure 5: 4 weeks after 3x Frax 1550

Case 2

17-year-old patient presented with severe inflammatory acne and many bowl-shaped acne scars. He had been on monotherapy with 20mg isotretinoin daily for 4 months without topical acne treatment. Pre-treatment advisors strictly advised him against laser treatments under isotretinoin therapy.

We initially treated with PR530 7J, double pulse in the cheek area. There was a very rapid improvement of the erythema and inflammatory lesions. 4 weeks later we started the combination of PR530 with Frax 1550, 50mJ, 10mm, 3 passes. Estimated 3-4 sessions at 4 week intervals.



Figure 1: Monotherapy with 20mg isotretinoin daily



Figure 2: Result 4 weeks after treatment with PR 530, 7J/cm², double pulse

Conclusions:

Postoperative scars can be treated very efficiently with the non-ablative Frax 1550. An early postoperative therapy start has a favourable effect on scar healing and the aesthetic result.

In acne treatment, Selective Waveband Technology with the PR 530 handpiece and Frax 1550 are an integral part of the therapy from the beginning. Thanks to the anti-inflammatory and antibacterial effect of the SWT in combination with the dermal remodelling by the Frax 1550, we achieve not only the healing of the acne but also a scar-free skin appearance.

First published in the PMFA Journal December / January 2023 issue

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Acne Treatment with the Nordlys™ System Using Selective Waveband Technology (SWT®)

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Introduction

Acne vulgaris is a common dermatologic disorder of the pilosebaceous unit that affects individuals of all skin types and ages.¹ Prevention and early treatment of acne are a primary strategy against the formation of scars commonly associated with acne.² Treatment with conventional topical and systemic therapy is based on severity of the acne.³ However, the onset of effect, antibiotic resistance, and significant side effects associated with oral and topical therapies affect patient compliance and success of treatment.¹⁻⁴ Intense pulsed light (IPL) and nonablative fractional lasers that heat the sebaceous glands and their blood vessels, thereby decreasing sebum production, offer alternative treatments for acne, particularly for recalcitrant cases that fail conventional treatment.²⁻⁵

The Nordlys™ system is a multi-platform device that incorporates Selective Waveband Technology (SWT®) narrowband IPL with light and water filtering technology to filter out the shorter and longer infrared wavelengths and to correspond with the absorption spectrum of a specific skin chromophore for pigmentation, vascularity, and

hair removal. Heat to the surrounding tissue is minimized, so there is no need for skin cooling. The Nordlys™ system is CE marked to treat 24 clinical indications, including treatment of inflammatory acne vulgaris with the SWT PR and PRS 530 applicators (530 – 750 nm).^{*} A 1550-nm nonablative fractional laser (Frax 1550™ applicator) is also available with the Nordlys system for deep skin resurfacing. The Frax 1550 applicator's scan width can be adjusted between 4-12 mm to quickly treat large areas or treat smaller areas. The Nordlys system also features a fractional nonablative laser (Frax 1940™ applicator) for epidermal skin resurfacing and treatment of actinic keratosis, and a Nd:YAG 1064 nm laser indicated for vascularity, nail, and wart treatment.

In our clinic, we use the Nordlys™ system with the SWT PR 530 applicator (530 – 750 nm) to treat acne and the Frax 1550 applicator for deep resurfacing of the skin tissue, particularly in areas where acne scarring and textural irregularities are present. We present here a case study of acne treatment.

Case Study

A 16-year-old healthy female with Fitzpatrick Skin Type II presented to our clinic with inflammatory acne on her face (Figure 1). She refused prescribed antibiotics or Accutane therapy. The patient underwent a total of 8-monthly Nordlys treatments, administering split-pulses (2.5 ms duration/10 ms delay/2.5 ms duration) with the PR 530 applicator (530 – 750 nm) and fluence of 7 J/cm². For treatment sessions #5-8, treatment with the PR 530 applicator was followed by resurfacing with the Frax 1550 applicator. Topical numbing cream was applied for 10 minutes prior to 3-4 passes of Frax 1550 resurfacing in a crosshatch fashion with

energy of 36 mJ, 2.7 msec pulse duration, 25% coverage, and scan width of 10 mm. During the 7th treatment, the scan width was reduced to 4 mm on the 3rd pass to resurface four areas with textural irregularities on the right cheek and three areas on the left cheek. Zimmer cooling was used during the Frax 1550 procedure. ZO® Skin Health by Zein Obagi, MD Hydrating Crème and Eminence Organic Skin Care's Lilikoi Daily Defense Moisturizer SPF 40 were applied post-procedure. A nightly skincare regimen of over-the-counter acne cleansers was recommended along with hyaluronic acid and retinol serums and moisturizer.



Courtesy of Eric Pulsfus, MD; Darcey Howe, RN, BSN, CME
Fountain of Youth Spa & Laser Center, Florida, USA

All photos are unretouched. Individual results may vary.

Figure 1: A 17-year-old female with inflammatory acne before treatment (left) and nearly one year after completing 8-monthly treatments with the Nordlys system (right).

Conclusion

Clinically visible improvement of acne and skin texture was seen after the treatment series. Improvement was maintained at nearly one year after the eight Nordlys treatments in this patient. Resurfacing with Frax 1550 was not started until midway through the treatment regimen, but once initiated, the healing process was accelerated. After each Frax 1550 treatment, the patient experienced a “sandpaper” texture of the skin, as well as a minor surface pustular breakout that would clear in several days if left untouched. She began leaving her salicylic acid foaming face wash on for five minutes, as a face mask, before rinsing on the nights she used it, which helped to exfoliate the dry skin and eliminate the small pustules more quickly. We have since begun initiating Frax 1550 after the first PR 530 treatment with acne patients at risk of scarring and have seen the number of treatments needed reduced by half for many of them.

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* Frax 1940 for Nordlys and Frax Pro System, CE mark



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Modern Laser-Assisted Acne Therapy In Practice

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Laser and light-based technologies have expanded the therapeutic arsenal for acne. Intense pulsed light (Nordlys™ SWT®) in combination with non-ablative fractional laser treatment (Frax 1550™) improves the skin appearance of inflammatory acne and scarring residuals in a short time, which at the same time, increases patient compliance and satisfaction. Despite the large number of studies and experience reports, prejudices against laser and light procedures in acne therapy still exist.

Acne is an inflammatory dermatosis in which pathophysiological seborrhoea, follicular hyperkeratosis and perifollicular inflammation are in the foreground. Depending on the severity, it is treated topically or in combination with systemic medication. As a basis for an individual therapy approach, it is particularly important to diagnose the exact type of acne by a dermatologist.

In our dermatological practice, we see it as our task to intensively accompany the affected adolescents

in particular. For them, the period of puberty is a very important and conflict-ridden time. Patient and caring counselling cannot only help patients emotionally, but also lay the foundation for their later relationship to skin, body and skin care and, last but not least, for their self-confidence.

Our basic treatment concept includes daily skin care and cleansing, sufficient hydration and consistent sun protection. In our practice, we use cosmeceuticals based on salicylic acid, alpha-hydroxy acid (AHA) and chlorhexidine, which have a keratolytic, disinfecting and anti-inflammatory effect. This significantly reduces the initial dryness of the skin. Feelings of tension and painful cracks disappear. We also train patients to choose and correctly apply appropriate make-up and to cleanse the skin themselves. In addition, we discuss eating habits in detail with teenagers and how these can be optimised by reducing the intake of carbohydrate-containing foods ^[1].

Laser and light-based therapy: Useful at every stage of acne

	Juvenile Acne	Adult Acne	Acne Excoriée
1	Mild juvenile acne: consistent use of cosmeceuticals based on chlorhexidine, salicylic acid and AHA, possibly in combination with topical antibiotics and zinc oxide.	SWT® narrowband IPL selective, in combination with Frax 1550™ for dermal remodelling, isotretinoin 20mg/day (low dose), quickly reduce to super low dose (20mg/ 1x week), cosmeceuticals with AHA, SA, HA	SWT® narrowband IPL, in combination with Frax 1550™, isotretinoin 20mg/day (low dose), quickly reduce to super low dose (20mg/ 1x week), cosmeceuticals with AHA, SA, HA.
2	Mild acne papulopustulosa: SWT® narrowband IPL selectively and / or over a wide area (2-3 times every 4 weeks). In combination with #1 above.		
3	Severe acne papulopustulosa: Section # 2 above in combination with Frax 1550™. If necessary, start with Isotretinoin 20mg/ Tag (low dose). Can add #1 above.		

Laser and light-based therapy is an often underestimated, but very effective procedure with minimal side effects in the treatment of acne.

With the “Selective Waveband Technology” (SWT®), in which only certain wavelengths of “intense pulsed light” (IPL) are applied, inflammatory teenage acne, acne tarda or inflammatory rosacea can be treated anti-inflammatory (using the Nordlys™ multifunctional platform). This technology causes a higher absorption in the target chromophore thanks to special water filters, which enables a treatment with reduced energy. Compared to other IPL devices, there are fewer side effects such as erythema, swelling and pain [2].

Even in the highly inflammatory stage of acne, treatment with SWT® can reduce the number of bacteria and thus pro-inflammatory triggers. As a result, the inflammation and the severity of the acne, which is calculated using the “global acne grading system” (GAGS), improves quickly and significantly. This is most likely due to reduced sebum production, which rebalances the skin microbiome and reduces the number of Cutibacterium acnes [3]. Treatment with IPL also leads to a histologically confirmed reduction of inflammatory cells [4].

After 30 minutes of application of a local anaesthetic (lidocaine 7 %, prilocaine 7 %, tetracaine 6 %, benzyl alcohol 6 % in base cream), SWT® treatment is well tolerated by all patients and can be performed quickly. With the exception of a temporary erythema, there are no side effects that would lead to a downtime. As a result, we experience a significant increase in patient compliance and satisfaction.

The Frax 1550™ is a non-ablative fractional laser that improves the skin texture in a targeted manner and induces dermal remodelling in already formed acne scars without causing side effects such as infections or post-inflammatory hyperpigmentation. As a diode laser with a targeted wavelength of 1550 nm, the Frax 1550 reaches up to 800 µm deep into the dermis and leads to thermally coagulated micro-scopic zones, which in turn support dermal remodelling. In fractional mode,

approximately 25% of the skin area is treated. The surrounding non-injured cells serve as a reservoir from which rapid and safe healing and new collagen formation starts [5]. This is an effective treatment that spares patients a long downtime.

Myths about laser treatment in acne therapy

Especially among non-dermatologists, persistent, outdated prejudices against laser and light-based therapy for acne continue to circulate.

1.Myth: Isotretinoin should not be taken at the same time as the laser treatment is performed.

This statement is still widespread, but it refers to the once much higher isotretinoin doses of over 0.5 mg/kg body weight and to ablative lasers only.

Nowadays, most patients are adjusted to a low-dose therapy of initially a maximum of 20 mg/day isotretinoin. This achieves better tolerability with fewer side effects and good efficacy [6].

Non-ablative fractional lasers are safe in combination with oral isotretinoin and do not lead to wound healing disorders [7, 8]. Today, there is a consensus that all lasers used in the treatment of acne are safe and can be used in combination with isotretinoin. In the case of CO₂ lasers, the decision should be made on the basis of the skin condition: If the skin is very fragile and sensitive, caution is advised.

2.Myth: The inflammatory acne should be treated first, and only afterwards the scars.

The earlier scars are treated with collagen induction, the faster the desired treatment goals can be achieved.

In our practice, we combine the anti-inflammatory SWT® narrowband IPL therapy with the Frax 1550™ non-ablative fractional laser at an early stage and achieve rapid improvement in inflammation and skin texture. Despite of the combination treatment, our young patients have almost no downtime and go back to school the next day. Even with low fluence and specific SoftCool™ air cooling technology, it is recommended to use a local anaesthetic cream during treatment to reduce pain.

3.Myth: Laser treatments can only be carried out in winter.

Consistent sun protection with sun protection factor 50 is essential when taking isotretinoin, as well as during laser treatments. Patients in our practice are informed in detail and are very compliant with this respect. In Mallorca, with an average of 300 days of sunshine per year, we treat all year round and see no increased side effects such as hyperpigmentation.

Two case studies are used to illustrate the advantages of using laser procedures in addition to standardised acne therapy.

Case 1

The 15-year-old patient (Fig. 2) presented for optimisation of her acne therapy. At the time of the first consultation, she was suffering from very severe inflammatory papulopustular acne conglobata with already developed acne scars, especially in the cheek area. The patient had already been taking isotretinoin 20 mg ("low dose") for three months. On the recommendation of the pre-treatment dermatologist, no topical treatment or targeted skin care was given. The patient was expressly warned against laser therapy, which was contraindicated while taking isotretinoin.

We recommended an intensified combination therapy consisting of SWT® narrowband IPL, Frax 1550™, isotretinoin and topical skin treatment with acne-specific wash lotions, as well as an antibacterial and cornification-dissolving peeling gel. In addition, we recommended combined laser treatments to the patient to improve inflammation and skin texture.

Session 1: Two "passes" SWT PR 530 with a fluence of 7 J/cm² as a double pulse (3.5 J/cm² each) with 2.5 ms; for deeper located pustules fluence of 10 J/cm² as single pulse with 10 ms

Session 2: (Four weeks later) : SWT PR 530 for single pustules with a fluence of 7 J/cm² as a double pulse; additionally Frax 1550 40 mJ, 25 % coverage, 3 passes

Session 3: (4 weeks later): Frax 1550 with 40mJ, 25% coverage, 3 passes



All photos are unretouched. Individual results may vary.

Case 2

The 16-year-old patient (Fig. 3) had already been taking isotretinoin 20 mg as monotherapy for three months at the time of initial presentation in our practice. On the recommendation of the pre-treating dermatologist, neither topical nor targeted skin care was applied. We recommended acne-specific washing lotions and an antibacterial and cornification-dissolving peeling gel to optimise acne therapy. In addition, we also advised him to have a combination laser treatment.

Session 1: Two SWT narrowband IPL PR 530 passes with a fluence of 7 J/cm² as a double pulse (3.5 J/cm² each) with 2.5 ms; for deeper pustules fluence of 10 J/cm² as a single pulse with 10 ms; additionally three Frax 1550 3 passes with 40 mJ and 25 % coverage.



All photos are unretouched. Individual results may vary.

Conclusion

Modern acne therapy should always combine several treatment pillars. Since highly inflammatory acne carries a high risk of permanent scars, we recommend intensifying the therapy at an early stage, also with low-dose isotretinoin.

Laser and light-based procedures are nowadays an integral part of the therapy of acne patients of all ages, as they are very potent and have few side effects. SWT® narrowband IPL treatments result in the reduction of inflammatory triggers as well as sebum production. The non-ablative fractional laser treatment with Frax 1550™ leads to dermal remodelling even in the inflammatory phase and reduces already formed scars.

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Images courtesy of
Dr. Cora Christ & Dr. Cordula Ahnhudt-Franke, mySkin Dermatology Mallorca



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Non-Ablative Fractional Treatment and Use of IPL In Acne Scars

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Introduction

Acne is a frequent pathology in dermatology that represents a great social impact, due to the emotional decline that exposes the sequelae of those who suffer from it.¹ It is more common in puberty, but cases can arise in patients older than 25 years.

The pathophysiology of acne is multifactorial. It affects the pilosebaceous follicles starting with an injury to the epidermal barrier, which triggers a cascade of inflammation. Among the main factors that cause the appearance of this disease we can list genetic predisposition, increased seborrhea, follicular hyperkeratinization, bacterial colonization and dermal inflammation.² Additionally, the aggravating factors can be endogenous (hormonal metabolic disorders) and exogenous factors (sedentary lifestyle, nutrition, and cosmetics).³

The clinical spectrum is wide, from comedones to inflammatory lesions of mild to moderate intensity such as papules, pustules, nodules and cysts.⁴ Post-inflammatory hyperpigmentation due to increased melanin production is common and can cause scarring.³ The places where skin is most affected are the face, neck, upper chest, and back.⁵

The diagnosis is clinical, there is no need for laboratory tests, only if there is suspicion of endocrine disturbance.

Treatment for acne is based on topical and oral antibiotics, which continue to be the gold standard in this pathology. In addition, aesthetic medical procedures are incorporated (extraction of comedones, physical and chemical exfoliations and injection of corticosteroids), therapies and complementary methods with laser and IPL (Intense Pulsed Light) and nutritional advice.⁶

Acne can have a negative impact on the quality of life of patients, cause stress and have important psychological complications.⁴ Acne scars can be avoided or attenuated with combined treatments.⁷ In our dermatological clinic, we have the most advanced technology to restore scar tissue integrity, and provide a smoother appearance to the skin while offering risk-free treatments with minimal downtime.

Candela's Nordlys multi-application platform allows for dermatological and aesthetic procedures to be carried out with the intention of offering an adequate treatment for the various sequelae of acne. The SWT® PR 530* features a narrowband wavelength type (530 – 750 nm) and a pulse duration of 0.5 – 99.5 ms for vascular lesions and photorejuvenation.⁸ It is accompanied by the Frax 1550 fractional non-ablative laser treatment to produce a punctiform coagulative effect with a regenerating result, focused on the tissues of the dermis through selective photothermolysis to stimulate collagen. It features a laser wavelength of 1550 nm and 1 - 20 ms pulse duration. In addition, it includes integrated SoftCool air cooling for better patient comfort during the therapy.⁹

Fractional non-ablative laser treatment is becoming more popular in our environment. One should also note the immediate recovery after the procedure and the significant decrease in acne sequelae and side effects,¹⁰ as documented in various testimonials from our patients when treated with the combined therapy of PR 530 and Frax 1550.

*Selective Waveband Technology® (SWT) - a proprietary technology on Nordlys™ system IPL applicators that protects skin from unnecessary light and heat. It includes light and water filters, as well as customized pulse technology.

Case 1

A healthy 24-year-old woman with Fitzpatrick Skin Type III presented to our clinic with inflammatory acne (Figure 1). The patient underwent 6 sessions of laser treatment, with an interval of 30 days for each session. The procedure consisted of two treatment modalities. Initially, the necessary asepsis was performed in the area to be treated and with security measures in place, the PR 530 treatment (5.8 mJ / 3 pulses / 2.5 ms) was carried out with 2 full-face applications and 2 subsequent SWT applications (6.3 mJ / 3 pulses / 1.5 ms), followed by a non-ablative fractionated laser (40 mJ / 20%) with two applications on the same area. Immediately after the session sunscreen was applied and the patient was advised to avoid the sun. As post-treatment preventive care, it was suggested to use thermal water and reapply sunscreen every 3 hours on the treated area. Significant improvement of the acne lesion was observed after completion of the entire treatment session.



Figure 1: Acne lesion patient before the treatment (left) and at 6 months post 6 treatments (right). Significant improvement was noted after using PR 530 and Frax 1550 non-ablative fractional laser 5.8 mJ / 3 pulse / 2.5 ms and 40 mJ / 20% respectively.

Case 2

A healthy 19-year-old male with Fitzpatrick Skin Type I presented to our clinic with inflammatory acne lesions and scars on the face. (Figure 2). The combined treatment with laser technology the patient completed was of 6 sessions with intervals of 30 days between each session. The procedure began with adequate hygiene in the area to be treated and placing eye protection on the patient, after which PR 530 (5.6 mJ / 3 pulses / 2.5 ms) was used with 2 full-face applications, followed by two applications of intense pulsed light in the same area, but with lower applicator specifications (6 mJ / 3 pulses / 1.5 ms). The treatment was complemented by the non-ablative fractionated laser (50 mJ / 20%) with 2 applications on the affected area. No adverse reactions were observed after the combined treatment. As a post-treatment care, the patient was advised to apply thermal water and reapply the sunscreen every 3 hours. Significant improvement of the acne lesion was observed after completion of the entire treatment session.



Figure 2: Acne scar and lesions patient before the treatment (left) and at 6 months post 6 treatments (right). Significant improvement was noted after using PR 530 and Frax 1550 non-ablative fractional laser 5.6 mJ / 3 pulse / 2.5 ms and 50 mJ / 20% respectively.

Case 3

A healthy 22-year-old woman with Fitzpatrick Skin Type III presented to our clinic with severe inflammatory acne (Figure 3). Due to the presence of deep inflammatory lesions, oral treatment was performed and was complemented with the two modalities of laser procedures, to obtain better results. Seven months of treatment were required, 7 sessions with an interval of 30 days for each session. With security measures and after the necessary asepsis in the area to be treated, the PR 530 treatment (5.7 mJ / 3 pulses / 2.5 ms) was started with 2 full face applications, continuing with 2 SWT applications on the affected area (6.6 mJ / 3 pulses / 1.5 ms), in addition, the Frax 1550 non-ablative fractionated laser (60 mJ / 20%) was integrated into the treatment with two applications in the same area. Sunscreen was applied immediately after the session and the patient was advised to avoid the sun. As post-treatment preventive care, it was suggested to use thermal water and reapply sunscreen every 3 hours in the treated area.



Figure 3: Acne scar and lesions patient before the treatment (left) and at 7 months post 7 treatments (right). Significant improvement was noted after using PR 530 and Frax 1550 non-ablative fractional laser 5.7 mJ / 3 pulse / 2.5 ms and 60 mJ / 20% respectively.

Case 4

A healthy 29-year-old woman with Fitzpatrick Skin Type IV presented to our clinic with severe inflammatory acne (Figure 4). Due to presenting scar tissue and inflammatory lesions that compromise the deepest layers of the skin, two laser treatment modalities of 8 sessions were carried out with an interval of 21 days for each session. To carry out the laser treatment correctly, proper asepsis must be initiated in the area to be treated and with security measures, the PR 530 treatment (5.7 mJ / 3 pulses / 2.5 ms) with 2 full-face applications and subsequent 2 SWT applications adjusting the energy range and pulse duration (6.3 mJ / 3 pulses / 1.5 ms), followed by Frax 1550 non-ablative fractionated laser (50 mJ / 25%) with two applications in the same area. After each session sunscreen was applied and the patient was advised to avoid the sun. As post-treatment preventive care, it was suggested to use thermal water and reapply sunscreen every 3 hours in the treated area.



Figure 4: Acne scar and lesions patient before the treatment (left) and at 8 months post 8 treatments (right). Significant improvement was noted after using PR 530 and Frax 1550 non-ablative fractional laser 5.7 mJ / 3 pulse / 2.5 ms and 50 mJ / 25% respectively.

Conclusion

Acne is a common skin disease that, due to a late diagnosis or treatment, causes scars, affecting patients' confidence. Currently, with the benefit of advanced laser technology, dermatological aesthetic therapy can be added to the conventional treatment, which allows for laser treatment to be used for the rehabilitation of the affected tissue.

Representative results were achieved with the multi-application Nordlys system, showing a more uniform, fresh skin with a smooth texture. The SWT PR 530 handpiece with the narrowband technology led to the exceptional photorejuvenation of the skin and vascular lesions, accompanied by the non-ablative fractional Frax 1550 method that eliminated the epidermis damaged by the hyperpigmentation of acne sequelae.

The appropriate therapy for acne must be tailored to each patient, that is, the number of sessions with the non-ablative fractional method should be optimized depending on the level of the exposed scar tissue.

Furthermore, it is important to mention that there were no side effects during the procedures presented above, and it should also be emphasized that the patients already noted improvement after the first session. The positive evolution is a sign of the perseverance, discipline, and adherence of the patient to the treatments and recommendations.

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All photos are unretouched. Individual results may vary.

Images courtesy of Kléber Ollague Córdova, MD.

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Nordlys™

Nd:YAG Treatment of Periorbital Veins

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 Laserologist

Hady Hamade is a highly experienced Cosmetic Laser Specialist with over 8 years' experience in laser skin solutions. He is currently the Director of The Laserologist INC, a clinic in Hamilton, ON, Canada. Hady has treated over a thousand patients, which led him to master his personalized combination of rejuvenating and anti-aging techniques to achieve remarkable patient-specific results.

Introduction

This Case Spotlight showcases the effectiveness of utilizing the Candela® Nordlys™ multi-application platform with the long-pulsed Nd:YAG 1064 nm laser applicator to treat prominent periorbital veins (POVs). The Nordlys platform is a multi-modality system offering a Nd:YAG 1064 nm laser, non-ablative fractional lasers (1550 nm and 1940 nm), as well as a range of Selective Waveband Technology (SWT®) narrowband IPL applicators to address a variety of skin conditions.* Unlike invasive surgical therapies for prominent POVs that can leave unsightly scars, the Nd:YAG vascular laser with its long 1064 nm wavelength can penetrate deep into the skin to heat the entire vessel wall and coagulate visible POVs with minimal post-treatment care.^{1,2}

We report here on two case studies of POVs successfully treated with the Nd:YAG 1064 nm laser. Patients were instructed to avoid excessive sun exposure for at least one month prior to treatment and to avoid exfoliants, Alpha Hydroxy Acid (AHA) or Beta Hydroxy Acid (BHA), or retinoids (vitamin A derivatives) for two weeks pre-procedure. Post-treatment care consisted of applying a hydrating cream (La Roche-Posay® Cicaplast) for seven days followed by sunscreen. Under-eye puffiness subsided within hours to one week post-treatment.

Case Study 1



A 25-year-old female with brown hair and blue eyes presented with a network of POVs that due to her fair skin (Fitzpatrick Skin Type II) were quite visible and perceived as dark circles under the eyes. She received two Nd:YAG treatments, at a 6-week interval, for optimal cosmetic outcome. Treatment was performed directly over the vessels, with no overlap, to clinical endpoint of vessel disappearance.

TX	Fluence (J/cm ²)	Spot Size (mm)	Pulse Duration (ms)	Number of Pulses (Range)	Treatment Time (min)
1	210	3	45	10 - 20	5
2	240	3	45	5 - 10	5

Case Study 2



This 35-year-old female with brown hair and brown eyes and Fitzpatrick Skin Type III had a prominent blue POV that appeared raised and several smaller vessels. A single Nd:YAG treatment significantly minimized the prominent vessel.

TX	Fluence (J/cm ²)	Spot Size (mm)	Pulse Duration (ms)	Number of Pulses (Range)	Treatment Time (min)
1	233	3	45	5 - 10	5

Summary

The two case studies presented here demonstrate a successful treatment technique using the Nordlys Nd:YAG applicator to quickly and non-invasively treat or minimize prominent POVs. The long-pulsed Nd:YAG 1064 nm laser targets hemoglobin in the blood vessels, causing coagulation and vessel closure without damaging the surrounding skin. The treatment involves precise application along the periorbital vein, inducing rapid disappearance of the characteristic blue hue because of efficient hemoglobin absorption and subsequent coagulation. There were no treatment complications, and downtime was minimal for the patients.

Treatment of periorbital veins is an advanced treatment and should be performed by experienced treatment providers. Always perform test spots and observe treatment response prior to performing full treatment. Ocular shields should be utilized when treating near the eye. The number of treatments can be customized according to the patient's cosmetic concerns and to the vessel size.

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* Nordlys and Frax Pro Systems, CE Mark

Treatment of Striae Utilizing the Frax 1550™ on the Nordlys™ System

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Introduction

The Nordlys™ system from Candela is configured with pre-set aesthetic and medical treatment parameters designed to meet the needs of today's dermatologists. A single platform consists of four different technologies designed to treat a range of indications. These include Selective Waveband Technology (SWT)® - narrowband IPL for skin rejuvenation*, acne, pigmented lesions, vascular treatments, and hair removal; Frax 1550™ for non-ablative fractional skin resurfacing and soft tissue coagulation, acne and surgical scars as well as the treatment of striae; Frax 1940™ for superficial skin resurfacing and treating actinic keratosis and Nd:YAG 1064 nm laser for treating benign vascular lesions, port wine stains and fungal nail infections.** The non-ablative fractional and Nd:YAG lasers include SoftCool™ for patient comfort.

Striae distensae, or stretch marks, are a common dermatologic condition caused by excessive mechanical stretching of the skin with damage to dermal elastic fibers.¹ The lesions are arranged perpendicular to the direction of skin tension. Striae are often associated with rapid growth during adolescence, excessive weight gain, and late stages of pregnancy.^{2,3} It is also associated with some medications and medical conditions. Recent striae initially appear pink or purple (striae rubra), eventually becoming atrophic and white (striae albae).⁴ Common locations for stretch marks are thighs, buttocks, and breasts. Although striae are clinically benign, they can have a significant emotional impact, leading many affected individuals to seek treatment.⁵ Early stretch marks are more amenable to treatment; however, there is no universally agreed upon treatment of striae distensae.⁴

Clinical Case: Frax 1550™

A 35-year-old female presented to my clinic with a history of striae distensae that occurred 2 years earlier during her first pregnancy. The patient attempted numerous preventative treatments during her pregnancy and following delivery to treat her striae, with little effect. Striae rubrae were clearly visible on her abdomen and lateral flanks or “love handles”. It was decided that optimal treatment was likely to be achieved using the Frax 1550™ laser because it addresses deeper skin resurfacing needs with short downtime and minimal side effects.⁶ For the treating physician, it is an easily and accurately reproducible procedure.

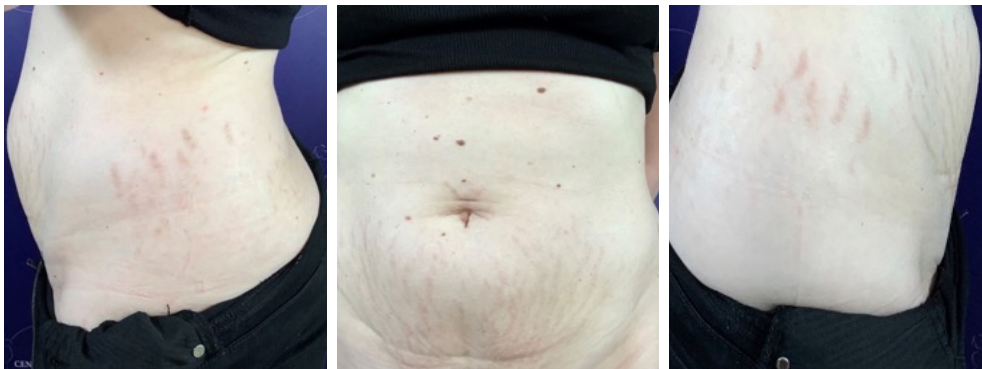
The patient provided a signed consent to undergo treatment and permission to publish pre- and post-treatment photos. The first treatment session was planned to occur in 2 weeks. In the interim, the patient was advised to avoid sun exposure. A topical numbing cream was applied to the planned treatment area 1 hour prior to treatment. Based on

the striae type, location, and patient skin color, the laser parameters were selected as: 39 mj (770 micron depth), 10 mm scan width, and 4 passes.

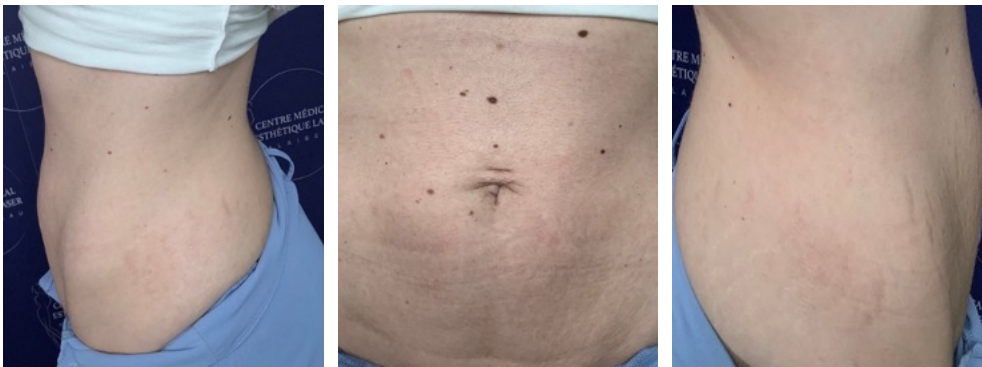
It should be noted that treatment settings can be altered based on patient response to an initial treatment. In the current case, the patient’s skin quality had improved, and it was decided to apply higher fluence for even better results. The second treatment was performed 1 month later. The settings for the second session were 4 passes with 39 mj (780 micron depth), 10mm scan width.

After both sessions, proper post-operative care was administered to help avoid complications. Following the treatment of striae distensae, post-treatment edema and redness decreased in hours to days. The use of sunscreen is mandatory, and a repair cream was prescribed for skin dryness and peeling that might occur. The patient expressed her satisfaction with the procedure verbally and her increased confidence and self-image. She has not reported any adverse events following the final treatment session.

Frax 1550™ Treatment



Before



After 2 treatments

Photos Courtesy of Diana Haykal, MD, France
All photos are unretouched. Individual results may vary.

Conclusion

This case study supports the use of Frax 1550™ for improving the appearance of striae distensae by stimulating neocollagenesis and elastic fiber synthesis. Repeated treatments may be an effective approach to improving the treatment of striae distensae. Randomized controlled trials are necessary to firmly establish the efficacy of Frax 1550™ for treating striae distensae.

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* Skin rejuvenation through the treatment of Sun-Damaged Skin to Reduce Diffuse Redness and Pigment Disturbances and Improve Texture (Photorejuvenation)

** Frax 1550 for Nordlys and Ydun [Frax Pro] CE Mark."

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Bibliography

Bibliography & Selected References

This bibliography contains 38 selected peer-reviewed journal articles referencing various Nordlys technologies and applications, as listed by PubMed and other published sources. This list was developed to serve as a strong reference research tool regarding treatments with the Nordlys device and its applicators for our customers.

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Non-ablative Fractional Laser Resurfacing of Photoaged Skin and Addressing Vascularity and Pigmentation Aspects of Scar Tissue with SWT Narrowband IPL

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Before and After Photography

Nordlys™

SWT® IPL Treatments

Acne & Diffuse Redness

4 Treatments
PR 530



Photos Courtesy of Kléber Ollague Córdova, MD (Ecuador)
All photos are unretouched. Individual results may vary.

Rosacea (Cheeks)

1 Treatment
PR 530



Photos Courtesy of Marta Vilavella, MD (Iberia)
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SWT® IPL Treatments

Photorejuvenation

2 Treatments
VL 555, PR 530



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Diffuse Redness and Pigment

1 Treatment
VL 555, PR 530



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SWT® IPL Treatments

Photorejuvenation

3 Treatments
VL 555, PR 530



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Photorejuvenation

1 Treatment
VL 555, PR 530



Photos Courtesy of Franco Gemigniani, MD (Chile)
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SWT® IPL Treatments

Photorejuvenation

2 Treatments
VL 555, PR 530



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Rosacea

1 Treatment
PR 530



Photos Courtesy of Franco Gemigniani, MD (Chile)
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SWT® IPL Treatments

Photorejuvenation and Vascularity

2 Treatments
VL 555



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Facial Telangiectasias

3 Treatments
VL 555, PR 530



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1940 nm Non-Ablative Fractional Laser Treatments

Skin Resurfacing

1 Treatment
1940 nm



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Skin Resurfacing

3 Treatments
1940 nm



Photos Courtesy of Konika Schallen, MD (USA)
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1940 nm Non-Ablative Fractional Laser Treatments

Skin Resurfacing

3 Treatments
1940 nm



Photos Courtesy of Konika Schallen, MD (USA)
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Skin Resurfacing

3 Treatments
1940 nm



Photos Courtesy of Konika Schallen, MD (USA)
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Nd:YAG 1064 nm Treatments

Vascular Lesions

2 Treatments
Nd:YAG 1064 nm



Photos Courtesy of Hady Hamade, Cosmetic Laser Specialist (Canada)
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Vascular Lesions

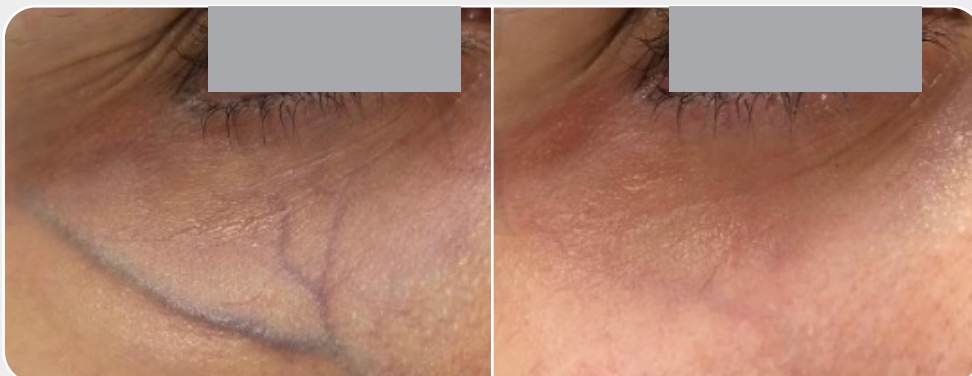
2 Treatments
Nd:YAG 1064 nm



Photos Courtesy of Hady Hamade, Cosmetic Laser Specialist (Canada)
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Vascular Lesions

1 Treatment
Nd:YAG 1064 nm



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Light & Bright™ Treatments

Telangiectasias, Diffuse Redness

5 Treatments

VL 555, PR 530, 1550 nm



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Skin Resurfacing

2 Treatments

VL 555, 1550 nm



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Light & Bright™ Treatments

Skin Resurfacing

1 Treatment

VL 555, 1550 nm, Nd:YAG 1064 nm



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Photorejuvenation, Skin Resurfacing

1 Treatment

PR 530, 1550 nm



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Light & Bright™ Treatments

Scars & Skin Resurfacing

2 Treatments

VL 555, PR 530, 1550 nm



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Photorejuvenation, Skin Resurfacing

2 Treatments

VL 555, 1940 nm



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Light & Bright™ Treatments

Acne and Skin Resurfacing

6 Treatments
PR 530, 1550 nm



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Acne and Skin Resurfacing

8 Treatments
PR 530, 1550 nm



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Light & Bright™ Treatments

Acne and Skin Resurfacing

6 Treatments
PR 530, 1550 nm



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