

Biolift four points technique: new horizons for the administration of cross-linked fillers at three different molecular weights

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Abstract. Hyaluronic acid is one of the main constituents of injectable fillers, medical devices widely used in aesthetic medicine to prevent or treat skin aging. Fillers differ in rheological and physico-chemical properties derived from their production process such as molecular weight, concentration of hyaluronic acid, mechanism and degree of cross-linking. Zhoabex Soft Touch Filler is a hyaluronic acid formulation with three molecular weights and can be used in the minimally invasive approach named Biolift Four Points technique. The Biolift Four Points technique arises from the analysis and comparison of different techniques and it consists in identifying four specific anatomical points of the face for a functional and effective administration. The administration of Soft Touch with the minimally invasive Biolift Four Points technique improves hydration and texture with an appreciable lifting effect.

Key words: hyaluronic acid, soft touch zhoabex, filler, biolift four points minimally invasive technique

Introduction

The concept of 'beauty' is a highly complex topic. In the modern era, beauty is intended as the preservation of the harmony of our proportions, even approaching a more advanced age, with the aim of improving one's perception of themselves and consequently their social well-being.

Aesthetic medicine acts with a multi-disciplinary approach aimed to realize, for those who desire it, a global effect of kinesthesia enhancing the aesthetic strength of each patient.

Minimally invasive approaches are a novel method in the treatment of a complex, such as the meta-crone and multi compartmental phenomenon²⁸ known as facial ageing, with a formulation of hyaluronic acid-based fillers synthesized with sophisticated

technologies that adapt each formulation to the different needs of a patient, through a remodeling and natural redefinition that goes beyond the simple treatments of facial wrinkles.

Hyaluronic acid (HA) is a medical device for the prevention, restoration and treatment of skin ageing, and it has a pivotal role in aesthetic medicine treatments.

The physical-chemical properties of medical HA have been extensively studied over time and the evidence accumulated, has led to the development of different formulation of HA employed in a series of clinical applications in different medical fields (ophthalmology, visco-supplementation in orthopaedics, wound healing) among which aesthetic medicine plays a key role¹.

HA is a natural component of the extra cellular matrix of the dermis synthesized by fibroblasts: it is a linear polysaccharide formed by the repetition of disaccharides (D-glucuronic acid and N-acetyl D glucosamine) that have a hydrophilic capacity giving moisture, firmness and elasticity to the dermis.

Ageing alterations of the skin are characterized by the reduction in quantity of HA with the loss of all its healthy properties.

In the aesthetic field HA not only plays a role as filler for volumization in different facial areas, but it also acts as a bio-regenerating and bio-restructuring factor, with the aim of giving to the dermal layers greater vitality and improving the levels of hydration, firmness and plasticity^{2,3}.

Hyaluronic Acid is a medical device most widely used as a type of injective treatment because its properties make it handy and performing.

Formulations of HA differ for rheological properties that will fit the needs of different areas of the face.

For these reasons HA is a great ally to counteract skin aging, because it allows to perform minimally-invasive treatments with optimal results for patients.

Materials and methods

The study has tested a medical device based on a three molecular weight hyaluronic acid (MWAH) formulation named Soft Touch® (Zoabex Rosepharma) (see Table S1 in Appendix).

This formulation is composed by low molecular weight Hyaluronic acid (Low MWAH 500 KD), medium molecular weight HA (Medium MWAH 1000 KD), and high molecular weight HA (High MWAH 2000 KD), chemically cross linked with a very low residual BDDE (<0.1 ppm).

High-MWAH remains superficial, maintaining hydration and increasing the brightness and firmness of the epidermis⁴.

Medium-MWAH penetrates the intermediate layer, supporting tissues and Low-MWAH penetrates the deep layer for a significant bio-revitalising action^{4,5,6,7}.

Soft Touch MD results from an innovative technology with many applications that allow to obtain a

deep hydration of the dermis, volume modulation and skin lift effect thanks to the interplay among these three components.

We used a qualitative assessment before and after treatment to examine the effects of Soft Touch inoculation:

- The clinical evaluation was based on the Modified Fitzpatrick Wrinkle Scale (MFWS) (Table 1), Wrinkle Severity Rating Scale (WSRS) (Table 2) and the Global Aesthetic Scale (GAIS) (Table 3)
- A Pintch Test was performed to assess skin elasticity¹⁰
- All participants had pre- and post-treatment photographs. All photos were taken with a full-frame camera Sony ILME FX3 with a basal setting in automatic mode and a diaphragm

Table 1. Modified Fitzpatrick Wrinkle Scale (MFWS).

Class 0	No visible wrinkles; continuous skin lines
Class 0.5	Very shallow yet visible wrinkles
Class 1	Fine wrinkles. Visible wrinkles and slight indentations
Class 1.5	Visible wrinkles and clear indentations, <1-mm wrinkle depth*
Class 2	Moderate wrinkles. Clearly visible wrinkles, 1-to 2-mm wrinkle depth*
Class 2.5	Prominent and visible wrinkles; 2 – to 3 – mm wrinkle depth*
Class 3	Deep wrinkles. Deep, furrowed wrinkle; *>3-mm wrinkle depth.

**Wrinkle depth is based on assessors' estimation rather than physical measurement.*

Table 2. Wrinkle Severity Rankle Scale (WSRS).

WRINKLE SEVERITY RATING SCALE	
SCORE	
1	Absent
2	Slight
3	Moderate
4	Severe
5	Extreme

Table 3. Global Aesthetic Improvement Scale (GAIS).

VERY MUCH IMPROVED	Optimal cosmetic result for the implant in this patient
MUCH IMPROVED	Marked improvement in appearance from the initial condition but not completely optimal for this patient; touch-up would slightly improve the result
IMPROVED	Obvious improvement in appearance from the initial condition, but touch-up or retreatment is indicated
NO CHANGE	Appearance essentially the same as the original condition
WORSE	Appearance worse than the original condition

and ISO in manual mode, depending on the surrounding lighting.

Ten aesthetic doctors blindly evaluated the quality of this method looking at the pictures of the patients before and after treatment, to judge its effect using the Global Aesthetic Improvement Scale (GAIS). Assessments were done within 1 hour following treatment and again two weeks later

- A Facial Ultrasound assessment of the inoculated bolus and detection of its stay after a two weeks was performed^{8,9}. A high frequency linear probe (8-12 MHz Philips) was used on the midface in a semi-sagittal position, with reference point at the level of projection of the zygomatic bone, at the insertion level of the greater zygomatic muscle, sliding the probe towards the nose and following the facial anatomical structures up until reaching the lateral ends of the lips.

Clinical study

A retrospective observational study has been conducted on a clinical database collected from June 2018 to December 2019.

Selection of patients

Fifteen female participants with ages ranging from 35 to 65 years were included in this study.

Demographic data, the history of medical, surgical, or aesthetic procedures, physical examination, vital signs, and concomitant medications were evaluated and recorded at baseline.

The inclusion criteria for this study involved patients in good health, patients that were not undergoing any other treatments, and patients that presented mild/moderate to severe photo-aging measured with the Modified Fitzpatrick Wrinkle Scale (MFWS) and Wrinkle Severity Rating Scale (WSRS).

The patients were asked to not modify their lifestyle and were required to provide a written consent form.

The exclusion criteria consisted of patients that had undergone other medical-aesthetical treatments, patients who were pregnant or breast feeding, or having autoimmune conditions and intercurrent cutaneous diseases.

Data was collected from a clinical database (Table 4) wherein informed consents expressed authorization to utilize images, photos and the characteristics of treatments in scientific reports.

Protocol treatment

THE BIOLIFT TECHNIQUE

The BIOLIFT technique is a medical-aesthetic treatment that has been designed and finalised with the use of the medical device (MD) known as Soft Touch (Zhoabex, Rosepharma).

The name of the BIOLIFT Technique is derived from 'BIO' from the etymology of the word 'life', to generate a real structural biogeneration, and 'LIFT' to improve lifting, redefinition and harmonization.

The formulation of the Soft Touch MD consists of HA with three different molecular weights (PM): low, medium and high PM.

Soft Touch MD is cross-linked with very low residue BDDE (< 0.01 PPM) and is the result of an innovative type of technology with versatile applications, which allows to obtain a deep rehydration of the dermis, a modulation of volumes and a significant 'lift' of the tissue.

Three-molecular-weight formulation (TMW) HA allows to trigger a synergistic action; in fact, the

Table 4. Characteristics of patients enrolled in the study.

Patient	Sex	Age	Device used	MFWS pre	WSRS pre	WSRS after 1 w	GAIS after 2 w
1	F	52	Needle	2	3	2	3
2	F	47	Needle	2	2	2	2
3	F	35	Needle	1,5	2	1	2
4	F	39	Needle	2	3	2	2
5	F	65	Cannula	3	4	3	2
6	F	55	Needle	2,5	3	2	2
7	F	51	Needle	2	3	2	2
8	F	49	Needle	2	2	2	3
9	F	39	Needle	1,5	3	1	1
10	F	44	Needle	1,5	3	2	2
11	F	56	Needle	2,5	4	3	2
12	F	63	Cannula	3	4	3	2
13	F	37	Needle	1,5	2	2	3
14	F	45	Needle	2	3	2	2
15	F	53	Needle	2	2	2	2

share of HA at low PM penetrates into the deep layer of the dermis as a foundation of the biostimulation process; the HA at medium PM penetrates into the superficial layers of the dermis, increasing hydration and giving tone and volume, and the HA at high PM remains very superficial, maintaining hydration and increasing the brightness and firmness of the epidermis⁴.

Thanks to its versatility, Soft Touch MD can be used for the treatment of skin blemishes through different applications:

- as a regenerating and lifting therapy,
- as a pre-implantation substrate of a volumizing filler,
- as a filler for a refined effect.

Thanks to its rheological characteristics, Soft Touch MD can be used with the minimally invasive Biolift Four Points technique.

This allowed us to identify four specific anatomical points of the face for a functional and effective administration based on an expert's technique and a good understanding of the facial anatomy.

The treatment requires 1 ml of Soft Touch (0,5 ml each side): in each of the four points identified in

the medium third of the face through the Biolift technique, we have injected a microbolus (0,1-0,15 ml) in the medium-deep dermis through a 30 G needle. The treatment is to be repeated every 4 - 6 months according to the patient's needs, in order to accentuate the lifting and moisturising characteristics of Soft Touch.

The first point (Figure 2) is at the level of the tragus, in the depression between it and the mandibular condyle, an area anatomically located above the parotid gland and free from vascular and nervous 'danger' points.

In traditional oriental medicine, this anatomical region is an acupuncture point. In fact, acupuncture can also lead to benefits in facial rejuvenation, such as the mitigation of any skin imperfections and the improvement of texture and tone^{17,21,22}.

The intention is to maximize the benefits of administering the filler by combining them with the stimulation of an energy point, thus generating a reflex action on muscle function and microcirculation also improving hydration, firmness and plasticity.

The location indicated above represents the acupuncture point IG19, indicated for improving sensitive skin and skin relaxation. The action of the filler and the stimulation of an energy point are therefore part of a

tradition that has lasted centuries, generating a reflex action on muscle function and microcirculation.

The second point (Figure 3) identified is TR 23 (Triple Heater), detectable in the depression at the outer end of the superciliary arch: this point has a local draining effect, allows the eyebrows to lift and also represents a point of muscle myomodulation in facial mimicry.

If the second point described above presents difficulties in its detection and inoculation due to the presence of dense vascularization, the anatomical point corresponding to the projection of the zygomatic bone at the insertion level of the greater zygomatic muscle can be alternatively infiltrated in consideration of the dynamics of the muscular mimic of the face, functioning as a lifting vector with a traction and fulcrum effect^{15,16}.

In skin ageing it is necessary to evaluate the change of the skin, the adipose compartments and bone tissue, as well as changes in the muscle component.

The myomodulation concept consists of using injectable hyaluronic acid (HA) fillers to modulate the action of mimetic muscles to improve one's facial appearance^{18,19}.

Accordingly, a bolus of filler placed beneath the muscle near its origin (e.g., in the malar region) could substitute for a loss of structural support from adipose and osseous tissues.

The filler acts as a fulcrum, recreating the convexity and tension of the muscle and thus increasing its contractility or restoring the tonus at rest providing support under the muscle between its origin or insertion (creating a fulcrum or pulley effect), or improve tensile strength by increasing distance between the origin and insertion, thereby reducing slack¹⁸.

Facial aging is characterized by the loss of muscle property and by alterations of the balance of their length-strength relationship. One technique for counteracting it, is to inject below the muscle to obtain a modulation of the muscle movement (myomodulation) itself^{15,16}.

It operates on the muscle pulley and lever system by acting on the SOOF (sub orbicularis oculi lateral fat pad) at the level of the greater zygomatic muscle with the aim of lifting the corners of the mouth, mimicking a smile, and harmonizing the zygomatic profile¹⁵.

This action acts in a functional group of muscles, working in harmony and synergy, and helps to improve the patient's appearance²⁰.

The injection of a bolus of Soft Touch MD filler deep into the medium-deep dermis increases its convexity and acts as a fulcrum, increasing its mechanical advantage and all following: administration depth, correct needle inclination, administration technique and product quantity, for visible and reproducible results¹⁵.

The third point (Figure 4) identified is about 2 cm from the wing of the nose, with particular attention to the course of the angular artery, which allows product diffusion and also a slight opening of the corner of the nasolabial wrinkle.

Lastly, the fourth and last point (Figure 5) is in the anterior angle of the mandible, in a depression detectable on the anterior edge of the masseter muscle E5 (mandibular angle): it improves the three-dimensionality of the lips and the microcirculation of the cheek.

By drawing and joining the four inoculation points on the face, a rhombus is outlined that develops a traction and lifting effect and hides the triangle of beauty in its geometries.

Throughout the execution of the treatment, the operator's respect of the injection depth, volume, speed, and precision are always fundamental for an optimal result.

Despite rare exceptions, the maximization of clinical effect can be obtained with an implant every four months or so, for example after medical evaluations spaced out 30-40 days from each other.

To obtain a similar effect with Soft Touch MD in older patients with advanced skin ageing, HA can be administered through a cannula: this allows to carry out the treatment in a less invasive way, given the small number of access points, one for each side of the face, and to distribute the Soft Touch MD filler in a fan-like manner on the middle cheek region with high tissue integration, with a bio stimulating, moisturizing and lifting effect.

The cannula is an atraumatic, flexible device with a chamfered tip and exit hole at the end.

Using such a device has the advantage of reducing the access points, with a lower likelihood of vascular

puncture and haematoma formation, lower redness, and pain²³.

Even if there are no clinical differences in patients treated with a needle or cannula it is known that the use of the cannula is less traumatic and reduces inflammatory cutaneous reactions compared to needle inoculation²³.

Post-treatment, there is an improvement in the texture, an attenuation of nasolabial wrinkles, with an excellent refreshment of the middle third, which regenerates and evolves in the following days so as to also highlight a visible hydration of the lips.

Results

The Biolift four points technique is of easy execution, minimally invasive and can be easily reproduced to minimize potential errors.

No adverse effects or intolerances presented themselves. The treatment caused minimal discomfort, without any post-treatment pain. All patients returned to their everyday activities immediately after the treatment. The participants felt satisfied with the treatment.

Fifteen female patients aged 48 ± 9 (mean \pm standard deviation) affected by lower-medium level facial skin ageing, were enrolled in this study to undergo the Four Point Biolift Technique; 13% of patients (2 out of 15 pts) with severe skin ageing were subjected to the inoculation of Soft Touch MD with a cannula on the third medium of face.

The areas treated were examined through a qualitative assessment by touching and putting pressure using a Pinch Test which revealed an enhancement of mechanical skin elasticity.

Before the treatment assessment of MFWS demonstrated that the medium level of the patient's aging was characterized by moderate and clearly visible wrinkles with 1-2 mm of wrinkle depth (mean \pm sd $2,1 \pm 0,5$).

The results were defined with the Global Aesthetic Improvement Scale (GAIS), used as a reference parameter, assessed after two weeks, that showed average values of $2,1 \pm 0,5$ which means marked improvement in appearance from the initial condition, even if not completely optimal for this subject.

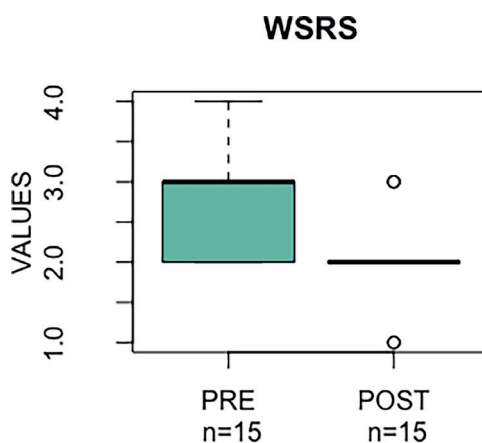


Figure 1. Wilcox Test (wsrs_pre, wsrs_after_1w, paired = true).



Figure 2. Point 1 of Biolift Technique: 0.15 ml at the tragus in the depression between it and the mandibular condyle.



Figure 3. Point 2 of Biolift Technique: 0.10 ml in the depression at the outer end of the superciliary arch, TR23.

A summary of the patient's characteristics and scores obtained is provided in Table 4.

Values of WSRS assessed after one week compared to the WSRS values assessed before treatment



Figure 4. Point 3 of Biolift Technique: 0.15 ml at two centimetres from the wing of the nose.



Figure 5. Point 4 of Biolift Technique: 0.10 ml at the angle of the mandible, in the depression on the anterior edge of the masseter muscle, E5.



Figure 6. Example case of facial rejuvenation: a female patient at the beginning of the treatment and at the end of the treatment after two weeks.

showed a statistically significant difference with the Wilcoxon signed rank test with continuity correction (p-value = 0.001586) as demonstrated in Figure 1.

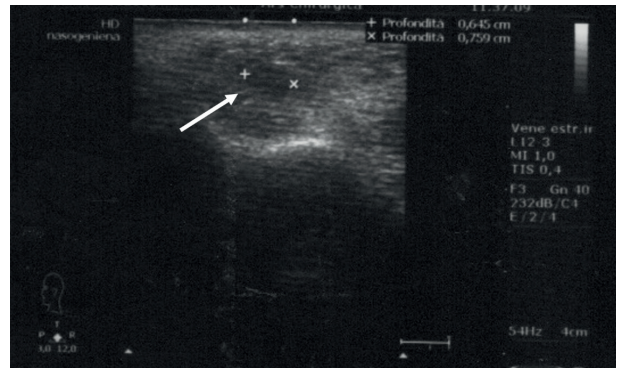


Figure 7. Ultrasound screenshot of HA inoculum after two weeks of treatment.

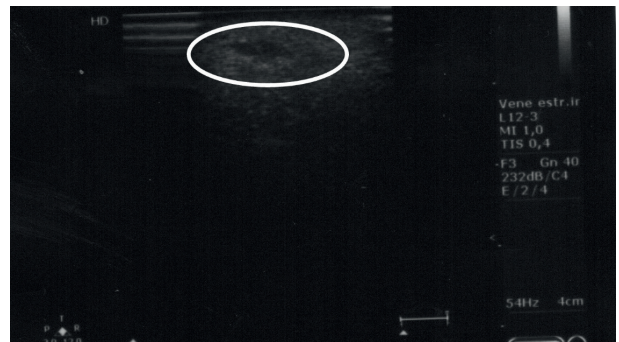


Figure 8. Ultrasound screenshot of sub-cutaneous hydration after two weeks of treatment.

The photographic evaluation performed at the beginning and at the end and after two weeks of treatment, has confirmed the improvement of skin brightness, firmness, and texture but, above all, we have encountered a visible eye opening, as confirmed by all aesthetic doctors involved in the qualitative judgement of the patient's pictures.

All clinical findings have confirmed through ultrasound evidence²⁴ an improvement of tissue moisture (Figure 8) at fourteen days from treatment, especially in patients younger than fifty, and a stay of micro bolus injected optimally integrated in the inoculum site (Figure 7).

Discussion

This study evaluated a new technique of mesotherapy for facial skin rejuvenation, known as Biolift 4 Points.

Other forms of mesotherapy have shown improvement of both clinical and histologic skin changes.

The present study evaluated the simple and minimally invasive form of mesotherapy for skin rejuvenation utilizing the TMW HA formulation named Soft Touch.

The aim of mesotherapy for skin rejuvenation is maintenance and/or recovery of youthful skin. Mesotherapy increases the biosynthetic capacity of fibroblasts and the reconstruction of an optimal physiologic environment, the enhancement of cell activity, and the synthesis of collagen, elastin, and hyaluronic acid^{25,26,27}.

HA is progressively reduced over time with the consequent loss of its structural and physiological role. For this reason, it represents a point of reference treatment in the aesthetic field. The various HA fillers differ from each other in their different rheological and physical-chemical properties based on molecular weight, concentration, and their cross-linking degree, resulting from their production process. The restoration of hydration through the moisturizer effect of HA counteracts skin laxity, giving the skin new elasticity.

We have applied the minimally invasive BioLift Four Points technique in several patients, trying to minimize the risk of possible complications not only through the technique itself, but also based on a careful history and evaluation of any exclusion criteria such as autoimmune diseases or known allergies and especially considering the real needs of the patient¹¹.

The minimally invasive technique has proven to be an effective treatment for reducing the signs of skin ageing, for improving texture, associated with a visible lifting effect and with a good tolerability.

The Four Points technique for the administration of the Soft Touch MD product comes from the study, analysis and comparison of different techniques.

Identifying the area to be treated, appreciating the underlying tissues and administering slowly keeping in mind depth, the injected volume, the speed of injection and precision aim to minimize risks and optimize product properties^{11,12,14}.

Our usage protocol exploits some anatomical points that tend to minimize the risks related to inoculation, while trying to optimize the efficacy and outcome¹³.

Our study has limitations in the small number of patients enrolled, in the short time of observation and in the measurability of results that have been expressed mainly with qualitative data of the evident clinical improvement.

Data collected by WSRS demonstrated a statistical positive trend of improvement of skin quality despite a short period of acquisition of results in a small sample.

In conclusion, these new minimally invasive mesotherapy techniques, thanks to the characteristics of HA-TMW formulation, and the implant with the minimally invasive Biolift Four Points technique with Soft Touch MD, can improve the clinical appearance of the skin in different age patients, via action on the maintenance and/or restoration of healthy and youthful texture of skin with a clinical, ultrasonographic visible lifting effect (Figure 6).

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Appendix – Supplementary files

Table S1. Characteristics of Soft Touch formulation.

SOFT TOUCH	
Active Component	CROSS-LINKED HYALURONIC ACID
Concentration	2,5% (25 mg/ml)
Reticulating Agent	BDDE (residual < 0,1 ppm)
Molecular Weight	2 M Da + 1 M Da + 0,5 M Da
Volume per siringe	1,1ml
Needle	Cannula 27 G 38 mm
Duration	5 - 6 month
Deep of injection	Hypodermis
Indications	Large volumes (cheeks)