Rex Moulton-Barrett, MD
08-2016

STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING RESTYLANE® INJECTIONS

I. POLICY

A. Circumstances under which the clinically trained RN may perform Restylane® 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 Registered Nurse 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 Restylane, 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 over the age of 21 years of age
   . 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.

5. Precautions:
   a. Injection should be limited to 1.5mL per treatment site.
   b. do not inject > 0.3ml per minute,
   c. avoid lateral needle movement in subdermal plane
   d. stop if any blanching, avoid using high pressure when injecting
   e. Patient is aware of potential adverse events following injection of Restylane®. These are bruising, redness, swelling, tenderness and itching
   f. restylane is not indicated for the use of cannula devices , though the use of a 27g, 1.5 inch cannula has been described for the nasolabial fold with possibiliy diminished risk of intravascular injection

g. restylane is not indicated for use in the tear trough infraorbital area, however one study describes the use of cannula in this area using no more than 0.5mls in the suborbicularis plane using serial punctures with less erythema noted at 4 weeks

II. PROTOCOL

A. Definition:

The administration of the Restylane®, a hyaluronic acid, derived from streptococcus bacteria, 1% x cross linking, Produced by Galderma in three forms:

i. **Silk**, with 0.03% lidocaine, more liquid 220microm particles, good for peroral lines, can be placed intradermally mid dermis not more superficial, or submucousal into the lip, 330gprime, no elastic support, does not tindle, has lidocaine always, do not inject into muscle can cause angioedema, lasts 6 months

ii. **Restylane**, 530 gprime 600microm particles, can use in lips at vermillion border into mod and deep folds, deep dermis, nasolabial folds, has lidocaine, off label tear troughs

iii. **Restylane Lift,** equivalent to Perlane, 545 gprime, 1000microm particles, place periosteal and subcutanius, lasts >= one year, antomical landmarks for lift: tragus in females, tragus to oral commissure in males, then line from lateral orbital rim to oral commisure. Place depos of 0.1ml from lateral to medial on Zygoma following Hindel's Line. When injected medially and placed on the anterior face of the maxilla, inject deep onto the bone and then fan out and thread 0.1ml subcutaneously and always lateral and inferior to the infraorbital neurovascular bundle.

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 Restylane® at room temperature up to 77º F. Refrigeration is not needed. Do not freeze and protect from sunlight.
   Restylane® 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. Restylane® does not require a test implant.
3. Treatment:
   a. Patient will remove all make-up from treatment area.
   b. Photographs and consents obtained
   c. Define areas to be treated.
   d. Prep site with alcohol.
   e. use sterile gloves
   e. Inject area to be treated.
      i. Silk: 30 g needle, ½ inch, Linear thread technique: 30 degree angle parallel to length of rhytid, lip, fold, into mid-deep dermis, not intramuscular for lip, thread as withdraw: retrograde injection, no overcorrection. Or Serial puncture technique maximum per lip 1.5mls for augmentation and maximum for perioral rhytids is 1ml per lip.

   f. Post treatment – cleanse site with alcohol.
4. Patient Education:
   a. See Restylane®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 bruising could occur and last 7-10 days.
   f. Inform patient redness and slight swelling may occur at the injection site.
   g. Patient to notify MD 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, Restylane® 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: Graduate of RN program with current California RN license.

B. Training:

1. Training by Dr. Moulton-Barrett or trained and qualified Registered Nurse specifically trained in Restylane® 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.

. On-going evaluation:

   a. Random MD visits during treatment sessions. MD will observe 1 treatment quarterly.

   b. Annual performance evaluation by MD.