Clinical Study to Evaluate the Efficacy and Safety of Matrix Pro Treatment for Facial, Submental and Neck Laxity

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Evaluate the efficacy and safety of the Matrix Pro Applicator on Profound Matrix system in the treatment of facial, submental and neck laxity.

Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON57184

Source
ToetsingOnline

Brief title
PFX22003

Condition

- Epidermal and dermal conditions

Synonym
sagging of skin, skin conditions

Research involving
Human

Sponsors and support

Primary sponsor: Candela Corporation
Source(s) of monetary or material Support: Candela Corporation;een commerciele fabrikant van medische hulpmiddelen

Intervention

Keyword: Candela Profound Matrix System, Dermatological, Electrocoagulation, Matrix Pro applicator, Radiofrequency microneedling

Outcome measures

Primary outcome

Evaluation of facial, submentum, and neck laxity reduction based on correct identification of subject*s post-treatment photograph (study endpoint: 3 months post last-treatment) and at least a 1-point decrease on the Facial Laxity Rating Scale (FLRS) at study endpoint relative to baseline as rated by the 3 independent blinded raters. Success criteria is defined as a responder rate of at least 70% of study subjects meeting the co-primary endpoints by at least 2 of the 3 independent blinded raters.

Adverse events will be tabulated by type, severity, relation to treatment, action taken and outcome.

Secondary outcome

Investigator FLRS at 1- and 3-month follow up

IGAIS at 1- and 3-month follow up

Subject GAIS at 1- and 3-month follow up

Subject satisfaction questionnaire at 1- and 3-month follow up

Subject ratings of treatment discomfort/pain immediately post-treatment via

Numerical Rating Scale (NRS)

Local skin response to treatment will be assessed immediately after treatment

by type and severity according to the Post-Treatment Severity Scale

Study description

Background summary

In recent years, there has been a growing demand for non-surgical procedures to improve skin imperfections. As demand from patients and healthcare providers has grown, new treatments and technologies have also been introduced. This technique creates a small damage in the skin using needles in combination with radio waves, allowing a natural healing response of the skin. This technique is already widely used in practice. Experience and research show that this technique using radio waves is safe, even for people with skin that is difficult to treat, such as dark skin. Handpieces are used that are connected to a central system ('console'). The Profound Matrix system has three handpieces: Matrix Pro, Sublative RF and Sublime applicators. The Matrix Pro handpiece uses a combination of radio waves and microneedles and is the handpiece that will be used in this study.

The Matrix Pro applicator uses new and advanced technology to provide users with a customizable treatment approach based on patient needs. The Matrix Pro applicator features an array of the thinnest microneedles on the market that fractionally deliver short-pulse RF energy to the skin. The device design ensures improved patient comfort, reduced risk of side effects and reduced downtime for patients, while delivering clinical results via RF microneedle technology. Additionally, the Matrix platform is the first of its kind and uniquely equipped with impedance monitoring and depth intelligence technology and software to ensure accurate energy delivery, provide real-time user feedback and enable consistent patient outcomes.

The combination of fractional RF microneedle technology coupled with the unique impedance feedback and depth intelligence technology highlights the advantages of the Matrix Pro applicator over competing devices and comparable energy-based aesthetic technology. There is an unmet patient need for nonsurgical options for the treatment of laxity. Although surgical methods and aggressive laser treatments (such as CO2 lasers and ablative lasers) are considered the gold

standard for skin laxity complaints, they face a high rate of complications and serious risks for patients, as well as pain and discomfort and prolonged periods of downtime. . The new Matrix technology offers this effective non-surgical alternative without the potential risks of current treatment modalities.

Study objective

Evaluate the efficacy and safety of the Matrix Pro Applicator on Profound Matrix system in the treatment of facial, submental and neck laxity.

Study design

This is a non-randomized, multi-center, open-label prospective clinical trial evaluating clinical treatments with the Matrix Pro Applicator on the Profound Matrix delivery system for the improvement of facial and/or submental and neck laxity.

There will be up to three (3) study treatments, each 6 weeks ± 2 weeks apart.

Follow-up visits will occur at the following timepoints:

1-month (4 weeks ± 2 week) follow up (after last treatment)

3-month (13 weeks ± 2 weeks) follow up (after last treatment)

Additional follow-up visits may be required per Sponsor and PI discretion

Study burden and risks

The treatments involve risks of skin reactions that also occur with other aesthetic treatments. The skin reactions are usually at the treatment site and often no more than mild to moderate. They often disappear a few days after treatment.

In addition, the subjects will only be asked to give their satisfaction and pain scores and the burden will consist of no more than the time the subject invests in participation. This extra time commitment is limited compared to comparable treatments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Healthy female and male subjects between 18 to 84 years of age with Fitzpatrick Skin Type I - VI.
2. Willing to receive Profound Matrix treatments with Matrix Pro applicator
3. Able and willing to comply with the treatment/follow-up schedule and comply with all study (protocol) requirements.
4. Willing to provide signed, informed consent to participate in the study
5.Willing to have photographs and images taken of the treated areas to be used in evaluations, publications, presentations, and marketing materials (Subject identity will be masked).

Exclusion criteria

1. Pregnant or planning to become pregnant, having given birth less than 3 months prior to enrollment into the study, and/or breast feeding
2. Pacemaker or internal defibrillator or any active electrical implant anywhere in the body
3. Superficial metal or other implants in the treatment area, except

superficial dental implants, unless the implants can be removed or covered with rolled gauze during treatment
4. Skin cancer in the treatment area or history of melanoma
5. History of current cancer and/or subject has undergone chemotherapy within the last 12 months
6. Severe concurrent conditions, such as cardiac disorders
7. Impaired immune system or use of immunosuppressive medications, except for topical products and inhaler medications per investigator discretion
8. Herpes Simplex Virus (HSV) in the intended treatment area unless treated following a prophylactic regimen
9. Poorly controlled endocrine disorders such as poorly controlled diabetes
10. Active skin condition in the treatment area such as skin infection, sores, psoriasis, eczema, rash, or open wounds
11. History of abnormal wound healing, keloid, or hypertrophic scar formation, as well as very thin or fragile skin
12. History of collagen vascular disease or vasculitic disorders
13. Known allergy to medication to be used during treatments such as allergy to topical anesthetic (e.g., lidocaine)
14. History of systemic corticosteroid therapy in past six months
15. Tattoos or permanent makeup in the intended treatment area
16. Excessively tanned skin
17. Facelift in the last 12 months
18. Aesthetics treatments/procedures (e.g., facial resurfacing and deep chemical peeling) within the last 4 months within the intended treatment area
19. Neuromodulator injections (e.g., Botox®), collagen, non-permanent dermal filler, fat injections or other methods of augmentation with injected biomaterial in the intended treatment area within the last 3 months
20. Permanent synthetic fillers (e.g., silicone) in the intended treatment area
21. Absorbable facial threads within the last 12 months or non-absorbable facial threads within the intended treatment area
22. In the opinion of the Investigator, the subject is unwilling or unable to adhere to the study requirements or is otherwise unsuitable for study participation.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	Matrix Pro applicator on Profound Matrix system
Registration:	No

Ethics review

Approved WMO

Date:	18-09-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84830.000.24