# A study of the efficacy and safety of Non-ablative Fractional Laser in the treatment of thyroidectomy scars

**NCT ID not yet assigned**

**Unique Protocol Id: S2024-594-01**

**Version Date: December 19, 2024**

Dear Participant,

We sincerely invite you to participate in a study titled "Non-Ablative Fractional Laser Therapy for the Effectiveness and Safety Study of Thyroid Postoperative Scars." This informed consent form provides you with relevant information to help you understand this clinical trial. Before deciding to participate in the trial, please read the following content carefully. If you have any questions or do not understand any medical terms, please ask the study doctor for a detailed explanation.

Please read the following information carefully, as it will help you understand the purpose of the trial, the design and process of the trial, the potential benefits, risks, and discomforts associated with participation, so that you can make an informed decision about whether to participate in this trial.

**I. Research Background**

Aesthetic outcomes have become an increasingly important component of patient satisfaction following surgery, with postoperative scars being a significant determining factor. "How to fade scars more quickly and make them unnoticeable at social distances" is usually the most concerning issue for patients after trauma or surgery and also a common challenge for physicians. Recent research has focused on scars caused by open thyroidectomy.

Thyroidectomy is commonly performed for thyroid cancer, which is one of the most common tumors in the head and neck region, with surgery being the primary treatment method. As a form of invasive procedure, surgery causes pathological changes in normal skin tissue, ultimately leading to scar formation. After thyroid surgery, scars can cause itching, pain, and traction at the affected site. Due to the special location of the thyroid gland, scars are often exposed on the body surface. Even minor scars can affect patients' emotional states and cause psychological burdens, especially in young women. Some patients may even refuse surgical treatment due to concerns about scarring.

Currently, clinical scar treatment measures mainly include topical medications, compression therapy, local injections, surgery, and radiation therapy. While some patients achieve satisfactory results, these methods are often associated with numerous side effects, such as skin atrophy, thinning, pigmentation, ulceration, and necrosis. Therefore, effective prevention and treatment of postoperative scars and reduction of local side effects after scar

regression are of great importance.

In 1993, the scar-improving effects of pulsed dye lasers were first reported. Over the past two decades, with the advancement of fractional technology, laser treatment for scars has made significant progress. Fractional laser therapy for scars has been proven to be effective, and many studies have applied fractional lasers to the treatment of thyroid postoperative scars. Multiple domestic and international studies have shown that non-ablative fractional laser therapy for thyroid postoperative scars is highly effective, especially when used early within one month after surgery.

The device used in this study, the 1565 nm ResurFX non-ablative fractional laser from Lumenis M22, scans in a fractional manner to create non-ablative matrices with diameters of 50-110 μm. The thermal coagulation holes can reach a depth of 1000 μm and are surrounded by normal tissue. The heat is conducted to the reticular layer of the dermis, stimulating the release of inflammatory mediators, activating fibroblasts, and promoting collagen regeneration and skin remodeling. Indications include periorbital fine lines, enlarged pores, melasma, rough and dull skin, surgical scars, acne scars, stretch marks, and striae. The advantages of the 1565 nm non-ablative fractional laser therapy include: the stratum corneum remains intact, the micro-holes and surrounding normal tissue allow for rapid wound healing, with complete epidermal cell regeneration within 24 hours; fiber lasers are directly excited, with fibers serving as both the laser medium and the light waveguide, offering high precision, high power, high tolerance, high stability, small size, and energy-saving features; advanced scanning technology creates precise, uniform, and consistent micro-beam energy delivery; CoolScan™ technology enables controllable non-sequential emission of micro-beams, extending the interval between micro-beams compared to traditional sequential scanning, reducing heat accumulation, thereby reducing patient discomfort and minimizing post-treatment erythema and edema; contact cooling technology enhances patient comfort.

To date, no laser-related parameters for the treatment of thyroidectomy scars have been established, such as high energy with low density or low energy with high density. It is essential to continue accumulating clinical data to further optimize laser treatment strategies for thyroid surgical scars and other types of scars. The laser device used in this study, ResurFX™, is based on the Lumenis M22 platform and uses the ResurFX non-ablative

fractional laser handpiece. This study aims to explore the efficacy and parameter settings of 1565 nm non-ablative fractional laser therapy for thyroid postoperative scars. We will conduct a prospective, self-controlled study to investigate the effectiveness and safety of 1565 nm non-ablative fractional laser therapy for thyroid postoperative scars.

This study has been approved by the Medical Ethics Committee of the PLA General Hospital, allowing clinical research to be conducted at this research center.

**II. Purpose of the Trial**

1. Effectiveness Study: To compare the effectiveness of 1565 nm non-ablative fractional laser therapy for thyroid postoperative scars with the control side.

2. Safety Study: To evaluate any adverse events and/or adverse reactions related to 1565 nm non-ablative fractional laser therapy during and after treatment.

**III. Research Content and Design**

This study plans to enroll 120 patients. A prospective, self-randomized controlled, open-label research method will be used. At baseline, the thyroidectomy scar on the anterior midline of the neck will be divided into two equal parts by the midline. One side will be randomly selected as the study side for 1565 nm non-ablative fractional laser therapy using a random number generator, while the other side will serve as the control side with sham treatment (laser probe contact with the skin without energy). Results and any adverse events and/or adverse reactions during and after treatment will be recorded to assess the effectiveness and safety of 1565 nm non-ablative fractional laser therapy for thyroid postoperative scars.

The trial will proceed as follows:

1. Screening Period (-2W to -D1)

After signing the informed consent form, the following information will be collected and checked:

Demographic information: including gender, age, Fitzpatrick skin type, skin type (dry, combination, oily), ease of tanning (within 12 hours, 24 hours, 3 days, or not at all), smoking history (whether smoking, duration), height, and weight.

Thyroid cancer history: including thyroid cancer histological type (papillary thyroid carcinoma, follicular thyroid carcinoma, oncocytic carcinoma, poorly differentiated thyroid

carcinoma, undifferentiated thyroid carcinoma, medullary thyroid carcinoma), tumor size, presence of lymph node metastasis, surgical procedure (total/near-total thyroidectomy, unilateral thyroid lobectomy + isthmusectomy, unilateral thyroid lobectomy + isthmusectomy + subtotal contralateral lobectomy, thyroid lobectomy, neck lymph node dissection), and surgical time.

Scar treatment history: including local corticosteroid injections, compression therapy, laser therapy, drug therapy, irradiation, ultrasound therapy, cryotherapy, systemic chemotherapy, zinc application, surgical excision, etc.

Additionally, allergy history and other past medical history will be collected, including diabetes, hypertension, neuromuscular diseases, bleeding/coagulation disorders, immunodeficiency, chronic liver disease, anemia, heart disease, etc.

After collecting all the information, the study doctor will assess whether you are eligible to participate in this study according to the inclusion and exclusion criteria of the study protocol. If you are not eligible, your study doctor will inform you of the specific reasons. If you are eligible, you will be assigned a random number, and the thyroidectomy scar on the left and right sides of the anterior midline of the body will be assigned numbers 0 and 1, respectively. A random number generator will be used to determine whether the left or right side will be the study side, with the other side serving as the control side.

Inclusion Criteria for Participants:

1. The patient is conscious, without intellectual disabilities or cognitive difficulties, understands, and signs the informed consent form.

2. Males and females aged 18 to 70 years old.

3. Fitzpatrick skin types I to V.

4. Women of childbearing age must use contraception within three months before enrollment.

5. Patients who have undergone traditional thyroidectomy through the neck within 15 days postoperatively, with a visible surgical incision along the anterior midline of the neck; or patients who have undergone traditional thyroidectomy through the neck within one year postoperatively, with a visible linear hypertrophic surgical scar along the anterior midline of the neck.

6. Able to comply with all visit, treatment, and assessment plans and requirements.

Exclusion Criteria for Participants:

1. Need for modified radical neck dissection or reoperation, or other surgical plans during the trial period that may affect treatment and follow-up.

2. Previous neck surgery.

3. Pregnant, planning to become pregnant during the study period, less than three months postpartum, or less than six weeks after completing breastfeeding.

4. History of keloid or delayed wound healing.

5. Uncontrolled medical conditions.

6. History of psychiatric disorders.

7. Skin tumors or skin inflammation in the treatment area.

8. Active infection in the neck area or systemic infection.

9. Oral photosensitizing drugs or retinoid drugs within six months before screening.

10. Use of anticoagulants, corticosteroids, immunosuppressants, or other drug treatments within three months before screening.

11. Exposure to strong ultraviolet radiation causing neck desquamation, erythema, or other symptoms within one month before screening.

12. Participation in other drug/medical device clinical trials within one month before screening or planned participation during the study period.

13. Use of any other treatments for thyroid postoperative scars other than silicone gel sheets and topical medications before the start of treatment.

14. Use of silicone gel sheets or topical medications for thyroid postoperative scars within seven days before the start of treatment.

15. Allergy to compound lidocaine cream or its components, with no alternative available.

16. Other conditions that the investigator believes may affect compliance or make the patient unsuitable for this study.

2. Baseline (D0)

For participants deemed suitable for this study, the thyroidectomy scar on the left and right sides of the anterior midline of the body will be assigned numbers 0 and 1, respectively.

A random number generator will be used to determine whether the left or right side will be the study side, with the other side serving as the control side. Before the first treatment, baseline data will be collected, including: ultrasound assessment of the scar (including echo width, depth, and intensity), mVSS score (including color, vascularity, pliability, thickness, pain, and itching), scar color, scar area measurement, POSAS score (including patient scar assessment scale: pain, itching, color, hardness, thickness, irregularity; observer scar assessment scale: vascularity, pigmentation, thickness, roughness, pliability, surface area), MSS score (including visual analog scale, color, luster, contour, deformation, texture), SF-36 score (including health and daily activities, your feelings, overall health status), and standardized assessment (two physicians' on-site blinded assessment, two physicians' blinded assessment based on photographs, patient assessment).

3. Treatment Period (D0 to M5)

All participants will begin intervention treatment one week after suture removal (approximately 15 days post-thyroidectomy) or within one year after thyroidectomy. Before laser treatment, compound lidocaine cream will be applied to the entire scar area for 60 minutes. The neck will then be cleaned with water and dried with sterile gauze. Both the doctor and the participant will wear protective goggles.

The specific treatment intervention is as follows:

Study side: The treatment device is the 1565 nm ResurFX non-ablative fractional laser from Lumenis M22. The reference parameters are spot diameter 10 to 16 mm, energy 40 to 45 $mJ/cm^2$, spot density 150 to 200 per $cm^2$, and 1 to 2 passes. During treatment, the laser probe will be in close contact with the patient's skin, with each spot overlapping by less than 10%. Each laser treatment will be performed by the same dermatologist who will not participate in the outcome assessment. Participants are advised to maintain good skin hydration, avoid ultraviolet exposure, and use sunscreen (SPF 50+) after treatment.

Control side: Sham treatment will be given (laser probe contact with the skin without energy).

Treatment-related adverse events and/or adverse reactions will be collected after treatment and before the next treatment.

Treatment cycle:

After the first treatment, subsequent treatments will be conducted monthly, with a visit window of ±3 days, for a total of six treatments over five months. Before each monthly visit and treatment, the following information will be collected: ultrasound assessment of the scar (including echo width, depth, and intensity), mVSS score (including color, vascularity, pliability, thickness, pain, and itching), scar color, scar area measurement, POSAS score (including patient scar assessment scale: pain, itching, color, hardness, thickness, irregularity; observer scar assessment scale: vascularity, pigmentation, thickness, roughness, pliability, surface area), MSS score (including visual analog scale, color, luster, contour, deformation, texture), SF-36 score (including health and daily activities, your feelings, overall health status), and standardized assessment (two physicians' on-site blinded assessment, two physicians' blinded assessment based on photographs, patient assessment). Treatment-related adverse events and/or adverse reactions will also be collected after treatment and before the next treatment.

4. Post-treatment Follow-up Period (M8, M11, M17):

Three months, six months, and one year after the last treatment, participants will be followed up. Each follow-up visit window is ±3 days, for a total of three follow-ups. During each follow-up, the following information will be collected: ultrasound assessment of the scar (including echo width, depth, and intensity), mVSS score (including color, vascularity, pliability, thickness, pain, and itching), scar color, scar area measurement, POSAS score (including patient scar assessment scale: pain, itching, color, hardness, thickness, irregularity; observer scar assessment scale: vascularity, pigmentation, thickness, roughness, pliability, surface area), MSS score (including visual analog scale, color, luster, contour, deformation, texture), SF-36 score (including health and daily activities, your feelings, overall health status), and standardized assessment (two physicians' on-site blinded assessment, two physicians' blinded assessment based on photographs, patient assessment), as well as collection of any adverse events and/or adverse reactions. The M17 visit will also include a histological assessment (scar thickness in HE-stained sections, average percentage area of collagen fibers in Masson's trichrome-stained sections, average percentage area of elastic fibers in elastic fiber-stained sections, average percentage of MMP9-positive cells).

**IV. Benefits, Risks, and Compensation**

1. Benefits of Participating in This Study

Participating in this clinical study may potentially improve thyroid postoperative scars and achieve aesthetic effects. The study promises that after the completion of the study, the control side treatment will be provided to the patients. It is also possible that the treatment may be ineffective for you, and you may not directly benefit from this study. However, your participation will contribute to the future treatment of non-ablative fractional laser therapy for thyroid postoperative scars. We extend our gratitude to you in advance.

2. Potential Risks

Although the laser device ResurFX™ used in this study has been used in numerous medical institutions worldwide for many years and is considered a safe, comfortable, and non-invasive technology and product, there are certain risks and unpredictability associated with the treatment. Complications may occur. Mild redness, burning sensation, and dryness may be experienced locally after laser treatment, but these usually subside on their own within a few hours or days. Although rare, the following complications should be noted: pigmentation, erythema, vesicles, purpura, ulcers, infections, etc.

If you experience any of the above or other discomforts after treatment, the following interventions can be taken: maintain good skin hydration, avoid ultraviolet exposure, and use sunscreen (SPF 50+) after treatment. Maintain good 作息 time and lifestyle habits.

3. Compensation

There will be no charges for participating in this clinical study. The laser device ResurFX™ used in this study will be provided free of charge. If other operational services are involved, the department will cover the related costs. No other financial compensation will be provided.

**V. How to Handle Damage Resulting from Participation in This Study**

The laser device ResurFX™ used in this study has been used in numerous medical institutions worldwide for many years and is considered a safe, comfortable, and non-invasive technology and product. We will do our utmost to prevent and address any harm that may result from the study treatment. If damage occurs during treatment, the study group's medical expert committee will determine whether it is related to the device and technology trial. The study doctor will be responsible for providing appropriate treatment measures for you. In the

event of serious damage related to the study, you will receive free treatment and compensation in accordance with relevant regulations. Even if you have signed this informed consent form, you still retain all your legal rights.

**VI. Right to Refuse Participation or Withdraw from the Study**

You have the right to choose not to participate in this study or to withdraw at any stage of the trial without providing any reason. Your medical treatment and rights will not be affected in any way. If you decide to participate in this study, please sign this informed consent form to indicate your agreement.

If you or your guardian request to withdraw from the study treatment and revoke the informed consent during the study period, your medical treatment and rights will not be affected in any way.

We sincerely hope that you will complete the entire study process if you choose to participate in this study.

**VII. Privacy and Confidentiality**

During the study, your personal information such as name and gender will be replaced with codes or numbers and strictly confidential. Only relevant doctors or researchers will have access to your information, and your privacy will be well protected. Study results may be published in journals, but no personal information will be disclosed. The hospital will retain all records related to this study, as well as relevant hospital and office records. Unauthorized individuals will not have access to this information.

If you agree to participate in this study, your medical records may be reviewed by regulatory authorities, members of the ethics committee, and research center staff to ensure the appropriateness of the study conduct. By signing the informed consent form, you agree to allow these individuals to review your medical records through on-site monitoring. As required by law, your medical records will not be disclosed.

**VIII. How to Obtain Help During the Study**

You can always access information and updates related to this study. If you have any questions regarding this study, please contact [Name of the Teacher] at [Contact Number].

If you have any questions regarding the rights of participants in this study, you can contact the Medical Ethics Committee of the PLA General Hospital at phone number: 010-

66937166.

**Informed Consent Form Signature Page**

After being fully explained by the researcher, I understand the content and purpose of this study. After fully understanding the content of the informed consent form and the potential benefits and risks associated with participating in this trial, I voluntarily agree to participate in this trial and make the following statement:

I have read the content of this informed consent form and understand the nature, purpose, and potential adverse reactions of this study. My questions have been satisfactorily answered.

I will comply with the requirements of the informed consent form and fully cooperate with the researchers to provide accurate and objective information about my health status and related conditions before, during, and after the follow-up periods of this study. I understand that participation in this trial is voluntary.

I have the right to choose not to participate in this trial or to withdraw at any time by notifying the researcher without facing discrimination or retaliation. My medical treatment and legal rights will not be affected in any way.

I have been informed that the doctors involved in this study, the heads of relevant departments, and the ethics committee of the First Medical Center of the PLA General Hospital have the right to review study records and case files. I agree that the above-mentioned individuals may directly access my study records and understand that this information will be handled confidentially.

I will receive a copy of the signed "Informed Consent Form."

After careful consideration, I voluntarily agree to participate in this clinical study.

Participant's Name (please print in block letters): _____

Participant's Signature: _____

Participant's Contact Number: _____

Date and Time of Signature: _____

I confirm that I have fully explained the details of this study to the participant, especially the potential risks and benefits associated with participating in this study, and provided a copy of the signed informed consent form with both signatures and dates to the participant.

Researcher's Name (please print in block letters): _____

Researcher's Signature: _____

Researcher's Contact Number: _____

Date and Time of Signature: _____