Dr. R. Moulton-Barrett
01-2015

STANDARDIZED PROCEDURE FOR REGISTERED NURSES(RN) AND MEDICAL ASSISTANTS(MA) / FRONT OFFICE (FO) STAFF (FO) PERFORMING THERMiSmooth (TiS)

I. POLICY

A. Circumstances under which the RN may perform ThermiSmooth(TiS)

1. Setting:

a. Aesthetic Medicine Program, in designated Treatment Room

2. Applicable Device:

a. Once clinically trained and certified upon completion and by Thermi, Inc , the RN can treat patients **TiS** Devise.

b. **TiS** is a class II devise and therefore the placement and removal of devise on/from the skin may only be performed by an Registered Nurse(RN), Physician's Assistant (PA), Nurse Practioner (NP) or Medical Doctor (MD). Patient scheduling, education and comfort management during the procedure may be performed by a medical assistant/front office staff.

c. **TiS** is used for the reduction of unwanted rhytids or excessive skin in a patient including but not limited to facial body skin and the labia majora/minora, vagina and interoitus

3. Supervision:

a. Physician, PA or NP will assess patient and/or review chart prior to treatment should there be any question regarding the patients suitability for **Tis**. This will involve a comprehensive initial health risk assessment followed by a care plan that addresses goals and objectives, services and benefits provided, and measurable outcomes.

b. No direct MD or RN supervision required during treatment.

c. MD will be available for questions or concerns in person or by phone.

d. All charts will be reviewed and signed by the MD within 10 working days of laser treatment

e. All consent forms must be signed by the RN prior to the onset of treatment and then counter signed by the MD according to 'd.'

4. Patient Conditions:

a. Consultation regarding patient's chief complaint completed. Specifically location of unwanted fat

b. Ensure patient is a candidate for **TiS** by discussing precautions below.

c. Relative contraindications include:

- Pregnancy
- Recent or ongoing bladder infection, vaginitis or urethritis, Bartholin's Cyst or perineal infection

d. Patient is aware of potential risks, such as mild pain or tenderness which may last several days
e. Patient understands that results are not immediate and may take several months
f. Patient may understands that multiple treatments may be required to obtain desired result for a given area, the number of which and the frequency of which as well as the cost including a package price is to be determined and documented in the chart prior to the onset of the first treatment
g. Informed consent given and consent form completed.

II. PROTOCOL

A. Definition:

1. **Tis** is the reduction of rhytids or skin laxity by transcutaneous radiofrequency collagen immediate remodelling and secondary subepidermal contracture through post imflammatory collagen deposition

B. Assessment:

1. Subjective:
   from whom a relevant medical history was obtained inlcuding but not limited to contraindications for the procedure
2. Objective:
   Patient presents with unwanted rytids and and or skin laxity and has had a good faith relevant physical from which there are no contraindications ot the procedure.

C. Plan:

1. Preparation for treatment:
   a. Patient to remove any lotions, creams and deodorant from area to be treated.
2. Treatment:
   a. Hand piece to be cleaned with isopropyl alcohol or Sniwipes and dried off with towel prior to each treatment.
   b. Input patient data into computer re TiS
      - Pre treatment photos are obtained
      - Witnessed consents obtained
   c. Start treatment at the given parameters unless reasons are noted to start at higher settings. Parameters vary according to location of the skin and body type. Parameter sheet is discussed and provided at training/educational class.

Treatment Check List:

1. Plug in ThermiUnit to mains
2. Turn on black console swirtch at back of unit
3. has been turned on
4. set up charged IR camera on tripod and position, connect to monitor and trun on

5. place ground pad under left buttock and connect to the ThermI machine
6. connect cleaned ThermiSmooth 10mm reusable RF hadn piece to unit via unit grey cable connector
7. clean skin with betadine iodoine and then alcohol pad
8. apply ultrasonic coduction gel to the skin
9. press white bottom right button to start, then again for RF lesion
10. then press dwon arrow at bottom right until set time is '0:00'
11. set temperature to 42 C
12. with flat head of head piece in contact with skin press foot pedal to start RF energy
13. once skin temp to 42 C the timer will start
14. work in facial area zones (see diagram) in circular motion and when temp to 42 C keep in same area for 5-7 minutes
15. You can verfiy with camera the external temp is 42C
16. Wipe excesss ultrasonic gel off
17. Post care instructions given to the patient
18. Schedule next treatment

e. Monitor for response of patient's skin and increase parameters only if indicated.

f. Expected responses:
   - Erythema
   - hardending

   Note: These expected skin responses should resolve within several hours

3. <u>Patient Education:</u>
   a. Any prolonged pain, redness and swelling should be reported to RN, PA, NP or MD.
   b. Any severe pain reaction which continues more than a few days should be reported immedicately to ThermI
   c. patient given post procedure instruction sheet
4. <u>Follow up:</u>
   a. Subsequent treatments to the same area no less than 4-6 weeks apart . There is no maximum of treatments can be peformed to the same area.
   b. Other areas can be treated simultaneously or at convenient timing thereafter without restriction.
5. <u>Documentation:</u> The following information must be recorded in patient's chart with each treatment.
   a. Patient's verbal response to last treatment (if any).
   b. Area treated.
   c. Photos taken using standardized positioning 1-4 and entered into the computer not greater than the end of the 4 week period
   c. Parameters used.
   d. Patient's response to treatment.

e. Any conditions or problems that may have arisen prior or during treatment, such as: tanned skin and sensitivity. Note: If infection is present, no treatment should take place.
f. Procure physician's review and sign-off on patient charts within 10 days post treatment.

III. REQUIREMENTS FOR RN and For Front Office / Medical Assistant

Education: 1. Graduate of RN program with current California RN license.
2. Certified Medical Assistant or Certfied with letter of verification from MD regarding proficiency and in office training as medical assistant
3. Completion ThermIRF In service course and passing training examination: for RN & medical assistant /front office staff

Training:

1. Formal radiofrequency (RF) trasncutaneous collagen remodelling and contraction education and training covering the biophysics and the safe use of TiS training of choice. Successful completion of basic training program devoted to the principles of RF, instrumentation and physiological effects and safety requirements. The initial program should include clinical applications of the TiS hand piece in the particular locations, how to place successfullly and use the ultrasonic jel, positioning the patient, turning off the devise and hands-on practical sessions with TiS with the appropriate therapeutic delivery
2. Experience: No previous experience necessary prior to the above training. See Initial Evaluation below.
3. Initial Evaluation: Successful completion of appropriate TiS training.
4. Ongoing evaluation:
5. Random MD visits during treatment sessions. MD will observe 1 treatment quarterly, specifcally:
a. Safety and efficacy issues
b. Contraindications and Precautions
c. Complications and side effect
d. Managing complications and adverse events (side effects)
e. Consultation, Assessment, and Patient education
f. Safe application of Tis
g. Formal completion on on ine inservice and vendor presentation followed by observed CS by qualified MD,PA or NP
6. Formal re-education Tis by product representatives to increase knowledge, experience and proficiency in the proper administration of the product.

IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of CS as a comprehensive working model.

This model will be reviewed annually and documented in the minutes of the meeting and will be kept in the Administrative office of Rex Moulton-Barrett,MD

This Standardized Procedure and Protocol (standing orders) have been approved by:

Rex Moulton-Barrett,MD
Medical Director Date: 12-14-2015

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Administrative Signature Date: