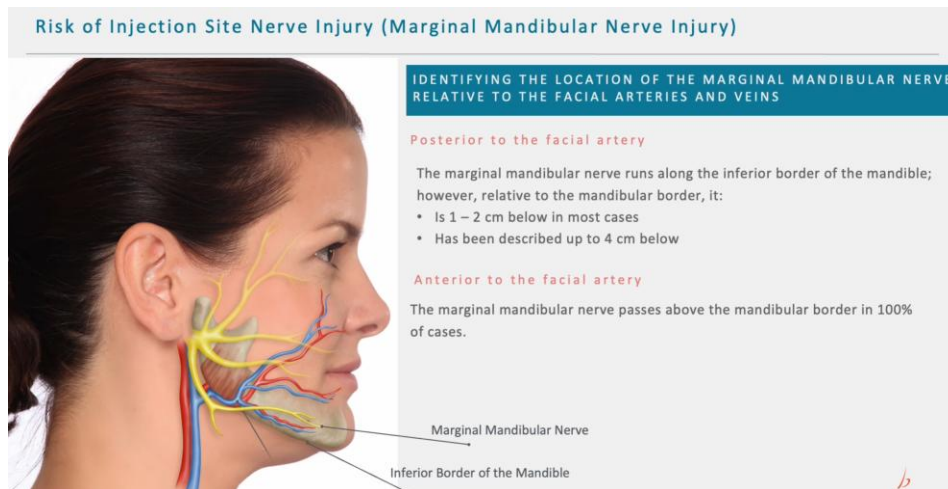
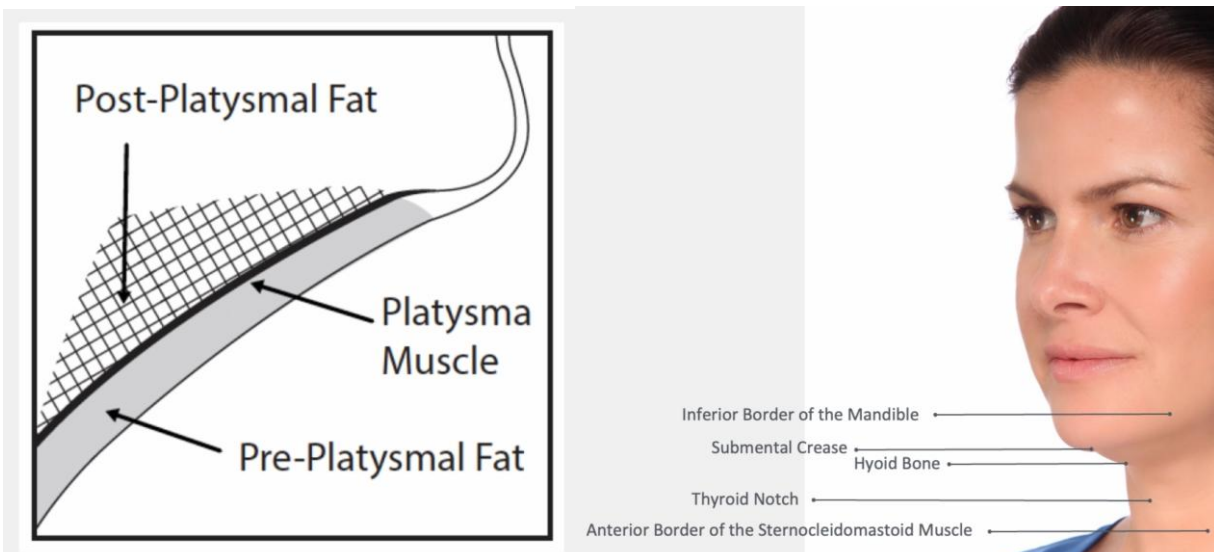


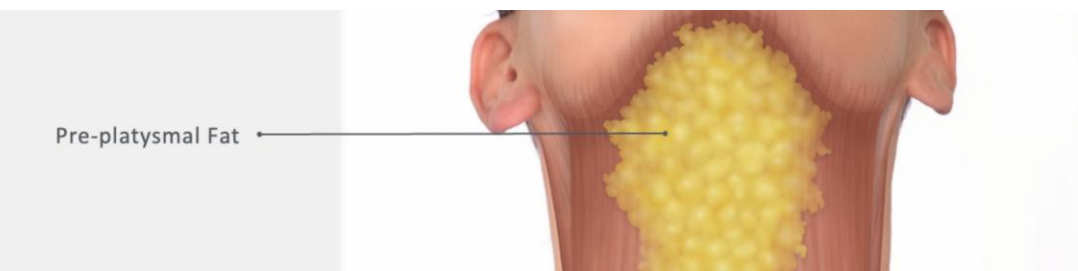
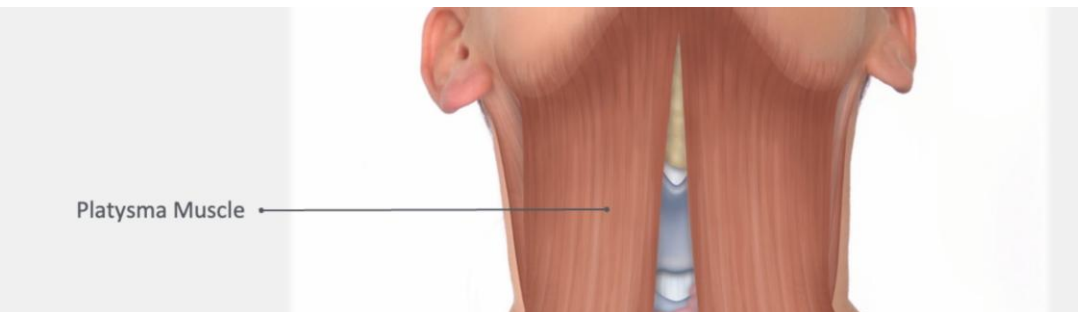
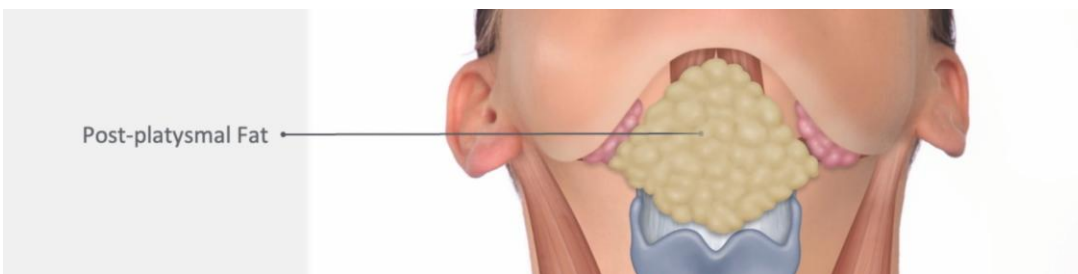
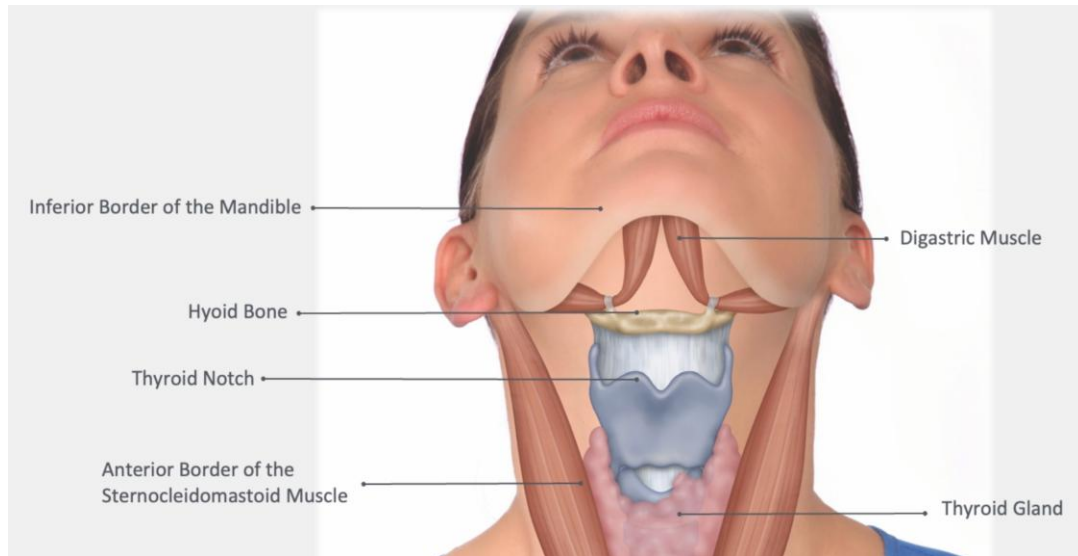
Belkyra® (deoxycholic acid) Injector Protocol

- Belkyra® is a non-human, non-animal formulation of deoxycholic acid, indistinguishable from its endogenous form, that act as a cytolytic agent within subcutaneous fat.
- It may only be used for submental fat.
- Must be injected 1-1.5cm below inferior border (from angle of mandible to the mentum) to avoid injury to marginal mandibular nerve.
- Must not be used in mild or extreme submental fat, below the age of 18 or over 65, or pregnant / nursing.
- Nerve injury, skin ulceration, infection, and injection site necrosis are all risks.
- In clinical trials, 4% of Belkyra® treated patients had injury to their marginal mandibular nerve. This resulted in an asymmetric smile or facial muscle weakness (paresis) that lasted in duration of 1 – 298 days (median 44 days).



- Inject needle perpendicular to skin, only in target submental treatment area.
- Never inject into dermis (too superficial) may result in skin ulceration and necrosis.
- Only inject into pre-platysmal subcutaneous fat in the submental area (not intradermal, intramuscular or into post-platysmal fat). Inject mid-way into the subcu layer. Avoid blood vessels.
- Do not withdraw needle while injecting (some will end up in skin).





- Supplies: topical anaesthesia, chlorhexidine, marking pen, injection grid, gauze, ice pack, UniTox syringes, Belkya.
- Store: 15-30C
- 2mL bottle of 10mg/mL

1. Evaluate submental fullness and appropriate patient

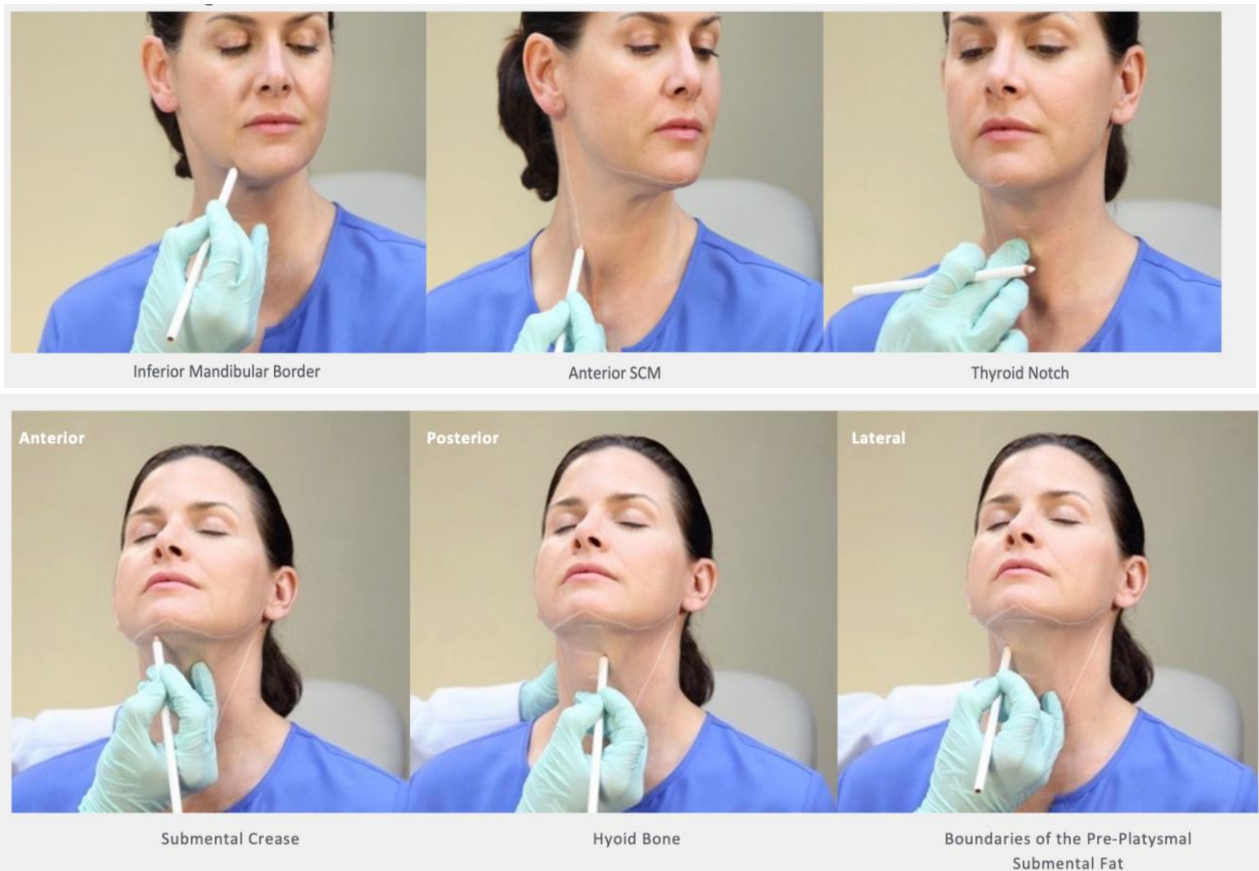
- Moderate submental fullness, minimal skin laxity, absence of prominent plat bands.
- Assess with grimace. Take pictures.



- Screen for thyromegaly, cervical lymphadenopathy, history of dysphagia, use of ASA or anticoagulation, active infection/induration/inflammation.

2. Pre-treatment regimen and marketing

- Apply topical lidocaine (or injectable).
- Clean with chlorhexidine.
- Mark:

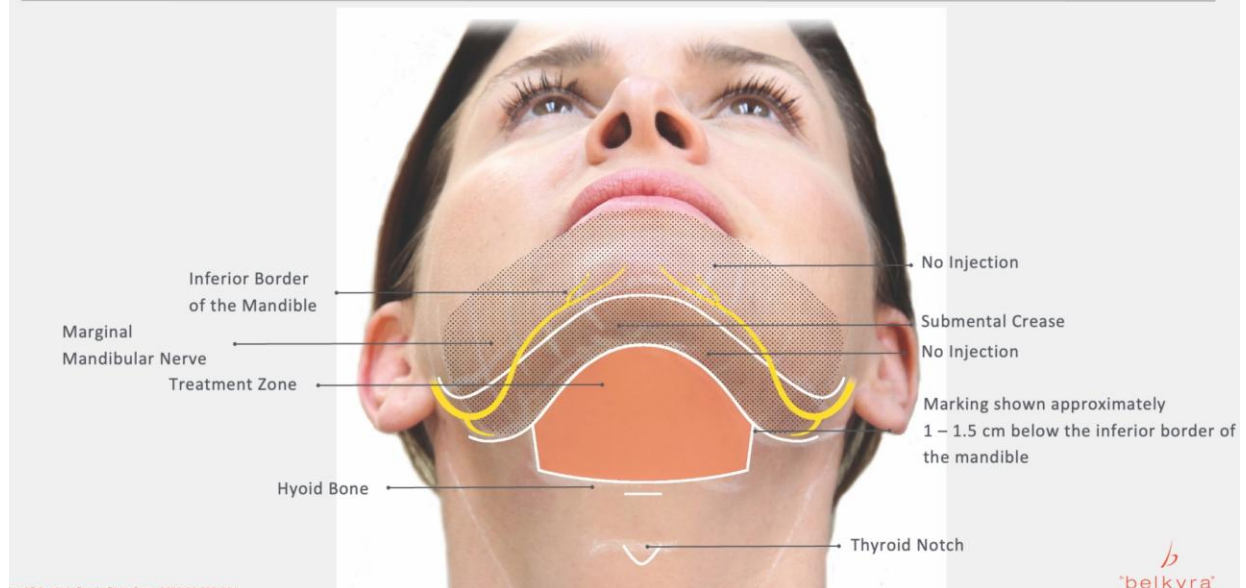


Mark a “No Injection” Zone to Reduce the Potential for Injury to the Marginal Mandibular Nerve

- Draw a line 1 – 1.5 cm below the inferior border of the mandible from the gonion to the mentum.
- Do not inject BELKYRA® above this line.
- Inject BELKYRA® only within the target submental fat treatment area.
- Do not inject BELKYRA® in the “No Injection” zone to avoid risk of injury to the marginal mandibular branch of the facial nerve, salivary glands (including salivary ducts), the thyroid gland, and the lymph nodes.
- Care should be taken to avoid inadvertent injection directly into an artery or vein as it can result in vascular injury.



Treatment Area Landmarks





CHECK PLACEMENT

Check general placement prior to the application; the shorter side of the grid should be closest to the tip of the chin.



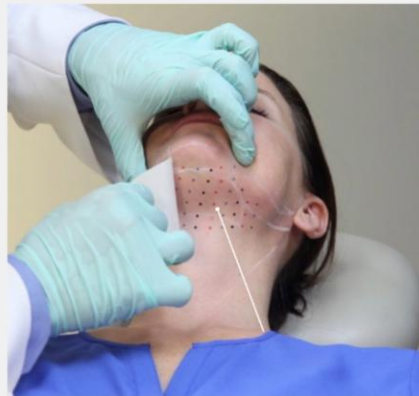
REMOVE PROTECTIVE TOP SHEET

Remove and discard clear protective top sheet of skin-marking grid from transfer.



PRESS ONTO SKIN AND DAMPEN

Before applying the skin grid, ensure antiseptic preparation of the injection area. Press skin-marking grid firmly onto clean dry skin with printed grid pattern facing skin. Thoroughly wet cotton ball/pad with sterile water or saline; press down and wet entire paper backing while maintaining even pressure.



PEEL BACKING AND ASSESS

Wait approximately 15 seconds, then peel off and discard backing; wait 15 seconds for transfer to settle; verify the grid pattern has transferred. Consider removing the dots outside the treatment area prior to injecting.

Only dots within the pre-marked treatment area will be injected; dots falling outside the pre-marked area will not be injected.



Use of ice/cold packs may enhance patient comfort

- After the grid has been applied
- Immediately before injection

3. Select dose and prepare syringes

- 2mg/cm² (dot) is to be injected.
- Each bottle has 2mL and concentration of 10mg/mL.
- Ensure no particulate matter or discolouration in the bottle.
- Each injection needs to be 0.2mL = 2mg.
- We can use our UniTox syringes for this. 1 syringe = 0.5mL = 20 units.
- Therefore 8 units in UniTox = 2mg Belykya = 0.2mL = 1 injection.
- Prime each UniTox with 16 units and this will give you two injections (8 units). However, remember with UniTox syringes, sometimes we get some drips at the needle end. Therefore, very important to leave the needle sub cu for at least 10 seconds after each injection (we don't want any Belkya in the dermis when you pull the needle out).
- 1 vial of Belkya will let you treat 10 injections (dots). This would prime 5 UniTox syringes to 16 units each (each syringe for 2 dots).
- Do not inject directly into the dots (inject to the side).
- Inject perpendicular to skin.
- A maximum of 5 vials can be given per treatment session. Current cost is \$900 for the first vial and \$350 for each additional one. 7.65% GST + square reader fee is added to this.
- This then needs to be repeat at least once more in 4-6 weeks (potentially up to 4 treatment sessions).



4. Inject and follow up

- Apply ice after injecting. Remove grid (isopropyl alcohol can help).
- Assess smiling and swallowing.
- Discussed expectant management and pain control. Book follow up treatment if applicable.
- Remember: do a neurological exam if facial asymmetry occurs, especially if delayed. Remember a differential diagnosis (e.g., Bell's, TIA/CVA, etc...).