

Consensus report on the use of PN-HPT™ (polynucleotides highly purified technology) in aesthetic medicine

Maurizio Cavallini MD¹ | Emanuele Bartoletti MD² | Laura Maioli MD³ |
 Alberto Massirone MD⁴ | Isabella Pia Palmieri MD⁵ | Marco Papagni MD⁶ |
 Maurizio Priori MD⁷ | Gloria Trocchi MD⁸ | As Members of The Polynucleotides HPT™
 Priming Board, Collegio Italiano delle Società Scientifiche di Medicina Estetica (Italian College
 of the Aesthetic Medicine Scientific Societies) – SIME, AGORÀ, SIES

¹Operative Unit of Dermatologic and Plastic Surgery, CDI Hospital, Milan, Italy

²Director, Esthetic Medicine Outpatients Service, Fatebenefratelli Hospital, Rome, Italy

³Maioli Private Practice Sassari, Sassari, Italy

⁴Agorà, President, Italian Scientific Society of Aesthetic Medicine, Milan, Italy

⁵Contract Professor, Esthetic Medicine Master, "Federico II" University Medical School, Naples, Italy

⁶Member of the Board, Agorà, Italian Scientific Society of Aesthetic Medicine, Milan, Italy

⁷President, SIES, Esthetic Medicine and Surgery Society, Florence, Italy

⁸Vice-President, SIME, Italian Society of Esthetic Medicine, Fatebenefratelli Hospital, Rome, Italy

Correspondence

Maurizio Cavallini, Operative Unit of Dermatologic and Plastic Surgery, CDI Hospital, Via Simone Saint Bon 20, 20147 Milan, Italy.
 Email: maurizio.cavallini@libero.it

Abstract

Background: Injective procedures using polynucleotides-based products to promote dermal rejuvenation and revitalization are steadily evolving, yet no structured protocols are available that discuss and provide guidance in aesthetic treatments with highly purified polynucleotides. The goal of this document was to provide consensus-based recommendations for the safe and effective use of Polynucleotides Highly Purified Technology™ (PN-HPT™) devices for skin rejuvenation.

Patients/Methods: A team of eight experts with extensive experience in treatments for skin rejuvenation and revitalization integrated the best available evidence and clinical judgment and devised a series of practical guidance to support dermatologists, plastic surgeons, and aesthetic physician in the use of PN-HPT™ products, alone and in combination, in aesthetic medicine.

Results: For most items, the expert group achieved a majority consensus. "Recommendations" (consensus >80%) were reached for the face, periocular area, décolleté and neck, hands, scalp, and stretch marks. Recommendations include details of techniques, information on dosage, volumes to be injected, and the ideal number of required treatment sessions, as well as time intervals between them for different areas of face and body. A lower agreement level of 60% was reached on but one item related to the initial treatment cycle for the face, leading to a "Consensus statement" for that area instead of a full "Recommendation."

Conclusion: The expert consensus illustrates the value of natural-origin, highly purified polynucleotides (PN-HPT™) as biostimulatory booster strategy for skin priming and revitalization of face and body and provides a detailed guide for the use.

KEYWORDS

PN-HPT™, polynucleotides, polynucleotides highly purified technology™, skin priming, skin rejuvenation

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1 | BACKGROUND

The modern trends in skin rejuvenation are changing, and “skin health,” “skin quality,” and “natural look” are the goals of most aesthetic treatments. Polynucleotides are natural, highly purified DNA molecules extracted from trout gonads. Polynucleotides-containing devices act as short time temporary fillers thanks to the viscoelasticity of the long DNA fragments and improve skin well-being and steady self-repair. The final outcome is more natural and in-depth tissue regeneration and a healthier look of the skin. An already extensive number of studies suggests that the dermal reactivating properties of polynucleotides may be stronger than other primary skin active principles such as hyaluronic acid; the same studies provide a solid rationale for polynucleotides as “bioreactivating primers” of skin.¹⁻³

Polynucleotides are more and more used in aesthetic medicine leveraging on previous experience in other clinical applications. Recent studies demonstrated the efficacy and safety of long-chain polynucleotides injections in dermatology and aesthetic medicine for skin rejuvenation, both over the face and other body areas.¹⁻³ The pore size and skin thickness improved markedly in 30-year-old subjects, whereas skin tone, melanin, wrinkles, and sagging were significantly ameliorated in 40-year-old individuals. No serious side effects were observed.¹ A clinical trial on 143 patients demonstrated an improvement of skin elasticity and hydration, together with high levels of patient and physician satisfaction.⁴

The implementation of injective approaches using polynucleotides-based devices to stimulate dermal rejuvenation and revitalization is a compelling line of investigation that warrants further consideration. To that goal, an Italian Scientific Board of distinguished aesthetic medicine physicians with extensive experience with polynucleotides-containing medical devices for biorevitalization convened to review available evidence and reach consensus-based recommendations for the safe and effective use of highly purified polynucleotides-based intradermal gels. Polynucleotides formulations based on Polynucleotides HPT™ (Polynucleotides Highly Purified Technology™, Mastelli Srl, Italy) are available as two lines of medical devices, for the treatment of the face and body. The PN-HPT™ concept, hereinafter extensively discussed, candidates the PN-HPT™ formulations as the most versatile skin boosters now available in Italy and in many other countries, allowing healthcare practitioners to deliver truly individualized treatments.

This report summarizes the findings and recommendations issued from the collective work of the Italian Scientific Board of aesthetic physicians.

2 | METHODS OF CONSENSUS DEVELOPMENT

An Italian Scientific Board of eight experts in the fields of Dermatology, Plastic Surgery, and Aesthetic Medicine with extensive

experience in treatments for skin rejuvenation convened for a meeting in Sanremo, Italy, in September 2019.

The first step for the Scientific Board was to review the published literature on polynucleotides and other skin rejuvenating options indexed on PubMed/MEDLINE and other leading databases. This literature review, carried out with a special reference to the issues of skin revitalization, was the background against which to discuss the benefits and merits of natural-origin PN-HPT™. This literature review was the framework that helped to steer both the Board's discussions and the development of the survey's questionnaire.

The Scientific Board developed a structured 24-item multiple-choice questionnaire about the aims and common practice patterns of aesthetic treatments with polynucleotides products.

Many questions admitted only a binary answer (yes or no), but more than one answer was usually admitted. The questionnaire was completed on a secured survey website by 40 specialists (23 female and 17 male specialists; mean age: 44 years old, min 33, max 71)—6 dermatologists (15%), 5 plastic surgeons (13%), and 29 aesthetic medicine specialists (73%). The Scientific Board deemed such varied sample representative of current clinical practices in aesthetic medicine in Italy. The interviewed specialists expressed their opinions about skin biorevitalization independently and blindly. The Scientific Board collected and analyzed the results of the online survey before the final consensus meeting held in April 2020.

As a rule, a consensus level of at least 80% of the participants was the formal threshold for the Scientific Board to accept the indication as “Recommendation” and a consensus between 60% and 80% the threshold for a “Consensus statement.” The final “Recommendations” need not necessarily be in strict agreement with the outcomes of the survey.

By integrating the best available evidence and clinical judgment, the goal of the Italian experts was to provide all specialists interested in aesthetic medicine with a reliable guidance for skin priming and revitalization with the products based on the PN-HPT™ technology and to support colleagues who wish to broaden their aesthetic medicine offer with PN-HPT™-based techniques.

3 | RESULTS

Following the discussion on the data collected from the survey, the Italian Scientific Board developed a series of consensus statements and recommendations for skin priming and revitalization using PN-HPT™ medical devices. The Experts defined treatment aims and appropriate strategies aiming to achieve the best aesthetic outcomes. They provided practical suggestions on indications, dosages, injected volumes, and on the number of required treatment sessions and intervals between sessions for different areas of face and body. The following material reflects the proceedings of the final consensus meeting.

The Scientific Board formulated a “Recommendation” for almost all the surveyed items but one: a “Consensus statement” for a single item related to the initial treatment cycle for the face. Occasionally,

the “Recommendation” was for two treatment schedules or two PN-HPT™ doses without a more precise indication.

3.1 | Aims and indications of the PN-HPT™-based skin treatments

Long-chain PN-HPT™ gels are an innovative intradermal treatment strategy that combines a short-time filling effect with biological properties that ease the recovery of and sound appearance the face and body skin areas where PN-HPT™ are applied. In addition, PN-HPT™ gels are highly biocompatible with a very low risk of adverse effects.

In the opinion of the Scientific Board, PN-HPT™-based medical devices are a safe and effective aesthetic treatment strategy for skin rejuvenation, revitalization, and tonification of the face and body. Intradermal PN-HPT™ injections normalize the physiological environment by restoring the normal efficiency of dermal fibrocytes. The procedure for skin priming and revitalization is always performed with the maximum comfort for the patient; untoward effects, if any, are always minor and rapidly transitory.

Based on current evidence arising from Italian clinical practice, the PN-HPT™ strategy induces improvements in skin quality in all treated skin areas. Aesthetic outcomes are most often distinctively outstanding in the cheeks and cheekbones regions, the perioral district, and the décolleté including the neck (Table 1).

3.2 | Benefits of PN-HPT™-based skin treatment

Skin aging is associated with qualitative and quantitative degeneration of skin components, including dermal collagen and elastin. The primary extrinsic causes of skin aging, including ultraviolet radiation, smoking, and stress, enhance oxidative damage by inducing an overload of reactive oxygen species (ROS) and a concomitant depletion of physiological antioxidants. Intrinsic skin aging is related to a progressive age-associated impairment in antioxidant efficiency, associated with increased ROS production from skin cells.^{5,6} Such multifactorial causes of skin aging provide the rationale for a strategy of combined treatments. The benefit of resorting to multiple contemporary options to achieve the best aesthetic outcomes when treating the face and body is well documented.⁷⁻⁹ The “PN-HPT™ priming” concept—“PN-HPT™ priming” meaning promotion by PN-HPT™ of stronger

and faster responses to a second skin revitalization stimulus—may be summarized as PN-HPT™ acting as background preparation of tissues, before and in combination with other treatments, to reach globally better aesthetic outcomes. This innovative concept of “PN-HPT™ priming” is most likely to apply to many procedures, both in wound care¹⁰ and in dermatology/aesthetic medicine.¹¹

The present Consensus Project supports a combination approach for skin priming and revitalization with PN-HPT™-based medical devices. Specifically, almost all the Experts agree on using PN-HPT™ in association with hyaluronic acid (PNHA) in combined formulations in the same device. This strategy develops a synergic effect by associating the strong effect on turgescence improvement due to hyaluronic acid with the useful action on hydration and, even more distinctively, the powerful dermal stimulating effect exerted by PN-HPT™.

According to the Board's opinion, the intradermal use of PN-HPT™ can also be useful as “PN-HPT™ priming” before another skin treatment strategy, such as lasers and other energy and light-emitting devices, fillers, peeling, needling, and surgery. The priming PN-HPT™ treatment produces greater results if started before the second treatment. However, even if performed only a week before the second aesthetic treatment, PN-HPT™ is still an effective background preparation (Table 2).

3.3 | Injective procedures and technical considerations

Appropriate, individually adapted injection techniques ensure a successful outcome and, in the experience of Board members, effectively prevent all patient's dissatisfactions. The injection procedures most frequently use thin needles and the microdroplet, linear, or fan techniques. Selecting the most appropriate among these different techniques is based on the skin area and the amount of product to be injected; it also depends on clinical assessment by the injector. The microdroplet technique and the linear retrograde method of injection are the two most frequently used procedures. The use of cannulas is also increasing, as suggested by experienced physicians. The choice of needle versus cannula in clinical practice depends on the physician's preferences, experience, and patient needs. Needles have the advantage of allowing injections of very high precision; on the other hand, cannulas less frequently cause trauma since fewer injection points are needed and the treatment of wider areas is

Polynucleotides			
Areas of treatment	Face area, décolleté including the neck	Body areas, back of the hands	Scalp, eyebrows, beard
Objectives	Skin rejuvenation Hydration Scar improvement	Skin rejuvenation Hydration Scar improvement Stretch mark improvement	Normalization of follicular activity Hair growth

TABLE 1 Goals of the PN-HPT™-based treatment

TABLE 2 Benefits of PN-HPT™-based skin treatment

Polynucleotides Use	Benefit	Other treatment
Combination approach	Improvement of tissue turgor and skin eutrophism	Hyaluronic acid (HA)
Priming	Valid preparation of skin before a second different aesthetic treatment	CO ₂ Laser Energy and light devices HA fillers Peeling Needling Surgery

easier.¹² However, infiltration with cannulas is normally performed at the level of deep dermis or hypodermis, and precise intradermal infiltration is difficult. Conversely, the microdroplet technique can reach the dermal layer with very high precision: all that is needed is to push the needle and plunger slowly until a small white bleb appears in the skin.

The Italian Scientific Board expresses a preference for the “microdroplet technique” and the “linear retrograde technique” in the dermal layer.

As regards the needle, the Experts recommend the use of a 30-32 gauge, 13-mm needle to deliver a thin, uniform dose of the PN-HPT™ formulations to the target treatment area (Table 3).

4 | RECOMMENDATIONS BY TREATMENT AREA

4.1 | Face

The use of intradermal injections for skin rejuvenation in minimally invasive facial aesthetic procedures has become increasingly popular. Choosing the most appropriate technique for the target area is based on the physician's experience. The physician's experience is also paramount to select the most appropriate dose, the volume to inject, the number of required treatment sessions, and the intervals between sessions, so that to ensure the most successful aesthetic outcome.

The manifestations of facial aging reflect the combined effects of progressive bone resorption, decreased tissue elasticity, and redistribution of subcutaneous fullness.¹³ Facial aging is also associated with the loss of soft tissue fullness in certain areas (forehead, and malar, temporal, mandibular, mental, glabella, and perioral sites) and the persistence or hypertrophy of fat in others (submental and lateral nasolabial folds).

TABLE 3 Intradermal injective procedure of PN-HPT™-based devices

Polynucleotides	
Injection technique	Microdroplet Linear retrograde
Skin layer	Intradermal
Needle	30-32 Gauge (13 mm)

In the opinion of the Experts, the benefits of skin priming and revitalization of face skin with PN-HPT™ gels are most significant even in case of advanced skin aging provided the highest concentration PN-HPT™ formulations is selected (intradermal injection of 40 mg/2 mL). It is strongly advised that patients receive the full content of 2 mL (all 40 mg) at each session. For PN-HPT™ priming of the face skin, the Italian experts suggest an intradermal injection every 14 or 21 days for a total of 4 sessions as initial treatment cycle (Table 4).

In specific cases of advanced skin aging, the Scientific Board suggests also the possibility to do less spaced treatment sessions, with an intradermal injection every 7 days for a total of 4 sessions. Low-concentration PN-HPT™ formulations are recommended for the sensitive facial skin and other delicate skin areas (eg, periorbital area).

4.2 | Delicate skin areas: periorcular, décolleté and neck, hands

Patients frequently seek aesthetic rejuvenation of the periorcular area. Age-related changes of soft tissues, acting in combination with photodamage of the overlying periorbital skin, can lead over time to eyebrow ptosis, drooping of upper eyelids, and crow's feet. Crow's feet originate from the lateral ocular side and project outward, most prominently during dynamic activities of mimic or extraocular muscles such as smiling or squinting.

Many factors contribute to the development of crow's feet and skin aging of the periorcular area, including sun exposure, smoking, lack of subcutaneous fat, and redundant skin.

In the opinion of the Scientific Board, treating the periorcular district with PN-HPT™ devices is safe and effective with predictable aesthetic results. For this face area, Italian experts recommend injecting the intradermal PN-HPT™ gels with the microdroplet technique (Table 5). In addition, they suggest 1- or 2-mL intradermal injections of 7.5 mg/mL polynucleotides at each session, with an initial treatment cycle of one injection every 14-21 days. The same approach can be used for other body areas with thin skin such as the décolleté, including the neck, and hands.

It should be noted that a few colleagues who participated in the survey indicated cannulas (27G, 40 mm) as the device of choice in the periorcular area. The goal of their suggestion is to distribute the product uniformly and homogeneously on the lateral and lower eyelid areas.

TABLE 4 Treatment protocols for skin priming and revitalization of face

Face treatments	PN-HPT™ 40 mg/2 mL	PNHA 40 mg/2 mL	PN-HPT™ 15 mg/2 mL	mL at each session	Treatment protocol
Normal skin	x	x		2 mL	One session every 14 or 21 d for a total of 3 sessions
Advanced skin aging	x	x		2 mL	One session every 14 or 21 d for a total of 4 sessions
Sensitive skin and delicate areas			x	2 mL	One session every 14 or 21 d for a total of 3 sessions

TABLE 5 Treatment protocols for priming and revitalization of delicate skin areas with PN-HPT™ devices (PN-HPT™: Polynucleotides Highly Purified Technology; PNHA: PN-HPT™ and hyaluronic acid combination)

Polynucleotides	Product	mL at each session	Treatment protocol	Technique
Periocular area	PN-HPT™ 15 mg/2 mL	1 or 2 mL	One session every 14 or 21 days for a total of 3-4 sessions	Needle microdroplet Linear retrograde
Neck	PN-HPT™ 15 mg/2mL	1 or 2 mL	One session every 14 or 21 days for a total of 3-4 sessions	Needle microdroplet Linear retrograde
Décolleté	PN-HPT™ 15 mg/2mL	2 mL	One session every 14 or 21 days for a total of 3-4 sessions	Needle microdroplet Linear retrograde
Back of the hands	PN-HPT™ 15 mg/2mL PN-HPT™ 40 mg/2mL PNHA 40 mg/mL	2 mL	One session every 14 or 21 days for a total of 3-4 sessions	Needle microdroplet Linear retrograde

4.3 | Scalp

Several factors contribute to functional and structural changes in the scalp's hair density.

The Scientific Board reached a high level of agreement on the efficacy of PN-HPT™-based treatments for hair thickening of the scalp. Intradermal injections of a PN-HPT™-based gel demonstrably help to revive hair follicles. The intradermal PN-HPT™ strategy promotes and accelerates hair growth and, once again, is demonstrably associated with the growth of stronger and healthier hair shafts.

For the treatment of the scalp, the Italian experts suggest a 2-mL intradermal injection of 15 mg in 2mL PN-HPT™ gel formulation at each session with an initial treatment cycle of one injection every 7 or 14 days for a total of 4 sessions. This initial cycle should be followed by additional 4 sessions every 21-30 days (Table 6).

The combination of the PN-HPT™-based gel with other interventions, such as the administration of biotin or hyaluronic acid, carboxytherapy, and topical therapy, can enhance the treatment benefits.

4.4 | Stretch marks

Striae distensae or stretch marks are very common, asymptomatic skin conditions frequently observed in women at all ages between 5 and 50 years. They often cause cosmetic morbidity and psychological distress. The distinctive features of stretch marks are the densely packed areas of thin, horizontally arranged bundles of collagen

running parallel to the skin surface, and the strong reduction in the number of fibrillin and elastin fibers in the papillary dermis.¹⁴

Of late, with the increasing emphasis on cosmetic management and awareness, more and more patients approach dermatologists for stretch mark treatment, and PN-HPT™ may definitely have a role as very recently confirmed.¹⁵

The Expert Board recommends injecting intradermal PN-HPT™ to promote the cosmetic and functional improvement of stretch marks and skin laxity. Initial treatment cycle: one session every 7 or 14 days for a total of 4 sessions, followed by one session every 21-30 days for a total of 4 sessions (Table 7).

According to about 18% of the experts who participated in this Consensus Project, the intradermal treatment with PN-HPT™ fillers can be combined with other outpatient treatment techniques. Examples of these techniques: carboxytherapy, laser, peeling, needling, at-home topical treatments.

5 | ADVERSE EVENTS

Local injection site reactions are the most common adverse events associated with soft tissue augmentation and may follow the intraskin injections of foreign substances. The potential for bruises is influenced by the needle size, the site of injection, the technique and speed of injection, and by the product choice.¹⁶ It is generally believed that biodegradable agents stimulate neocollagenesis for sustained aesthetic improvements with minimal side effects.

TABLE 6 Treatment protocol for scalp biorevitalization with polynucleotides gel (PN-HPT™: Polynucleotides Highly Purified Technology)

Polynucleotides	Product	mL at each session	Treatment protocol	Technique
Scalp	PN-HPT™ 15 mg/2 mL	2 mL	Initial treatment cycle: one session every 7 or 14 days for a total of 4 sessions Followed by one session every 21-30 days for further 4 sessions	Needle microdroplets

TABLE 7 Treatment protocol for stretch mark improvement with PN-HPT™ (Polynucleotides Highly Purified Technology; PNHA: PN-HPT™ and hyaluronic acid combination)

Polynucleotides	Product	mL at each session	Treatment protocol	Technique
Stretch marks	PN HTP™ + PNHA vials (4 mL)	1-4 vials	Initial treatment cycle: one session every 7 or 14 days for a total of 4 sessions followed by one session every 21-30 days for a total of 4 sessions	Needle microdroplets Linear retrograde

The most commonly seen complications observed in Italian clinical practice following the injection of PN-HPT™-based dermal gels are erythema and burning 12 hours after the injection, as well as occasional little hematomas.

Several strategies may help to prevent or manage the occurrence of adverse events after skin priming with PN-HPT™ gels. The main recommendations can be so summarized: avoid exposure to natural sunlight or to sun lamps for 48 hours; apply soothing creams and ice packs, and use topical anesthetics (eg, lidocaine) to reduce the discomfort associated with needle injections.

6 | CONCLUSION

The main strength of natural-origin, highly purified polynucleotides (PN-HPT™) is their reactivating efficacy on mesenchymal cells with special reference to dermal fibroblasts. The expert consensus illustrates the value of intradermal PH HPT™ as biostimulatory boosters for priming and revitalization of face and body skin thanks to their efficacy on dermal cells. The expert consensus also provides a detailed guide outlining the most effective intradermal administration of PN-HPT™ via PN-HPT™-based medical devices for different skin areas.

ACKNOWLEDGMENTS

The authors acknowledge the support of Dr Mauro Raichi for his support.

CONFLICT OF INTEREST

All the members of Scientific Board variably received grants from several aesthetic medicine companies as consultants for research and development and/or continuing medical education activities and/or for participating as investigators to national and international clinical studies in aesthetic medicine and surgery. Past sponsors of the members of the Board included Mastelli Srl., Sanremo, Italy, holder of the PN-HPT™ patents and producer of PN-HPT™-based medical devices. The development of both the digital survey and

the consensus report about PN-HPT™ and their role in aesthetic medicine was spurred by the acute need for expert guidelines in the fast-changing aesthetic medicine field. Competing interests were carefully avoided by all members of the Board. Mastelli Srl. supported only the secretarial and logistic expenses of the Scientific Board and will financially support the publication costs of the Consensus after acceptance of the manuscript.

DATA AVAILABILITY STATEMENT

Data available in article supplementary material.

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How to cite this article: Cavallini M, Bartoletti E, Maioli L, et al. Consensus report on the use of PN-HPT™ (polynucleotides highly purified technology) in aesthetic medicine. *J Cosmet Dermatol*. 2021;20:922-928. <https://doi.org/10.1111/jocd.13679>