Rex Moulton-Barrett, MD
12-2015

STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING RADIESSE ® INJECTIONS TO THE HAND

I. POLICY

A. Circumstances under which the clincially trained RN may perform Radiesse® injections.

1. Setting:
   - a Brentwood: Doctor's Office, Suite J-5, 1280 Central Blvd,
   - b. Alameda: Alameda Hospital, 4th Floor Doctor's Offices
2. Supervision:
   - a. The Physician or Nurse Practioner who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Restylane. The patient's Medical History Questionnaire will be discussed in-depth with patient. (Questionnaire attached).
   - b. The RN will then treat the patient with Radiesse, providing that the patient meets patient criteria, and Medical History Questionnaire has been completed.
   - c. The physician will review the treatment rendered and sign the chart upon review.
3. Patient Conditions:
   - a. Consultation regarding patient's chief complaint completed.
   - b. Patient must be at least 18 years of age, or parent/legal guardian may authorize treatment.
   - c. Informed consent given and consent form completed.
4. Contraindications:
   - a. Pregnancy.
   - b. For patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
   - c. No NSA'a, no anticoagulation, bleeding disorders
   - d. No recalcitrant herpes zoster
   - e. Age < 26 and > 79 years of age
5. Precautions:
   - a. Hands: Injection should be limited to 0.2-0.5ml per injection for a total of 1.5mL per treatment session per hand or a total of 3ml per hand
   - b. Patient is aware of potential adverse events following injection of Radiesse®. These are bruising, redness, swelling, tenderness and itching.

II. PROTOCOL

A. Definition:

The administration of the Restylane® is for mid-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

B. Assessment:

1. Subjective: The above patient conditions have been met.
2. Objective: The patient presents with soft tissue deficits as described in A. definition above

C. Plan:

1. Storage:
   a. Store Radiesse® at room temperature up to 77º F. Refrigeration is not needed. Do not freeze and protect from sunlight.
   Radiesse® must be used prior to expiration date on the package. Restylane® implants are packaged sterile in syringes and sold by the box. Order Restylane® per patients scheduled requirements.
2. Test Implant:
   a. Radiesse® does not require a test implant.
3. Treatment:
   a. Patient will remove all make-up from treatment area.
   b. Define areas to be treated. Prep site with alcohol.
   c. Inject area to be treated

   Hands:
   a. apply topical anesthetic for 20 minutes +/- ice
   b. prep with chlorhexidine or betadine iodine solution followed by alcohol wipes.
   c. Lift or 'tent' the skin with a pinch technique to elevate the 1st-4th intermetacarpel spaces dorsally at the mid metcarpel level.
   d. Inject using 27 g needle
   e. after mixing 1.5ml Radiesse with 0.8-1.0ml lidocaine
   f. inject bewteen 0.2-0.5mls in the subareolar tissue, ie just deep to skin in a bleb, maximum of 1.5ml per hand
   g. massage the bleb using u/s jel
   h. apply ice for up to 24 hours

3. Post treatment – cleanse site with alcohol.
4. Patient Education:
   a. See Radiesse postcare sheet and give copy to patient.
   b. Avoid strenuous exercise, extensive sun exposure and extensive heat.
   c. Avoid all alcoholic beverages for 4 hours following injection.
   d. Instruct patient not to massage treatment sites for 4 days.

e. Inform patient that swelling, pain and bruising could last for 12, 10, 21 days: respectively.
f. Inform patient redness and slight swelling may occur at the injection site.
g. Patient to notify office should any concerns or questions arise.

5. Follow-up:
   a. Patient may leave with ice to reduce swelling and discomfort.
   b. Subsequent treatment scheduled upon patient's desire for further additional correction.

6. Documentation:
   The following information must be recorded with each treatment.
   a. Number and size of syringes used
   b. Syringe lot numbers
   c. Specific areas treated
   d. Amount of material used
   e. Patient response to treatment.
   f. Procure physician review and sign-off of all patient charts within 7 days post procedure.

Note: For ease, Radiesse® comes with a patient record label that is part of the syringe label. Remove it by pulling the flap marked with three small arrows. This label is to be attached to patient records to ensure traceability of the product.

III. REQUIREMENTS FOR RN

A. Education:

1. Graduate of RN program with current California RN license.

B. Training:

1. Training by R. Moulton-Barrett,MD , and qualified Registered Nurse specifically trained in Radiesse® product knowledge and proper technique.
2. Formal education from product company to gain knowledge, experience and proficiency in the proper administration of product.
3. Initial Evaluation: Successful completion of in-service education, training and demonstration of competency to MD, including proctoring of (at least) 3 treatments.
4. On-going evaluation:
   a. Random MD visits during treatment sessions. MD will observe 1 treatment quarterly.
   b. Annual performance evaluation by R. Moulton-Barrett,MD.
5. Previous Experience:
   a. No previous injectible experience necessary prior to training
   b. Initial Evaluation: Successful completion of Radiesse education, training and demonstration of competency to MD.

4. Physician will review and sign-off all patient charts within 7 working days post procedure.
5. On-going evaluation:
    a. MD will observe random and or quarterly injection technique including but not limited to BoTox, Xeomin and fillers which are currently being used in the Alameda and or Brentwood offices of R. Moulton-Barrett,MD.
    b. Injection technique includes evaluation of patient safety including sterile technique, needle management, patient tolerance / comfort, location and amount of injection relative to the degree of the rhytid and post injection management of the patient.
    c. All evaluation will be documented in the RN evaluation book which is kept in the adminstraive office at all times.

IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of Rasdiesse 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: