

PROFHILO®



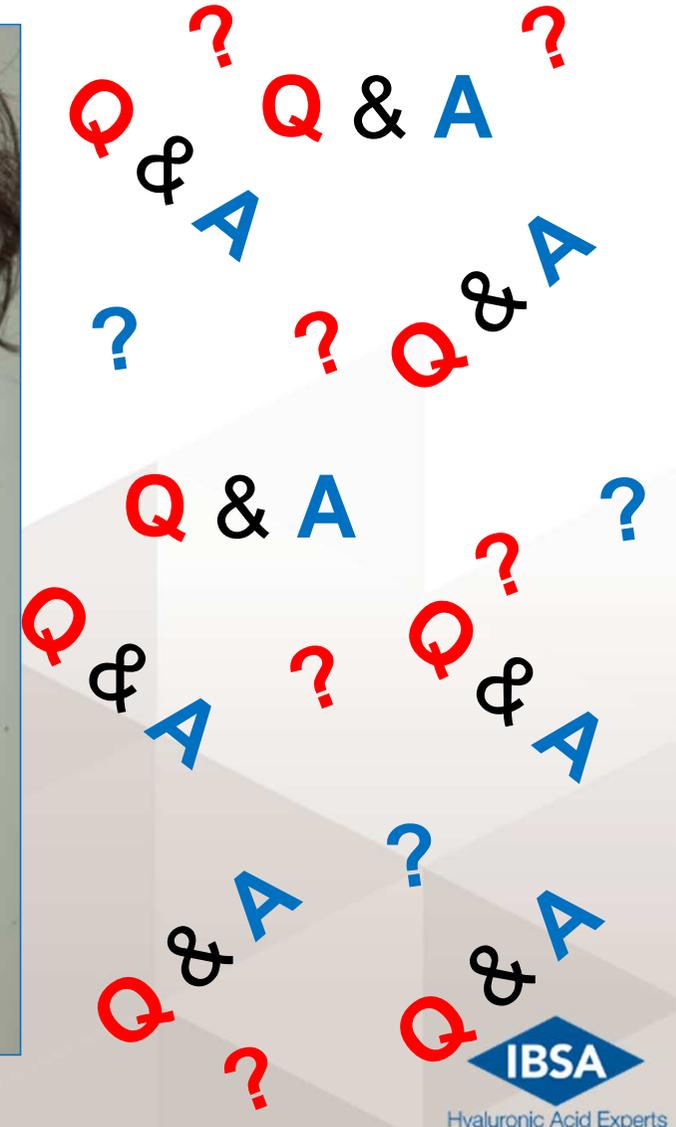
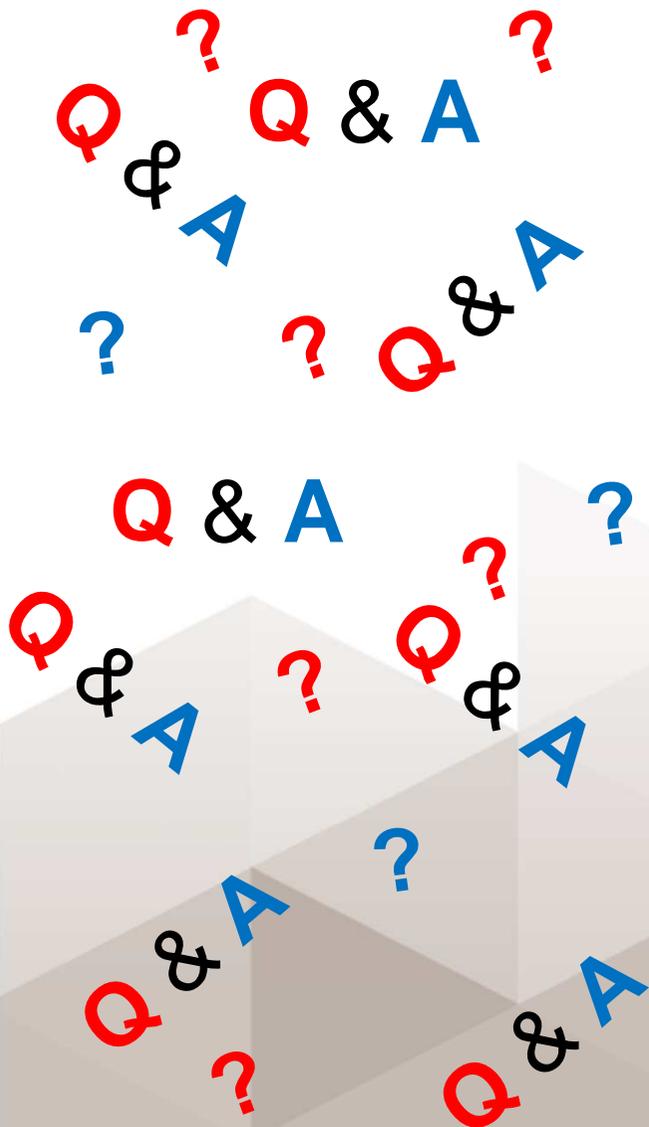
AMEC 2015 WINNER
Best Skin
Enhancement Device

IBSA

Hyaluronic Acid Experts

PROFHILO®

Frequently Asked Questions & Answers



Q Is Profhilo cross-linked HA?

Answer:

ABSOLUTELY NOT. Profhilo is developed using a patented technology resulting in hybrid cooperative complexes between high molecular weight HA and low molecular HA without the use of any chemical cross-linking compounds. These complexes increase the stability of HA to enzymatic and mechanical degradation.

Q Is Profhilo too concentrated ?

Answer:

NO. If it was free natural HA it could be considered too concentrated, but there is a slow and long lasting release of the natural HA owing to the hybrid cooperative complexes . This is also the explanation for the different biological behavior with respect to H-HA and L-HA alone.

Q Do hydrogen bonds have weaker interactions than cross-linking bonds?

Answer:

YES. Cross-linking bonds are stronger covalent bonds.



Q Do weak hydrogen bonds stabilize the high and low molecular weight HA molecules?

Answer:

YES. If these interactions are cooperative and form cooperative hybrid complexes.

Q Is Profhilo based on Resilient Hyaluronic Acid -RHA technology ?

Answer:

ABSOLUTELY NOT. Profhilo is developed using the patented **BDDE free** IBSA technology. RHA technology, patented by Teoxane, lowers the BDDE content, but does not eliminate it.

Q Is Profhilo a filler or bio-revitalizer?

Answer:

NEITHER. Profhilo is something new and indicated for skin bioremodeling. Therefore, defining Profhilo in either of these two areas is a losing strategy.

Q Does the L-HA in Profhilo cause an inflammatory reaction?

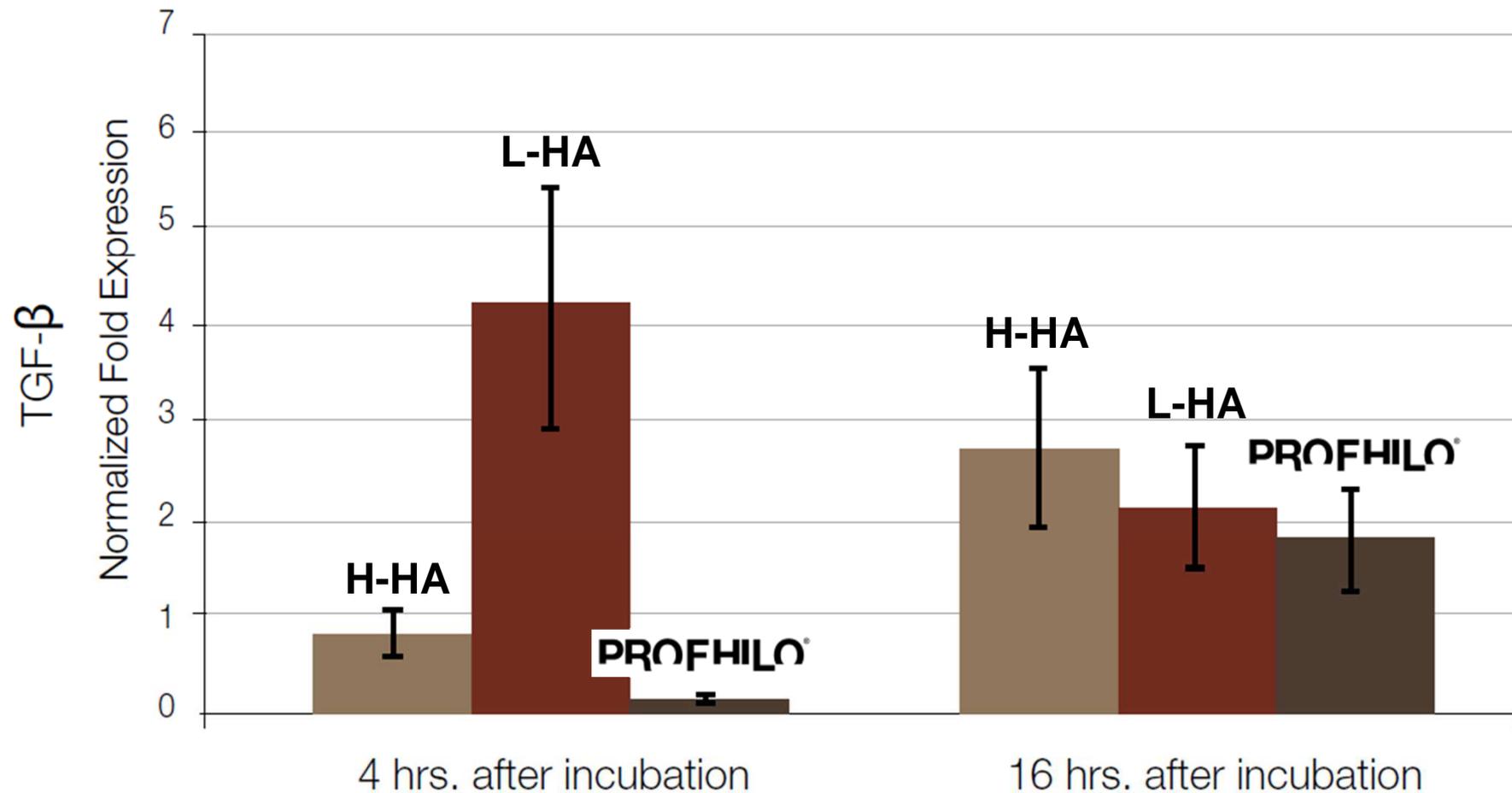
Answer:

NO. The *in vitro* data on fibroblasts shows that TGF- β , one of the main markers of inflammation, is not overexpressed in presence of Profhilo as it is with L-HA alone. This different and non-cumulative profile is justified by the hybrid cooperative complexes.

Results shown on the following graph.

Q Does the L-HA in Profhilo cause an inflammatory reaction?

Answer:



Q Which injection layer is suggested for Profhilo?

Answer:

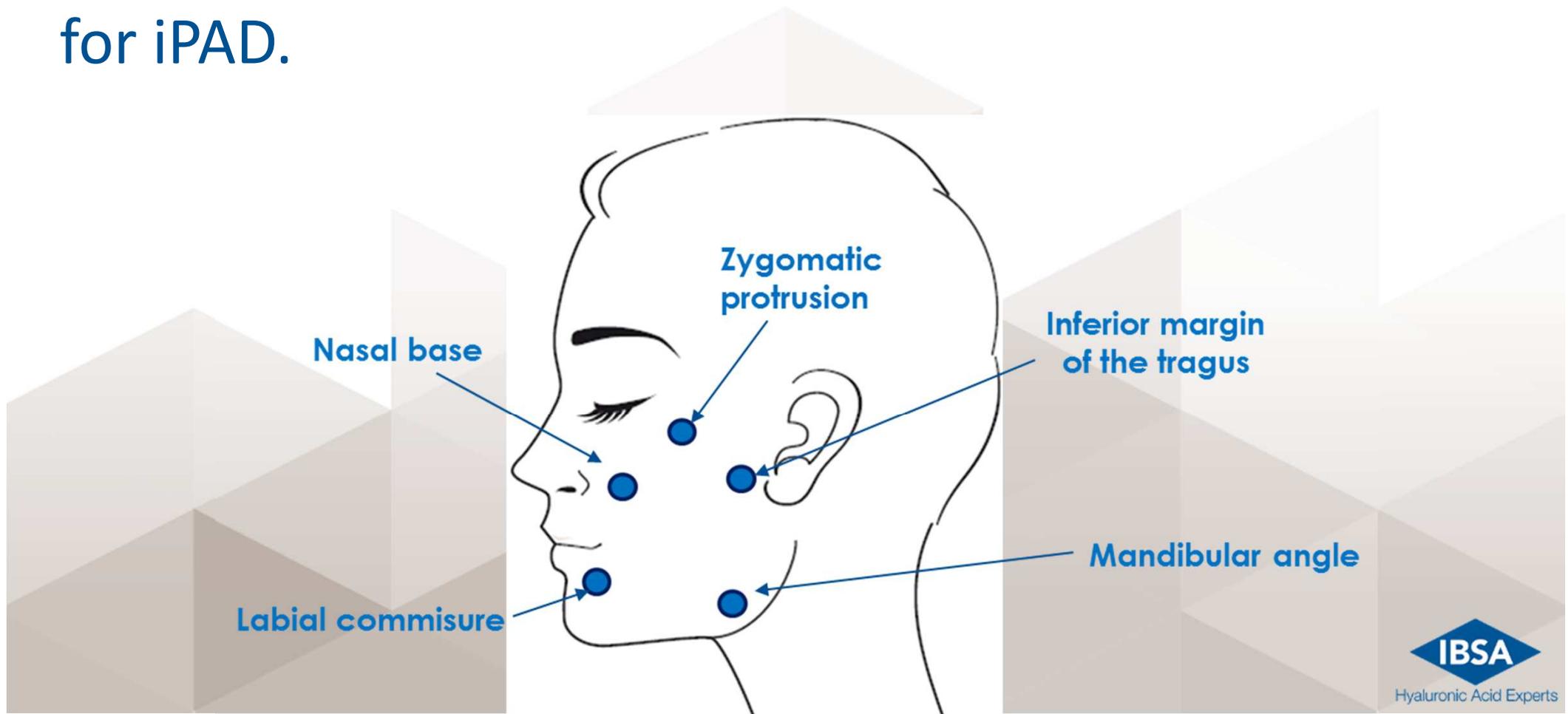
Deep dermis-superficial subcutaneous: needle depth 3 mm.

IBSA is also investigating the possible clinical advantages of deeper injection.

Q How can the 5 BAP be identified?

Answer:

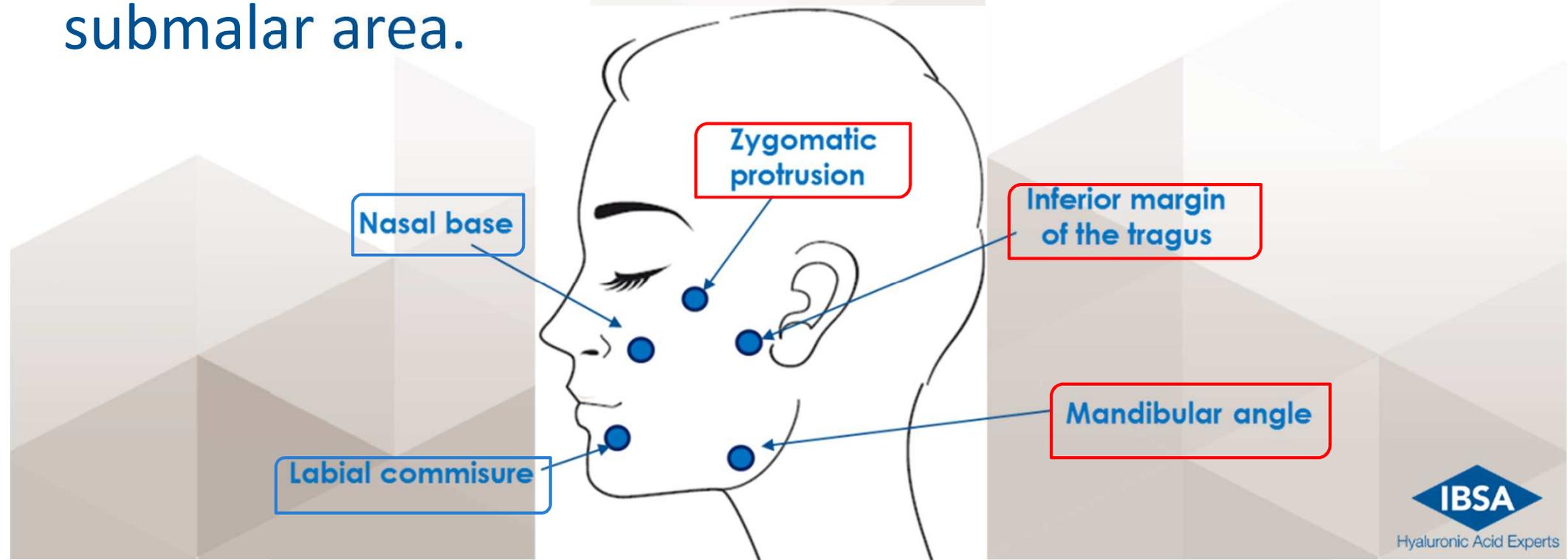
By following the instructions found in the package insert, BAP card or on the Profilo BAPP application for iPad.



Q What is the rationale behind the BAP technique?

Answer:

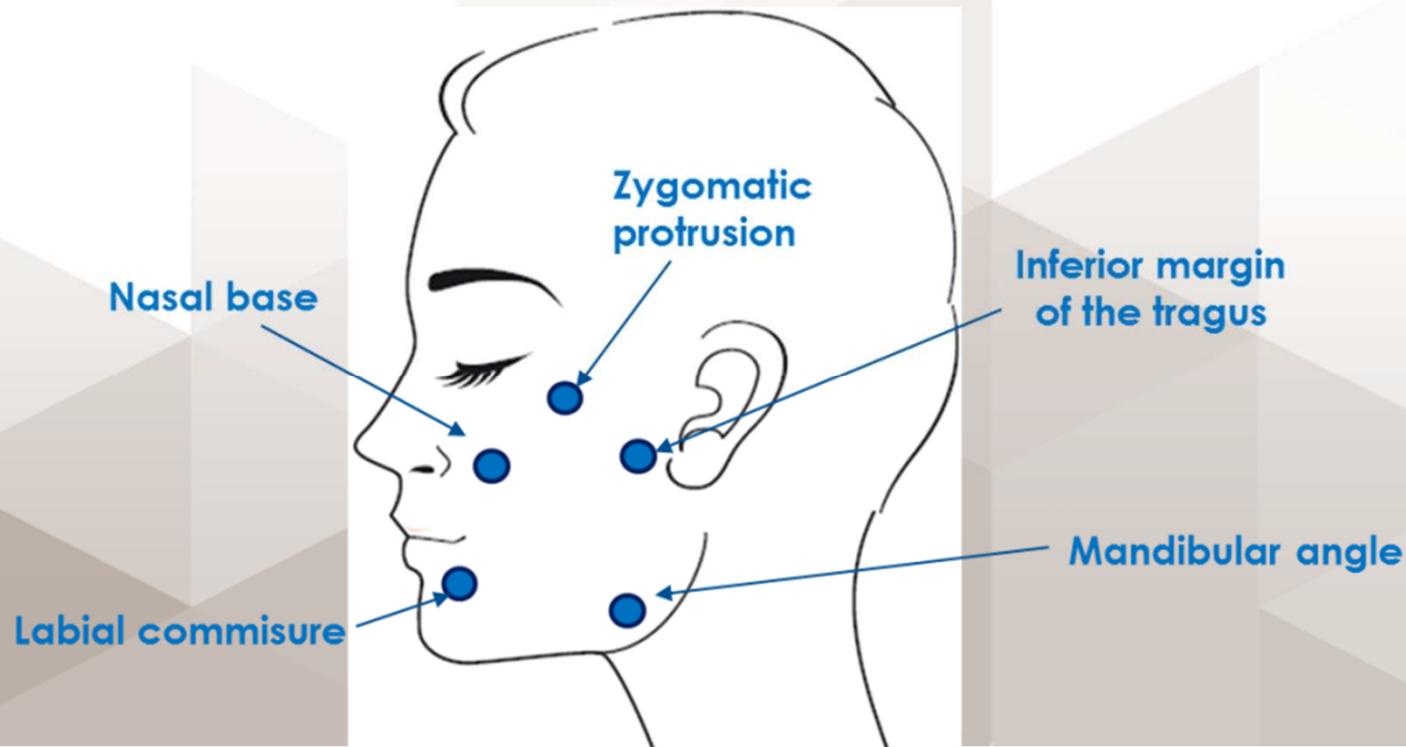
Reducing the risk by injecting in anatomically safe areas, increasing patient compliance and achieving global **lifting** and **corrective results** on the malar-submalar area.



Q Is the BAP technique clinically proven?

Answer:

YES. IBSA has collected the instrumental and clinical results on 64 patients. It has been proven that the BAP technique improves the malar-submalar area of Caucasian women.



Q Can I use Profhilo with other techniques?

Answer:

YES. Many doctors are using a cannula with the linear retrograde technique.

It is important to avoid injecting too superficially.

Q Why isn't a cannula included in the package?

Answer:

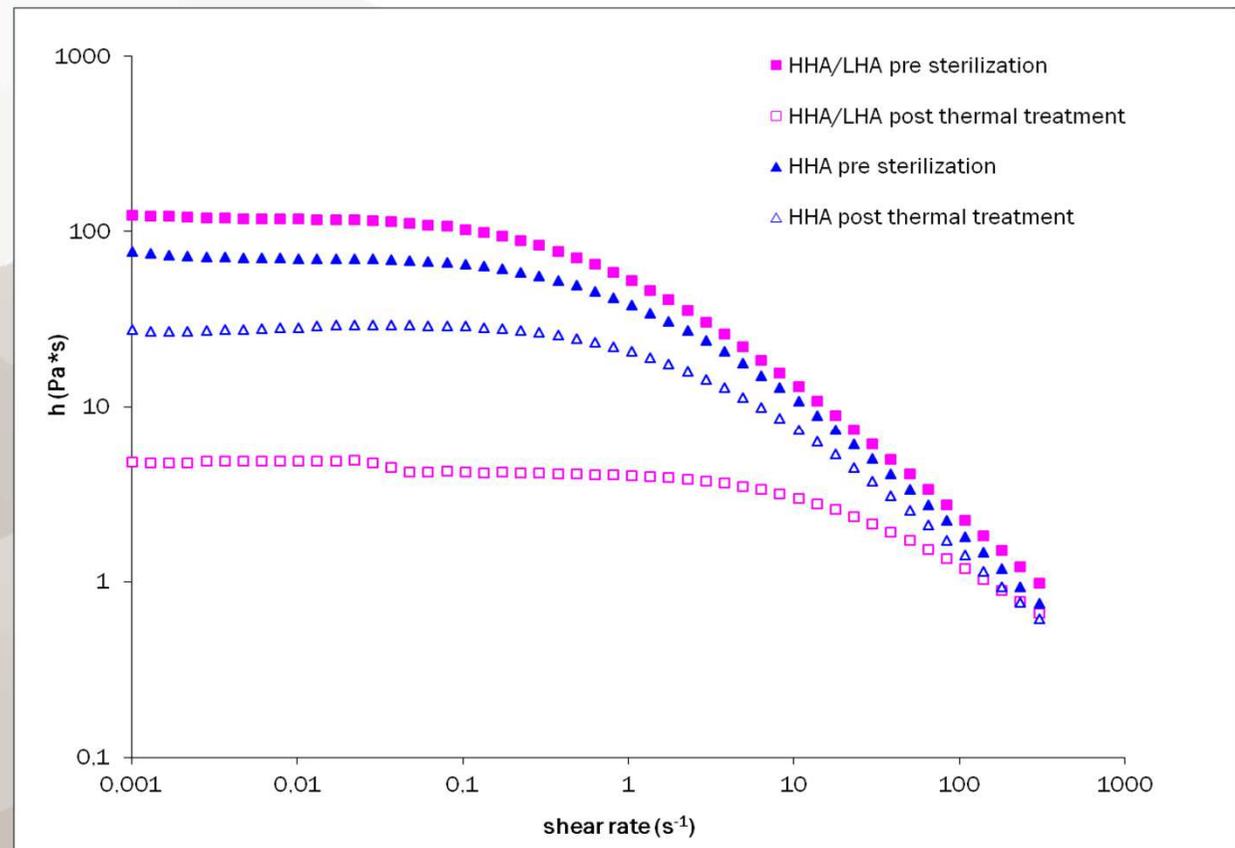
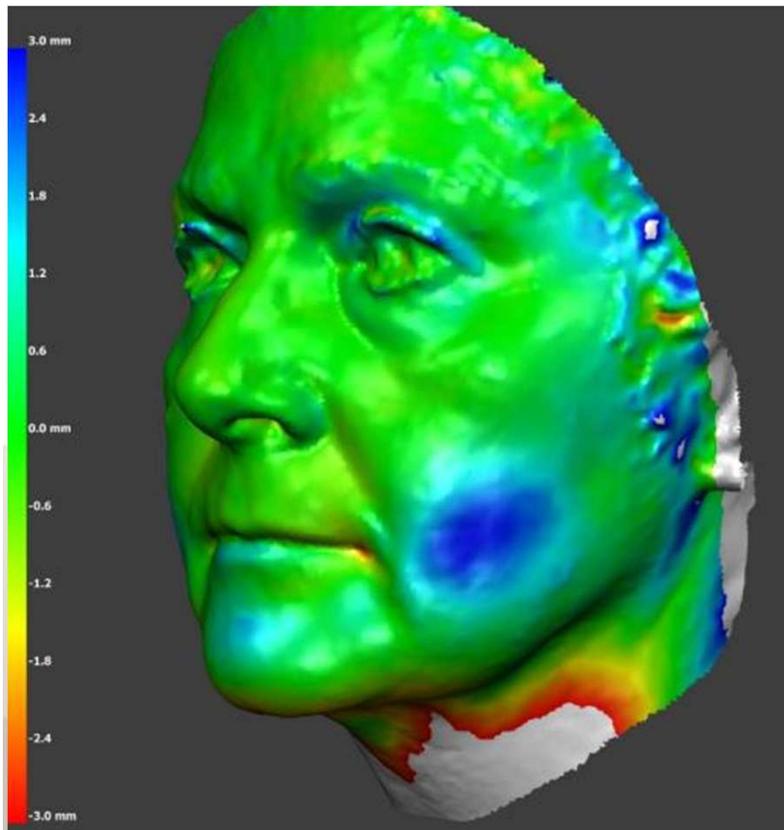
Many products do not include cannulas in the package. But we are thinking about it.



Q Why is it possible to reduce the number of injection points?

Answer:

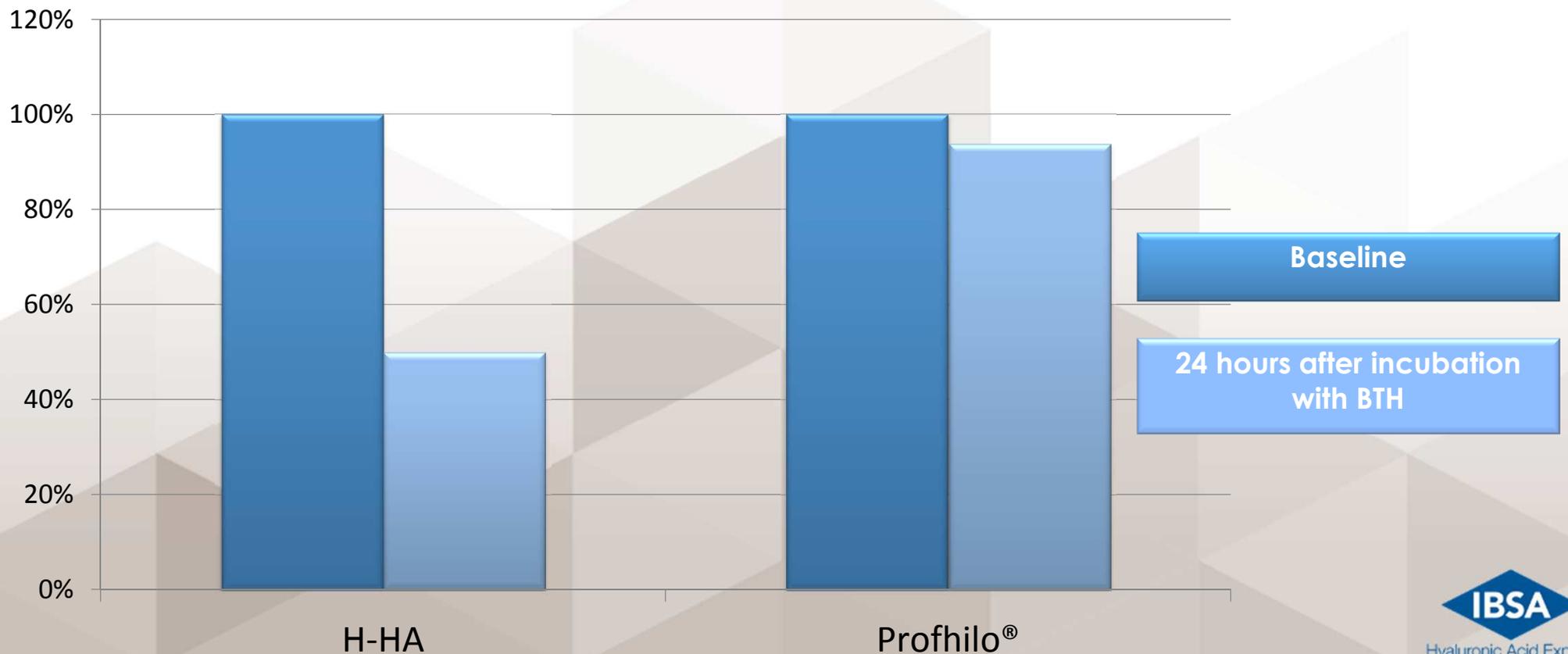
Thanks to the high HA concentration combined with high spreadability features.



Q Why is it possible to reduce the number of treatments?

Answer:

The presence of hybrid complexes makes Profhilo more resistant to hyaluronidase breakdown.



Q Which age is indicated for Profhilo?

Answer:

40-50 years. But as we have shown it is also really effective with younger and older patients.



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Q Which is the minimum recommended patient age for a Profhilo treatment?

Answer:

30 years.



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Q Which disinfectant should be used?

Answer:

An ammonium salt free disinfectant.

Q Should the injected area be massaged after the treatment?

Answer:

It is usually unnecessary. If the injected bolus is visible, a very delicate massage could help spread the product faster.

Q When are the results noticeable?

Answer:

After 1-2 days, but the full effect can be seen after one week. In some patients the improvement is not visible after one treatment: for this reason we suggest 2 treatments.

Q How long do the results last?

Answer:

4-6 months. According to the instrumental and clinical data collected, the results are still visible two months after the second treatment.

Q Does Profhilo cause swelling?

Answer:

NO. When Profhilo is injected correctly in the suggested injection layer (not too superficial) and in the suggested area (malar-submalar area) there is no swelling.

Q Are there expected complications?

Answer:

Some undesired effects which may appear at the injection site are pain, sensation of heat and reddening or swelling (as listed in the package insert)

These generally disappear in a short period of time.

The injection point on the zygomatic protrusion may disappear more slowly than the others (up to 1 week).

Q Are there any special follow-up recommendations after treatment?

Answer:

NO. They are the same as for other injection treatments:

- Use a cold pack or Viscoderm Hydrogel Patch to reduce swelling and/or redness.
- Use Viscoderm Cover Up to hide redness: first sterile cover up.
- Remind the patient to avoid:
 - ✓ Physical strain and sports on the first day after the treatment
 - ✓ Further cosmetic therapies for the first 2 days after treatment.
 - ✓ Sauna, steam bath, icy temperatures or UV radiation by the sun or a solarium for two weeks after the treatment.
- Remind the patient to stay hydrated (1.5-2.0 l water per day)
- Schedule the next visit (3-4 weeks later)

Q What about combined protocols with other fillers or treatments?

Answer:

IBSA is developing specific protocols. When in doubt, general recommendations of De Boulle et al. 2015 should be followed.

- Treated areas shouldn't be reinjected within 2 weeks of the initial procedure.
- Botulinum toxin: two weeks prior
- Microdermabrasion, chemical peel, IPL: 1–2 weeks pre or post treatment
- Fractional resurfacing 3–4 weeks distant
- Treatment should not be undertaken in the immediate period following other routine medical procedures (including vaccination).
- Dental procedures: at least 2 weeks pre or post treatment



Q Do you have clinical data?

Answer:

YES. Clinical and instrumental data on 64 patients will be published soon.



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Q Why aren't the results more evident?

Answer:

Profhilo results in a global effect, but this doesn't mean that it is not statistically significant.

One month after the first injection (T4W) Profhilo determined:

- a statistically significant improvement of FVLS score (**bio-revolumetric effect**)
- an important regularization of the skin surface microrelief (**smoothing effect**)

One month after the second injection (T8W) Profhilo determined:

- a statistically significant reduction of WSRS score (**anti-wrinkle effect**)
- a significant reduction of all profilometric parameters, index of **filler efficacy**
- an important reduction of torsionometric parameters, index of a significant increase of cheek firmness (**redensifying activity**)
- a statistically significant improvement of superficial deep skin hydration (**moisturizing activity**)

Q How does it work?

Answer:

- We know that Profhilo stimulates collagen (I, III, IV, VII and elastin) better than H-HA and L-HA, owing to the slow and long lasting release of HA from the hybrid complexes. This is due to an action on fibroblast and keratinocytes.
- But this is not enough to justify the long lasting effect. So our working hypothesis will also consider analyzing the effect in fat layers (clinical study) and ASC and MSC (*in vitro* evaluation).

Q Why Profhilo?

Answer:

Some words chosen by our KOLs to describe Profhilo could help to understand why:

- Plumping effect (P. Piersini)
- Plastoelasticity (A. Sparavigna)
- Soft tissues treatment (D. Cassuto)
- Lifting effect (A. Tateo)
- Remodeling (Ballestero)
- Redefinition (N. Zerbinati)

Tissue regeneration (A. Tateo, N. Zerbinati, D. Cassuto, A. Sparavigna)

Any other questions?



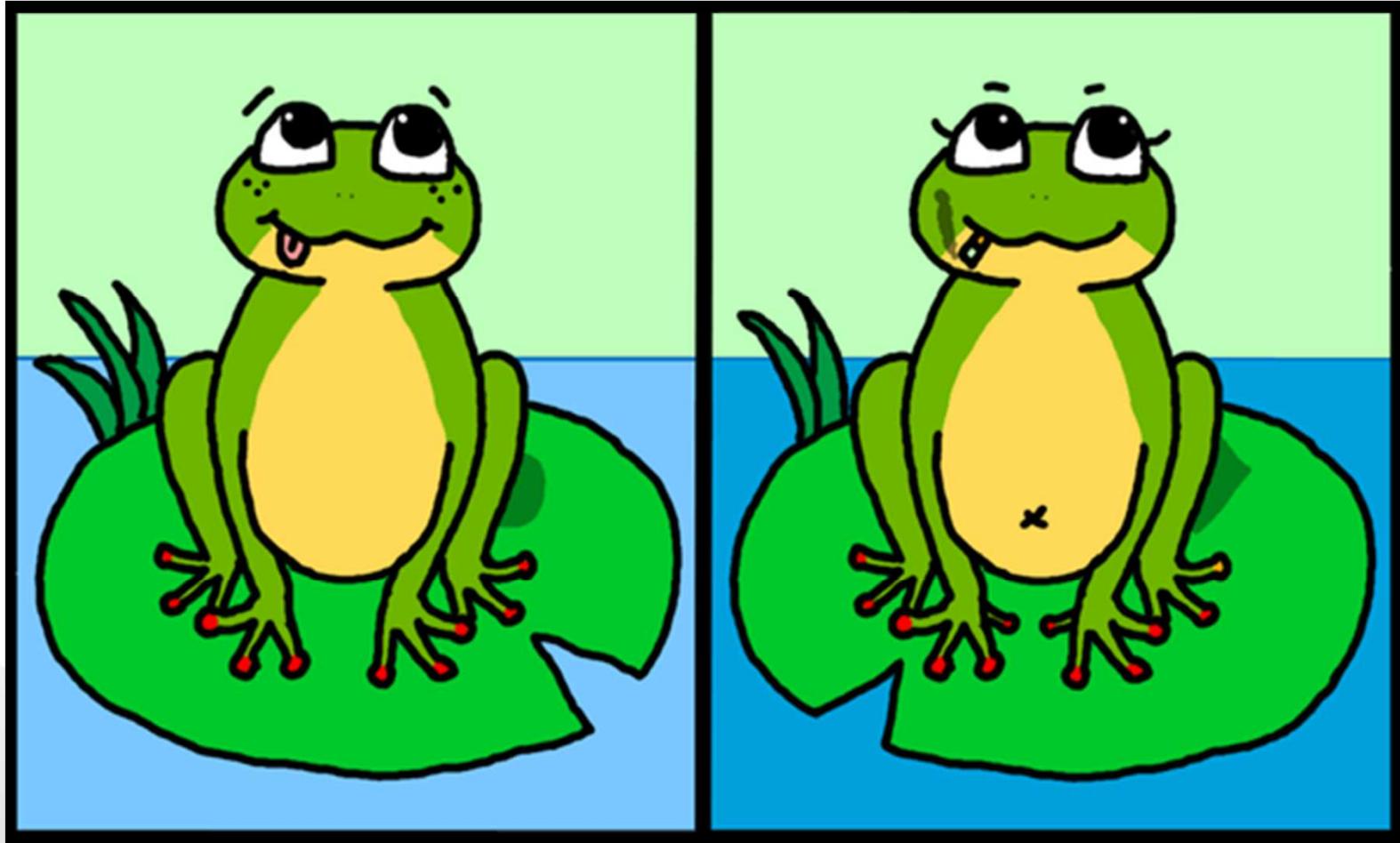
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And now....



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Game Time

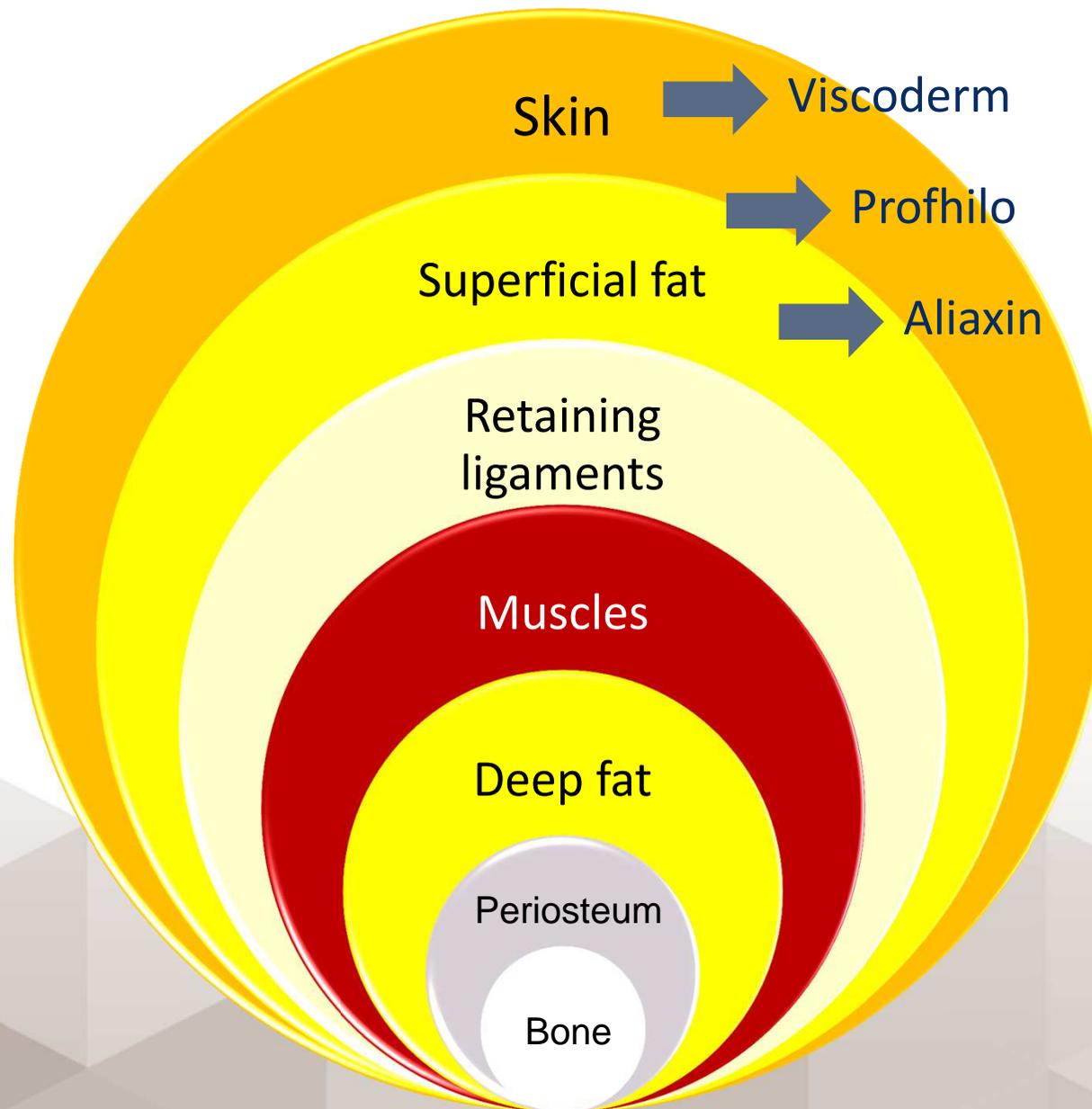


Find the differences

The differences

Product	Formulation	Mechanism of action	Injection layer	Intended use	Results
Viscoderm	Natural single MW HA Concentrations of 8, 16 & 20mg/ml	Biorestructuring of the SLEB	Superficial / mid dermis	Repair and prevent damage from photoaging	Hydration, elasticity, tone
Profhilo	Hybrid cooperative complexes of 2 MW HA Concentration of 32mg/ml	Bioremodeling of the connective tissue (and possibly fat tissue) thanks to collagen and elastin regeneration	Deep dermis/ superficial subcutis	Repair and prevent damage from cronoaging (skin laxity)	Skin redensification Tensor effect
Aliaxin SR	90% Cross-linked HA of 2 MW + 10% natural single MW HA Concentration of 25mg/ml	Frame reshaping + Biorestructuring of collagen fibers	Subcutis	Facial framing temples, submalar area + periorbital framing (inferior and superior rim)	Oval reshaping

Onion-like layers of the face



Three frames that make a face look more youthful

1. Facial frame **Aliaxin[®] SR**

2. Periorbital frame: **Aliaxin[®] SR**

Volume along the superior rim
Volume along the inferior rim

3. Perioral Frame

Fill the prejowl
Fill the labiomandibular sulcus
Fill the anterior chin/mental sulcus
Fill the nasolabial fold

