

Restylane® Skinboosters™ for the improvement of the skin quality

Results of a consensus meeting

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For every woman, beauty plays a significant role in their lives beyond the age 40. With a good constitution and an active lifestyle, women on average feel ten years younger than they are and they want to look as young as they feel. More than half of women define attractiveness through a firm, wrinkle-free skin [7, 18]. Study results from Fink et al. document that a smooth skin texture, therefore fine, tight, full skin without wrinkles, as well as a healthy skin tone with a special glow significantly influences perceived attractiveness. As a result, female attractiveness is assessed higher if the skin shows less blemishes [4, 12, 13]. In our society, youthfulness and beauty are positively attributed and also determine interactions and positioning in the social as well as the professional environment [2, 6, 10, 14, 17]. Therefore, the need for attractiveness is quite understandable. But with increasing age, the quality of the skin changes. Histological studies, for example, show a reduction and incorrect cross-linkage of the elastin fibers and a decreasing hyaluronic acid (HA) synthesis with reduced water binding (50% reduced HA concentration in 60-year-old women) [21]. The reduced number and activity of fibroblasts additionally leads to a reduced collagen synthesis and a decrease of dermal collagen I and III. Visible signs of the intrinsic aging process include dehydration, loss of tissue tightness and elasticity, wrinkle formation as well as a thinning of the skin and can be superimposed by extrinsic skin aging (especially UV-induced photo aging).

Minimally invasive aesthetic treatments intended to delay the skins aging

process are increasing in demand. Today, patients want an out-patient aesthetic treatment with little side effects and a long-term outcome, leading to effective but also natural results with minimal recovery time. Accordingly, the substitution of HA by means of intradermal injections is an established anti-ageing measure, with proven, evidence-based efficacy and safety.

In principle, injectable HA products can be classified into two groups with different therapeutic goals. Whereas HA-fillers are used for targeted wrinkle augmentation and volume substitution, skin boosters are injected superficially for the revitalization of the skin. They improve the signs of skin aging through stimulation of the extraellular matrix (ECM) [5, 22, 26]. The biological significance of HA for the skin as well as its excellent physicochemical properties, especially its high water-binding capacity, determine injectable HA based skinboosters for improvement of skin quality. Although native HA is ubiquitous in the human body, the largest amount is located in the skin. With 7-8 g of HA, the skin contains approximately 50-56% of the total body content. HA is a significant stabilizing component of the ECM, can bind large amounts of water and is essential for hydration homeostasis. Apart from its significance as a structure substance, HA is also an important functional tissue component, because extracellular substance transport (diffusion of electrolytes, nutrients and decomposition products in the tissue) as well as the activity of the immune system are associated with the hydration status of the ECM. In addition to this, HA is

pivotal for cellular processes such as proliferation, differentiation and migration. Amongst other processes, it stimulates fibroblast proliferation and activity with an increased biosynthesis of collagen and other components of the ECM. Apart from regenerative tasks such as improved wound healing under HA, it also has cell protecting properties against external noxious substances. In current studies, it is being discussed whether HA itself fulfills the function of a radical catcher for the deactivation of ROS or whether a reaction with free radicals attacks and leads to its destruction [11, 28].

The efficacy and safety of the widely applicable Restylane® Skinboosters™ are excellently proven on the basis of current data. According to these findings, they ensure an improvement of skin quality without significant volume changes. The skin is hydrated [8, 15, 27], its elasticity increased [8, 15, 16, 20, 23, 27], the skin surface smoothed [8, 16, 20, 27] and fine lines and wrinkles are reduced [16]. Restylane® Skinboosters™ are injected subcutaneously and have a clinically proven effect duration of up to 12 months [16]. The long lasting and significant effect is due to the use of non-animal stabilized hyaluronic acid (NASHA), especially in direct comparison with non-stabilized hyaluronic acid. This was proven by a number of studies including Carruthers et al. (2014) as well as Williams et al. (2009) [5, 27]. The substitution leads to a stimulation of fibroblast proliferation and activity with new synthesis of collagen, elastin and other extracellular components such as HA, leading to more skin elasticity, skin tension and moisture

GENERAL TREATMENT REFERENCES		
	Vital	Vital Light
Ingredients	20 mg/ml stabilized hyalurone with or without 0.3% lidocaine	12 mg/ml stabilized hyalurone with or without 0.3% lidocaine
Lifting capacity	Low	Very low
Technologi	NASHA™	NASHA™
Skin quality	Aged or thicker skin	Younger or thin or sensitive skin
Treatment areas	Face, neck, hands, décolletage, upper arms	Face, neck, hands, décolletage, upper arms
Tissue coverage	Strong	Weak
Injection depth	Subcutaneous	Subcutaneous

Table 1: Product recommendations.

[5, 25, 26]. The positive study results are supported by high patient satisfaction. According to blinded live-rating, skin quality improved in more than 80% of the patients. 85% assessed the therapeutic success positively and stated that they would repeat the treatment. Furthermore, patients as well as blinded evaluators indicated significant aesthetic improvements on the basis of the Global Aesthetic Improvement Scale (GAIS).

For the standardization of therapy protocols, a consensus meeting with six experts from the field of aesthetic dermatology took place (committee members see Appendix). The objective of the scientific expert committee was the compilation of an updated guideline for the application of Restylane® Skinboosters™. Current evidence-based studies and the expertise of the committee members were included in the new standardized treatment protocols for the various indications, which through clear recommendations (e.g. injection depth, application intervals) are intended to guide novices as well as experienced users towards Restylane® Skinboosters™ and provide support for the application in everyday practice. For the indication-appropriate application, the treatment protocols define the respective treatment area, the target group and indications, the protocol selection and injection amount, technique, points and volumes for every indication.

PRODUCT SELECTION

The target group for Restylane® Skinboosters™ are patients who want an improved skin structure. In the past, the choice for the correct Restylane® Skinboosters™ has been individually made for every patient based on the Glogau Scale (classification of akin aging in skin types I-IV). However, since this classification method is very complex, the Glogau Scale is now being replaced by a simpler system. This updated classification is supposed to help even novices to easily arrive at the correct product selection for their patients. It will also help experienced practitioners improve day-to-day efficiency.

First, the skin in the treatment area should be defined. The new classification differentiates between more mature, thicker, partially light-damaged skin with more covering tissue (Type A skin, e.g. cheeks) and younger, thinner, more sensitive skin with less covering tissue (Type B skin, e.g. neck). For Type A skin, the

use of Restylane® Skinboosters™ Vital is suitable with strong tissue coverage and low lifting capacity. For Type B skin, the practitioner can select Restylane® Skinboosters™ Vital Light with low tissue coverage and very low lifting capacity (Table 1). Special challenges could be posed by thick photo-aged skin, mature and thin or sensitive skin, although even younger skin can be associated with less tissue coverage in certain areas. Here, the success of the treatment is closely associated with the expertise of the practitioner, whose patient-individual choices are decisive for treatment results. For example, with an optimal treatment, skin aging symptoms (e.g. dehydration, loss of tissue tightness and elasticity, wrinkle formation, atrophy and photo aging) as well as deep acne scars can be reduced and skin quality can thereby be visibly improved. With UV-damaged skin, a more conservative application of Restylane® Skinboosters™ should be considered. The stronger the UV-damage, the more difficult it is to activate the fibroblasts. In this



Figure 1: Revised treatment protocol for Restylane® Skinboosters™.

INDICATION CHEEKS	
Definition cheek area	<p>Treatment area upper cheek: Zygomatic region bordering below the orbital rim; the periorbital region (crow's feet) is assigned to the upper cheek area.</p> <p>Treatment area lower cheek + chin: hollow cheek, tragus, chin</p>
Target group	Patients with aged skin and younger patients
Indications	Younger patients: prophylaxis, dry skin, fine lines
Product selection	Vital or Vital Light (see below CAVE)
Injection volume (per treatment area and per side)	Upper cheek area: 0.5 ml Lower cheek area + chin: 0.5 ml
Injection technique	Blunt; sharp
Injection points and volumes	<p>Blunt:</p> <ol style="list-style-type: none"> 1. Approx. 0.5 ml lateral and approx. 2–3 mm above the corner of the mouth <i>(to be able to treat the perioral region from here as well)</i> 2. In a line between the corner of the mouth and the tragus, medial to the M. masseter 3. Optional point for beginner practitioners: on the zygomatic arch <i>(to better cover the complete region (incl. distal))</i> <p>Sharp:</p> <ul style="list-style-type: none"> • Injection points see figure • Approx. 10 µl per Injection point • Bolus-Technique
<p>CAVE: For younger/thinner/sensitive skin the use of Vital Light is also possible.</p>	

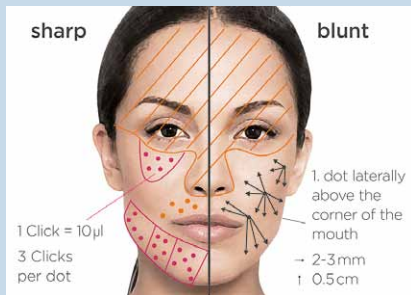


Table 2: CONSENSUS – Indication cheeks.

case, combination treatments or alternative treatments are preferred. Especially with UV-damaged skin, exclusive therapy with laser has been regarded as helpful. However, prior to laser treatment with a fractionated ablative CO₂-laser, Angelis and Tretti recommend the injection of stabilized hyaluronic acid [1]. The Restylane® Skinboosters™ stimulate the fibroblasts, which should then respond better to the thermal stimulation of the laser.

RESTYLANE® SKINBOOSTERS™ INJECTION

On recommendation of the experts and based on the current state of research, the injection of Restylane® Skinboosters™ should generally be performed superficially in the subcutaneous tissue. It is important not to equate Skinboosters treatment with mesotherapy. Whereas with mesotherapy non-stabilised hyaluronic acid and diverse other substances

are injected into various skin layers, the efficacy and safety of the Restylane® Skinboosters™, which exclusively contain non-animal stabilised HA, is clinically proven [19, 20, 23, 24, 27] and must be performed in the area of the deep dermis and subcutis.

Unwanted effects and results – apart from local injection-related reactions such as short-term erythemas or hematomas – usually occur due to incorrect treatment, for example by injecting the Skinboosters too superficially. If Skinboosters are applied too superficially and the skin is too thin, there is a risk for nodules/papules formation and an accumulation of the injected material. This undesirable effect can be prevented with injections into the correct skin layer. Nevertheless, if it occurs the committee recommends the application of the enzyme hyaluronidase. Another safety issue besides the defined injection depth is the selection of a suitable cannula. Depending on the expertise

of the practitioner the injection can be performed with blunt cannulas or with sharp needles. Blunt cannulas are principally associated with lower side-effects and are therefore usually preferred by the patients. Blunt ending cannulas (Pix'L23G - 50 mm to 25G - 40 mm) have been clinically proven to reduce injection-related reactions [3,9]. With less penetration points and a reduced risk of hematoma formation, patient comfort is increased. Furthermore, the lateral outlet of the cannula ensures a more even distribution of the Skinboosters and the treatment is experienced as being less painful. Through the optional SmartClick™ System, application safety can additionally be increased: for each 10 µl injected, a click is triggered, enabling the practitioner to completely focus on the injection and attend to the patient while the product is evenly delivered.

For an indication-conforming application, the injection amount, technique,

points and volumes are recommended in the treatment protocols for the respective treatment area (tables 2-5, figure 2).

APPLICATION INTERVALS

So far, the treatment regimen for Restylane® Skinboosters™ recommends three build-up treatments at an interval of four weeks and two repeated treatments after six months respectively. As Restylane® Skinboosters™ are medicinal products, deviations can be made from the described treatment scheme in clinical practice if safety is ensured.

Results from current studies and the experience of the experts suggest a reorientation in the recommendation on application intervals. The expert committee agreed that two applications lead to very good results and a current investigation from Kerscher et al. substantiates this [19]. The new treatment protocol (figure 1) recommends two, optionally three initial treatments at an interval of respectively four weeks. In everyday practice however, patient-individual decisions are recommendable: for patients who wish for less treatments, longer intervals can be planned between the appointments. Although a few days after the first treatment an increasing amount of water is bound in the patient's skin and a visible effect is achieved, only repetitive



Figure 2 : CONSENSUS – Restylane® Skinboosters™ Volume per Indication.

treatment can stimulate the fibroblasts and instigate a collagen biosynthesis. For high patient satisfaction and a long-term relationship to the treating physician patient education is paramount, especially regarding the expectations towards the delayed occurring effect. Furthermore, the revised treatment protocol is based on current research on the effect duration of the Restylane® Skinboosters™: for Restylane® Skinboosters™ Vital Light [24] a duration of the aesthetic effect of nine months was substantiated,

for Restylane Skinbooster Vital even up to 12 months [16]. Subsequent to the two to three initial treatments, two repeated treatments are only recommended after respectively 9-12 months (figure 1).

INDICATION PERIORAL (SMOKER'S LINES)	
Definition perioral area	Distal border: A few cm around the border of the vermillion around the vertically running smoker's lines
Target group	Younger patients (preventive treatment) as well as patients with loss of elasticity
Indications	Wrinkles and perioral loss of elasticity
Product selection	Vital Light or Vital (see below CAVE)
Injection volume (complete treated area per session)	0.25–0.5 ml
Injection technique	Blunt; sharp
Injection points and volumes	See figure "Indication cheek"
CAVE: Use of Vital possible, if the region above the lip is sunken in (use marginal injection volume)	

Table 3: CONSENSUS – Indication perioral (smoker's lines).

INDICATION DÉCOLLETAGE [1]	
Definition décolletage area	Upper border: Clavicula Lower border: Breast fold Lateral border: 2 treatment areas, see orange resp. grey shaded area (see also CAVE ¹ below)
Target group	Mostly patients with aged skin
Indications	Loss of elasticity/ decreasing skin quality
Product selection	Vital Light (thin skin) and Vital (thicker skin)
Injection volume (complete treated area per session)	1–2 ml depending on the treated area (s. figure above and CAVE ² below)
Injection technique	Blunt; sharp
Injection points and volumes	Blunt: <ul style="list-style-type: none"> • Injection points depending on desired treatment area, to treat the complete area • Retrograde injection
CAVE 1. Depending on choice of clothes and individual patient wishes (no precise anatomical definition of the region) CAVE 2. Too superficial application may result in nodules.	

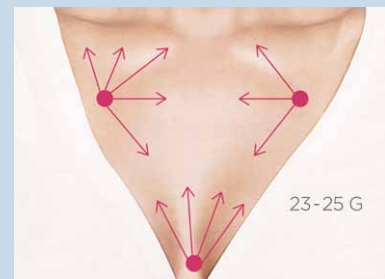
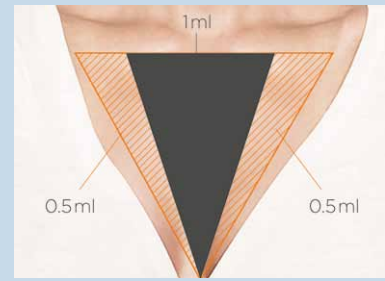


Table 4: CONSENSUS – Indication décolletage.

TREATMENT PROTOCOLS FOR FACE, DÉCOLLETAGE AND HANDS

CONSENSUS – FACE

Indication cheek / indication periorbital (crow's feet):

The indication cheek includes the upper and the lower cheek area. The indication periorbital (crow's feet) is allocated to the treatment area „upper cheek“ (table 2).

Indication perioral (smoker's wrinkles): (table 3)

CONSENSUS – indication Décolletage (table 4)

CONSENSUS – Indication hands (table 5)

The **indications forehead, temples and neck** are expert indications for Restylane® Skinboosters™ treatment. Therefore no recommendations are given in this consensus.

SUMMARY

Restylane® Skinboosters™ are outstandingly suitable for deep hydration of the skin, and their effect is long-term and safe. Natural treatment results fulfil the needs of the patients and increase the patient-practitioner relation. In the new guidelines on the optimal application of Restylane® Skinboosters™ Vital Light and Vital the indications, application intervals, injection technique and compliance are addressed in detail. Furthermore, illustrated application recommendations (e.g. injection amount, technique, points and volumes) for different target groups and treatment areas such as face, décolleté and hands will provide the practitioner security in handling Restylane® Skinboosters™.

Literature

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INDICATION HANDS	
Definition hand area	Distal border: only dorsum of the hand (no fingers) Proximal border: wrist
Target group	Mostly patients above 30 years; seldom younger (25–30 years)
Indications	Younger patients (Approx. ≥ 30 years): prophylaxis; dry skin, hands with clearly visible sinews (thin hypodermic tissue, bulging veins and sinews)
Product selection	Vital or Vital Light for dry, thin skin
Injection volume (per treatment area and per side)	0.5 ml (for 3 treatments) (see CAVE below)
Injection technique	Depending on expertise choice: blunt; 2. choice: sharp (bolus technique)
Injection points and volumes	<p>Blunt – possibility no. 1: Four points: between the finger joints, Retrograde injection</p> <ol style="list-style-type: none"> 1. Injection of multiple, small boli or 2. Injection of few, larger boli (0.1–0.2 ml, see figure) followed by distribution of depots (massage) <p>Blunt – possibility no. 2:</p> <ul style="list-style-type: none"> • One point: dorsum, proximal • Retrograde injection • 1. Injection of multiple, small boli or • 2. Injection of few, larger boli (0.1–0.2 ml, see figure) followed by distribution of depots (massage) <p>Sharp: (bolus technique):</p> <ul style="list-style-type: none"> • Four points: between the finger joints – Retrograde injection • 1. Injection of multiple, small boli (0.1–0.2 ml, see figure) or • 2. Injection of few, bigger Boli followed by distribution of depots (0.1–0.2 ml, see figure) followed by distribution of depots in direction of the arrows (massage)
	
CAVE: Small depots to avoid nodules.	

Table 5: Consensus – Indication hands.

THE COMMITTEE MEMBERS

Dr. med. Maja Waibel, Berlin – After working at the Benjamin Franklin clinic in Berlin, Dr. Waibel established herself in her own practice in Berlin as an expert for aesthetic dermatology, laser medicine and melanoma prevention.

Dr. med. Martina Hund, Berlin – Dr. Hund is specialist for dermatology and venerology in her own practice in Berlin. She is co-author of several dermatology reference books and has long-term experience working at the skin tumour centre of the Charité Berlin.

Dr. med. Alexandra Ogilvie, Munich – As a senior physician of the skin clinic at the University clinic Erlangen, Dr. Ogilvie was involved in various scientific advisory boards. She is a specialist for dermatology and allergology and works in her own practice in Munich.

Shirin Samimi-Fard, Gladbeck – Shirin Samimi-Fard is a specialist for dermatology and venerology, allergology and has a diploma in esthetic laser medicine. She is the head of the Derma Loft.

Prof. Dr. med. Martina Kerscher, Hamburg – Prof. Kerscher heads the cosmetic science workgroup at the University Hamburg. She is a specialist for dermatology and venerology and expert for skin physiology; skin ageing and minimal invasive cosmetic procedures.

Dr. med. Anna Mokosch, Düsseldorf – Dr. Mokosch is a specialist for dermatology and venerology in Düsseldorf. She is also a lecturer at the academy for cosmetic medicine in Düsseldorf.

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CAVE: The presented treatment scheme has proven (itself) to be evidence based, very effective and safe in most patients. There are, however, individual deviations of volume, frequency and injection time intervals, but their effectiveness is not scientifically proven.

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August 30 – September 1, 2018 – Hotel Park Royal Palace, Vienna (Austria)

August 28th & 29th, 2018

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