SkinStylus Microneedling System

Protocol for Clinical Study

Treatment of Ventral Torso Hypertrophic Scars

Trial Sponsor:
Esthetic Education LLC
7950 E. Acoma Drive
Suite 100
Scottsdale, AZ 85260

Principle Investigator:
Dr. Toni Stockton, MD

Trial number – 2017-002

04 August 2017

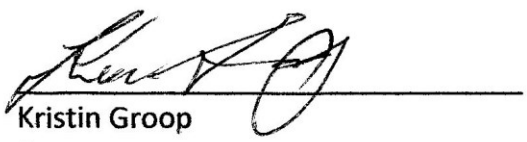
Protocol Synopsis for EE 2017-02

Title of Study:	The Clinical Efficacy And Safety Of SkinStylus Microneedling System for Ventral Torso Hypertrophic Scars: Clinical Results With 30 Patients
Principal Investigator:	Dr. Toni Stockton, M.D. F.A.A.D
Study Design:	Blinded, bias minimized comparison of pre and post treatment photographs
Target Population:	General population over the age of 22
Duration of Study:	Approximately 6 months
Treatment	SkinStylus® Microneedling
Study Objective:	This is a study to evaluate the efficacy of SkinStylus Microneedling for ventral torso hypertrophic scars

PROTOCOL APPROVAL PAGE

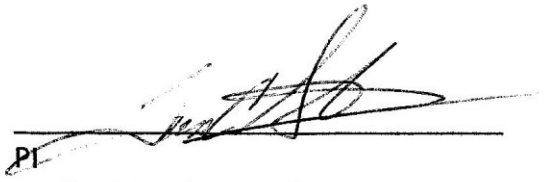
We the undersigned have reviewed this protocol and agree that it contains all relevant information and appropriate safeguards for human participants as required by the UK MHRA, GCP, ICH and USFDA requirements.

We further agree that the protocol will be executed exactly as written and approved by the Institutional Review Board (IRB) and/or Ethics Committee. Any change required or proposed shall be reviewed by the IRB/Ethics Committee prior to its implementation.



Kristin Groop
Owner
Esthetics Education, Inc.

8/21/17
Date



PI
Dr. Toni Stockton, MD

8/8/2017
Date

Investigator Signature Sheet

I have read the attached protocol and agree that it contains all the necessary details for performing the study.

I will provide copies of this protocol and of the preclinical information on the investigational product, which was furnished to me by the sponsor, to all members of the study team responsible to me who participate in the study. I will discuss this material with them to assure that they are fully informed regarding the study device and the conduct of the study.

Once this protocol has been approved by the Institutional Review Board (IRB), I will not modify it without obtaining the prior approval of the sponsor and of the IRB. I will submit the protocol modifications and/or any informed consent form modifications to the sponsor and the IRB, and approval will be obtained before any modifications are implemented.

I understand the protocol and will work according to it, the Code of Federal Regulations, the principles of Good Clinical Practice (current ICH guidelines), and the Declaration of Helsinki (1964) including all amendments up to and including the Scotland revision (2000).

PI
Dr. Toni Stockton, MD

8/8/2017
Date

General Information

Study Title - *The Clinical Efficacy And Safety Of SkinStylus Microneedling System for Treatment of Ventral Torso Hypertrophic Scars: Clinical Results With The SkinStylus® System for 30 Patients.*

A. Background

Device under investigation – The SkinStylus® Microneedling System is a handheld device that creates channels as well as microinjuries into the skin, by virtue of a 1A DC motor that rapidly reciprocates an array of 32 gauge microneedles that are no longer than 2.5mm. The device consists of a power source, a motor body with depth adjustment, a removable nosecone interface, and a disposable, single use cartridge containing an array of microneedles.

The power source consists of two separate systems. One option is a rechargeable lithium-ion battery that delivers no more than 5 volts DC and 1 amp of current to power the motor. The other option consists of an AC wall adaptor that converts 110v AC into 5v DC. A power cord connects the wall adaptor to the device via a USB connector and a standard 1/8" headphone plug on the device side.

The motor body is comprised of anodized aluminum with a dial mechanism that controls the depth of penetration of the microneedles from 0 mm to a maximum of 2.5mm.

The removable nosecone interface provides the SkinStylus® the unique ability to have an interface between the motor and the cartridge that can be autoclave sterilized.

The SkinStylus® cartridge is designed in three configurations, an 11 needle array with all needles @2.5mm, 36 needle array with all needles @2.5mm and a 36 needle array with 18 needles @2.5mm and 18 needles @1.0mm alternating in row.. The needle array is housed in a specially designed (patented) cartridge housing that prevents liquids from entering the motor body via the inside lumen of the cartridge. This has been an issue with other microneedling systems.

Research Supporting Safety

The SkinStylus® will be used to improve the appearance of ventral torso hypertrophic scars, such as abdominoplasty and breast augmentation scars.

Microneedling hypertrophic scars has an impeccable safety record as evidenced by the 30 articles attached at the end of this letter as a Resource List. Most notably in 2017, researcher Hou, et al, performed a comprehensive overview of the available literature regarding the efficacy and safety of microneedling performed for dermatologic conditions in human subjects. Hou's group stated the following with respect to adverse events associated with all of the studies analyzed,

"Microneedling is associated with a low rate of AE. Histologic examination taken 24 hours after therapy demonstrates an intact epidermis and no change in melanocyte number, resulting in limited downtime and minimal risk of dyspigmentation.[5] Adverse effects are rare and temporary, with transient post-procedure erythema being most common.[6]"

This study protocol was based, in part, on a microneedling study performed by Schwarz M, and Laaff H. titled, *"A prospective controlled assessment of microneedling with the Dermaroller device."* and published in Plastic Reconstructive Surgery 2011; 127:146e–148e. This study was reviewed by Hou et. Al and there were no adverse events reported in this study.

Indications for Use/Intended Use

The purpose of the trial is to provide objective evidence the SkinStylus may be used safely and effectively for the treatment of ventral torso hypertrophic scars.

Inclusion Criteria

1) Participants must be at least 23 years old
2) Each participant shall have at least one suitable ventral torso hypertropic scar of sufficient length that it may be easily visualized in two halfs.
3) The scar(s) present along a flat surface suitable for application of the SkinStylus® device and consistent medical photography.

Trial Summary

Each participant shall have at least one suitable ventral torso hypertropic scar of sufficient length that it may be easily visualized in two halfs. At the conclusion of the trial all participants shall be provided with a cross over treatment on the non-treated

portion of the scar identical to that which was provided within the trial for the purpose of "evening" the ventral torso hypertrophic scar. This is entirely voluntary and participants may decline the treatment if they wish.

Efficacy (primary) Endpoint

The Visual analogue Scale (VAS) scar scoring system was defined and validated by Duncan et al. in 2006. This scale consists of a 10-cm line representing scar quality, with 0 representing normal skin and 10 indicating a poor scar. The assessor places a mark along the line to represent the appearance of the scar. This mark is then translated into a score by measuring its position on the 10-cm line to one decimal place.

Visual Analogue Scale (VAS) scar scoring system

The improvement in the appearance of the scar will be evaluated using a paired t-test for the mean difference. The paired t-test will be used to compare the treated side and untreated (control) side of the scar to determine if there is a statistically significant improvement in the average difference of Visual Analogue Scale (VAS) measurements (difference determined by VAS measurements pre- and post-treatment). Efficacy will be determined by at least 2 out of 3 blinded physician evaluators, comparing baseline photographs to photographs taken approximately 90 days after the last treatment.

Subject Feedback (patient perception) Endpoint - Patient satisfaction will be determined by evaluating scores on a subject satisfaction survey to be completed approximately 90 days after the last treatment. Subjects will indicate on the survey whether they saw improvement in the areas treated. Baseline and 90 day post-treatment photographs will be made available for viewing by the patient for their assessment. Subjects will have access to a full length mirror in a room lit by natural light. T-tests will be used to determine if on average patients had a good experience and saw improvement in the appearance of the scar while being treated by evaluating ratings from the Self-Assessed Scar Improvement Scale and the Subject Global Aesthetic Improvement Scale. For the Self Assessed Scar Improvement Scale, ratings of 1 and

greater (1=1%-25% improvement, 2=26%-50% improvement, 3=51%-75% improvement, and 4=76%-100% improvement) indicate that patients were satisfied with the treatment. For the Subject Global Aesthetic Improvement Score, ratings of 3 and lower (1=very much improved, 2=much improved, 3=improved) indicate that patients were satisfied with the treatment.

The Subject Satisfaction Survey is a 6-point scale (1-6) describing an overall assessment as follows:

Rating	Description
6	Very satisified
5	Satisfied
4	Somewhat satisfied
3	Somewhat dissatified
2	Dissatified
1	Very dissatified

Safety Endpoint

For the purposes of determining a safety endpoint, the following conditions are not considered adverse incidents, have been known to occur with similar microneedling procedures, and are expected to occur as part of a normal and necessary healing process after each treatment:

a) Erythema – superficial reddening of the skin in the area treated
b) Edema – mild swelling in the area treated
c) Crusting – a scab
d) Mild to moderate pain during treatment that resolves within 2 hours after treatment
e) Hypo/hyperpigmentation, the skin in the treatment area becomes temporarily lighter or darker than the surrounding skin but resolves with 90 days of treatment
f) Mild Pruritis – mild itching around the treatment area
g) Mild to moderate petechiae – pinpoint bleeding that resolves (stops) within 1 hour of treatment

For the purposes of determining a safety enpoint, the following six conditions have been known to occur with similar microneedling procedures and are considered adverse incidents regardless if they result in the need for medical intervention or not:

1) Moderate to severe pruritis– severe itching not resolving within 24 hours
2) Moderate to severe pain that continues more than 2 hours after the end of the treatment.
3) The presence of active infection in the treatment area after treatment

4) Fever developing after treatment
5) Hypo/hyperpigmentation, the skin in the treatment area becomes lighter or darker than the surrounding skin and does not resolve with 90 days of treatment
6) Moderate to severe petechiae – pinpoint bleeding that does not resolve within 1 hour of treatment

Safety endpoint analysis
Subjects will be photographed approximately 180 days after the last treatment and asked about the incidence and/or persistence of any of the above six listed conditions considered to be adverse incidents.

Patient Population
The patient cohort shall be comprised of not less than 35 qualified persons (using the inclusion criteria). Any more than 5 dropouts shall be replaced so that a total of at least 30 participants complete the trial.

Regulatory Compliance
The trial will be conducted in compliance with this protocol, GCP, and the applicable regulatory requirements of the United States.

The trial shall be under the supervision of a duly accredited Institutional Review Board or equivalent ethics oversight committee. The SkinStylus® and this trial is considered a Non-Significant Risk (NSR) as the device is being used entirely within its foreign agency cleared performance specification.

The trial shall be monitored at planned and at unannounced intervals by a Registered Nurse who has appropriate training in the conduct of medical research. The RN Monitor shall ensure the trial is conducted according to the requirements of the approved protocol. In addition to examining the Case Report Forms (CRF) for each participant the RN Monitor shall review the digital photographs taken and will report to the PI any instance where an injury may have occurred.

The PI and all sub-PI's shall be appropriately trained in the *Protection of Human Subjects* as provided by the National Institute of Health or equivalent body.

C. Trial Design

1. The SkinStylus has been designated as a non-significant risk and therefore will be granted an Investigational Device Exemption (IDE). There are no meaningful

changes to the SkinStylus® instructions for use and specifically no new risks will be introduced.

2. There are three endpoints under investigation. The primary endpoint is a statistically significantly improvement using the VAS scale on page 7. The secondary endpoint is patient feedback by the Subject Satisfaction Survey on page 7. The third endpoint is safety related and is the absence of adverse incidents as previously defined.
3. The trial shall be blinded and bias minimized in that three (3) physicians who are either dermatologists or plastic surgeons (and not affiliated with the trial or Esthetic Education LLC) shall review the baseline and treatment photographs and score them using the VAS scale (see page 7).
4. Inclusion Criteria - patients age 23 years or older as described on page 6. The subjects shall all be volunteers. Subjects shall not be hand picked or otherwise manipulated or shown favor. There will be some effort expended to ensure reasonable representations of both sexes and of all Fitzpatrick Skin Types as shown below:

Type	Score	Description
I	0-6	Skin always burns; never tans. (Pale peach, blond, or red hair, blue eyes, freckles
II	7-13	Skin usually burns, tans minimally (peach; fair; blond or red hair; blue, green, or hazel eyes)
III	14-20	Skin sometimes mild burn, tans uniformly (light brown; fair with any hair or eye color)
IV	21-27	Skin burns minimally, always tans well (moderate brown)
V	28-34	Skin very rarely burns, tans very easily (dark brown)
VI	35-36	Skin never burns, always tans (deeply pigmented dark brown to darkest brown)

5. Exclusion Criteria – patients with any of the following shall be excluded from the study.
    a. Women who are or think they may be pregnant

b. Participants currently taking Coumadin/Warfarin® or heparin
c. Any type of bleeding disorder
d. Any history of keloid formation
e. Lidocaine, tetracaine, prilocaine, bupivacaine, or benzocaine hypersensitivity
f. Patients with mental disorders
g. Patients with metal implants around the proposed treatment areas
h. Patients with any undefined wasting disease (Cachexia for example)
i. Presence of an active infection in the treatment area other than mild acne
j. Presence of tumors or those who are being treated by chemotherapy or radiation therapy
k. Presence of severe cardiovascular and cerebrovascular disease
l. Presence of renal failure

6. Withdrawal from the study - the patient will be withdrawn from the study upon his/her request or if the PI determines the patient has become part of the excluded population. For example, during the trial a female participant discovers she has unexpectedly become pregnant.
7. The PI or his designee will discuss the study with each potential participant reviewing the SkinStylus® and its operation, the treatment protocol, the need of completion of the trial as written, the inclusion and exclusion criteria; the warnings and contraindications and the taking of photographs prior to obtaining informed consent. Any potential participant not meeting all the selection requirements shall not be accepted into the trial and therefore no informed consent from them shall be required.
8. Adverse Incidents – adverse incidents are defined above. The PI shall be immediately informed whenever an adverse incident, as defined above, is detected or even suspected to have occurred. The circumstances relating to adverse incidents, their resolution and the participant's condition and treatment shall be recorded on the CRF.
9. Photographs
    a. General – a digital photography system shall be used to take photographs. The system set up and the patient positioning shall be standardized across the population for both baseline and post treatment digital pictures. To the greatest extent possible the photographic equipment shall be fixed in a single location and not be moved or taken down during the trial. If the photography equipment must be moved, the exact location and orientation shall be recorded to permit the photography equipment to be reinstalled in a standardized orientation for baseline and treatment photographs. For each photograph taken the SkinStylus® settings, number and duration of treatments to the location shall be recorded in the CRF.

b. Baseline – prior to SkinStylus® treatment a digital picture of each treatment location shall be taken and a description of the hypertrophic scar shall be recorded in the CRF. The description should include skin assessment using the Fitzpatrick scale (see table on page 16).
c. 90 days following the final treatment a digital photograph using an identical technique to that used in baseline photograph shall be taken and used for evaluation
d. When taking baseline and post treatment digital pictures if the treatment location is in close proximity to the patient's face, the patient:
    - Shall not wear any makeup or skin care products in or around the treatment areas. Make-up includes any type of lipstick, mascara, eyeliner, foundation or any other article which alters the nature appearance of the skin in and around the treatment areas.
    - Patients shall not wear any jewelry in or around the treatment areas. This includes earrings; piercings; necklaces or other article which may obscure the digital photograph.
    - Patients shall not wear glasses.
    - The patient's hair shall be approximated identically in both baseline and post treatment photographs. The hair should be held up and away from the treatment areas using hairpins. Hairbands should be avoided. Preferably, the patient 's hair shall be covered using a white hair cover as is used in clean rooms
    - Patients shall be encouraged to make no facial expression to avoid altering the natural appearance of the treatment area.
    - The patient's eyes should be closed for each photograph.
e. When taking baseline and post treatment digital pictures if the treatment location is not in close proximity to the patient's face, the patient:
    - Shall not wear any makeup or skin care products in or around the treatment areas. Make-up includes any type of cosmetic, temporary tattoo or any other article which alters the nature appearance of the skin in and around the treatment areas.
    - Patients shall not wear any jewelry in or around the treatment areas. This includes piercings; necklaces or belts or other article which may obscure the digital photograph.

- The photograph shall be taken with the patient standing in a completely relaxed fashion.
- The patient's hair shall be approximated identically in both baseline and post treatment photographs. The hair should be held up and away from the treatment areas using hairpins. Hairbands should be avoided. Preferably, the patient 's hair shall be covered using a white hair cover as is used in clean rooms.

NOTE: Any personal identifying features shall be obscured electronically in order to avoid any twisting or other unintentional distortions within the photograph.

10. Dermal Spectroscope readings.
    a. General – a specialized dermal spectroscope may be used to measure the color of the skin in the treatment area. This device painlessly scans the skin and provides a melanin and redness reading in the form of an integer.
    b. For each set of data captured by the dermal spectroscope, the SkinStylus® settings, number and duration of treatments to the location shall be recorded in the CRF.
    c. Baseline – prior to SkinStylus® treatment, data readings from the dermal spectroscope of each treatment location may be taken and a description of the atrophic scar treatment areas shall be recorded in the CRF.
11. Records
    a. The CRF shall be considered the principal record of the study.
    b. The CRF shall contain all records of treatment as well as the photographs taken.
    c. The CRF shall be the only record used for source data.
    d. In consideration of HIPAA requirements, the CRF shall identify patients only by code using the first three letters of the device name and a numerical designation. For example – O17-1; O17-2, etc.
    e. The Study Coordinator (Kristin Groop) shall maintain a key which can be used to identify a particular patient, if necessary. The Registered Nurse Monitor (Terri Masaheri RN) shall have access to the key upon request.

12. Sequence of Treatment
    a. The patient shall wash the treatment area to remove dirt, cosmetics and other impurities from the treatment area.
    b. The technician administering the treatment shall further clean the treatment areas, if necessary.
    c. The hypertrophic scar to be treated shall be divided into two equal segments and the technician shall randomly choose one half to be treated.

d. The technician shall describe in the CRF, which half of the scar was treated.
e. Subsequent treatments shall only treat the same half of the scar that was initially designated the treatment side.
f. If the scar is to be locally anesthetized, the entire scar (both halves) are to be anesthesized.
g. A proprietary glide serum, EstheCeuticals® HA-Cu Serum, shall be applied prior to treatment and again as necessary. The purpose of the serum is to act as a glide and no therapeutic effect is known or anticipated. This serum has been used in several hundred microneedling treatments without any incidence of adverse events.
h. The depth settings and clinical endpoints shall be established by the PI.
i. Each participant shall receive three SkinStylus treatments .
j. Each participant shall receive one treatment using each of the three different array configurations. The order in which each is used shall be randomized at intake but a different array configuration must be used in each of the three treatments.
k. The treatments shall be not less than 12 days or more than 14 days apart.
l. The treatments shall consist of 2 to 3 passes at the targeted area over a period of 15-30 minutes.
m. While the technician may adjust the treatment settings, the treatment settings shall remain within the range specified by the PI, usually 2.5mm depth.
n. At the conclusion of treatment the technician completes the CRF as stipulated.
o. 90 days following the final treatment the post treatment photograph shall be taken and recorded in the CRF. There may be other photographs taken periodically during the trial in addition to the dermal spectroscope readings taken.
p. 180 days following the initial treatment the patients shall be evaluated to provided objective evidence of what adverse incidents, as previously defined, may have occurred.

D. Determination of Results

A panel of 3 physicians who are either dermatologists or plastic surgeons (and not affiliated with the trial or Esthetic Education LLC) shall review the baseline and post treatment photographs and score each them using the VAS scar score on page 7. A successful outcome on the primary endpoint (efficacy) shall be determined to a statistically significant improvement when comparing the score determined for the 90 day post final treatment photographs to the score determined at baseline.

A successful outcome on secondary endpoint (patient feedback) shall be determined by the evaluation of the Subject Satisfaction Survey on page 7.

The evaluation of the third endpoint (safety) shall be determined by the relative lack of adverse incidents as previously defined above.

E. Statistical Analysis for the SkinStylus® Clinical Study

The sample size for this study consisted of 30 subjects with assessable data. Performance will be evaluated by the (VAS) visual analogue scale scar score as described above from SkinStylus® treated sites and control sites at approximately 90 days after the final treatment.

The VAS scar scoring system was defined and validated by Duncan et al. in 2006. This scale consists of a 10-cm line representing scar quality, with 0 representing normal skin and 10 indicating a poor scar. The assessor places a mark along the line to represent the appearance of the scar. This mark is then translated into a score by measuring its position on the 10-cm line to one decimal place.

Measurements:

a) *Primary Endpoint:* A statistically significant improvement between the measurements taken at baseline and two weeks following the end of the treatment, on the VAS Scar Scale. The scores are determined based on a panel of three independent physicians (dermatologist and/or plastic surgeons).
b) *Second Endpoint:* The patient surveys shall be tabulated and reported. It is anticipated the patients shall have a good experience while being treated by the SkinStylus for scar revision.
c) *Third Endpoint:* - The tertiary endpoint is the relative absence of adverse incidents as previously defined.

Prior data indicate that the standard deviation of the paired differences in visual analogue scale scores is not expected to exceed 1.46.

Statistical analysis on the scoring will commence using appropriate measures for statistical significance using the standard cutoff for significance of $P<0.05$. The scoring will include the analysis of the VAS, the Subject Satisfaction Survey, and any post treatment complications.

Criterion Used:

The criterion for significance (alpha) has been set at 0.050. The test is one-tailed.

Power Findings:

The minimum power for the statistical analysis shall be least 80% power with a sample size of 30.

Resources in Support of SkinStylus® Ventral Hypertrophic Torso Scar Study

Hou A. Hou, B. Cohen, A. Haimovic, N. Elbuluk. "Microneedling: a comprehensive review." Dermatol Surg. 2017;43(3):321–39

Duncan JA, Bond JS, Mason T, et al. Visual analogue scale scoring and ranking: A suitable and sensitive method for assessing scar quality? Plast Reconstr Surg. 2006;118:909–918.

Gurtner GC, Werner S, Barrandon Y, Longaker MT. Wound repair and regeneration. Nature. 2008;453:314–321.

Thomas JR, Somenek M. Scar revision review. Arch Facial Plast Surg. 2012;14:162–174.

American Society of Plastic Surgeons. [Accessed March 5, 2013];2012 Report of the 2011 Statistics National Clearinghouse of Plastic Surgery Statistics. Available at: http://www.plasticsurgery.org/Documents/news-resources/statistics/2011-statistics/2011_Stats_Full_Report.pdf.

Gurtner GC, Dauskardt RH, Wong VW, et al. Improving cutaneous scar formation by controlling the mechanical environment: Large animal and phase I studies. Ann Surg. 2011;254:217–225.

Majid I. Microneedling therapy in atrophic facial scars: an objective assessment. J Cutan Aesthet Surg. 2009;2: 26–30.

Eilers Jr R. E., et al. "A Combination Approach to Surgical Scars." Dermatologic Surgery 42 (2016): S150-S156.

Birchall JC, Clemo r, Anstey A, et al. Microneedles in clinical practice–an exploratory study into the opinions of healthcare professionals and the public. Pharm Res. 2011;28:95–106.

A. Chambers." Unified Approach to the Treatment of Hypertrophic and Atrophic Scars." American Journal of Cosmetic Surgery Vol 33, Issue 4, pp. 176 –183, 2016

G. Fabbrocini, N. Fardella, A. Monfrecola, I. Proietti, and D. Innocenzi, "Acne scarring treatment using skin needling," Clinical and Experimental Dermatology, vol. 34, no. 8, pp. 874–879, 2009.

Alam M, Han S, Pongprutthipan M, Wareeporn D, et al. Efficacy of a needling device for the treatment of acne scars: a randomized clinical trial. JAMA Dermatol 2014;150:844–9.

Doddaballapur S. Microneedling with dermaroller. J Cutan Aesthet Surg. 2009;2:110–111.

Aust MC, Fernandes D, Kolokythas P, et al. Percutaneous collagen induction therapy: an alternative treatment for scars, wrinkles and skin laxity. Plast Reconstr Surg. 2008;121: 1421–1429.

Nofal E, Helmy A, Nofal A, Alakad R, et al. Platelet-rich plasma versus CROSS technique with 100% trichloroacetic acid versus combined skin needling and platelet rich plasma in the treatment of atrophic acne scars: a comparative study. Dermatol Surg 2014;40:864–73.

Fabbrocini G, De Vita V, Pastore F, Panariello L, et al. Combined use of skin needling and platelet-rich plasma in acne scarring treatment. Cosmet Dermatol 2011;24:177–83.

Harris Adam NC, Murrell D. Skin needling as a treatment for acne scarring: an up-to-date review of the literature. Int J Women Dermatol 2015;1:77–81

Chawla S. Split face comparative study of microneedling with PRP versus microneedling with vitamin C in treating atrophic post acne scars. J Cutan Aesthet Surg 2014;7:209–12.

Hassan R. Comparison of efficacy of micro needling for the treatment of acne scars in Asian skin with and without subcision. J Turk Acad Dermatol 2015;9:159–66.

Orentreich DS, orentreich n. Subcutaneous incisionless (subcision) surgery for the correction of depressed scars and wrinkles. Dermatol Surg. 1995;21:543–549.

Dogra S, Yadav S, Sarangal R. Microneedling for acne scars in Asian skin type: an effective low cost treatment modality. J Cosmet Dermatol 2014;13:180–7.

Vandervoort J, Ludwig A. Microneedles for transdermal drug delivery: a minireview. Front Biosci 2008;13:1711–5.

Schweinfurth JM, Fedok F. Avoiding pitfalls and unfavourable outcomes in scar revision. Facial Plast Surg 2001;17:273–8.

El-Domyati M, Barakat M, Awad S, Medhat W, et al. Microneedling therapy for atrophic acne scars. An objective evaluation. J Clin Aesthet Dermatol 2015;8:36–42.

Leheta T, El Tawdy A, Abdel Hay R, Farid S. Percutaneous collagen induction versus full-concentration trichloroacetic acid in the treatment of atrophic acne scars. Dermatol Surg 2011;37:207–16.