Review Article

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Surgical Research

Polynucleotides HPT™ for Asian Skin Regeneration and Rejuvenation — The Tridimensional Perspective

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Keywords

Emergent perceptual skin quality categories, EPCs, GAIS, Global Aesthetic Improvement Scale, Polynucleotides HPT™, PN HPT™, QuantifiCare, Skin quality.

Introduction

The paper "Polynucleotides HPT for Asian skin regeneration and rejuvenation, investigating more in-depth" was recently published [1]. The investigator-initiated study was performed in Malaysia; the principal indications for treatment were ageing, dyschromic, dry skin of rough texture, big and enlarged pores, skin laxity, and acne scars. The study's purpose was to investigate how a relatively new class of non-pharmacological ingredients of medical devices for intradermal injection might benefit skin ageing and deteriorating skin quality, as currently defined by the four emergent perceptual skin quality categories (EPCs) of "Skin Tone Evenness", "Skin Surface Evenness", "Skin Firmness", and "Skin Glow" [1,2]. The study was notable since it enrolled Asian subjects with their peculiar melanocyte biology, photoaging evolution, and weaker skin barrier functions [3]. The paper emphasised the quantitative skin quality outcomes, assessed with the Investigator and Patient rating subscales of the validated Global Aesthetic Improvement Scale (GAIS) [1].

After intradermal infiltration with a cannula, natural-origin Polynucleotides High Purification Technology (PN HPT™) for physiological skin bio-revitalisation, developed and produced with proprietary procedures by Mastelli S.r.l., Sanremo, Italy, hydrate the dermal microenvironment with a rapid filling effect and, over the longer term, physiologically support the activity and vitality of dermal fibroblasts [4]. The outcomes include new extracellular matrix production by fibroblasts, self-limited collagen deposition with no tendency to fibrosis, and more firmness and elasticity of the dermis in the face, neck, and décolleté areas [5].

The study protocol envisaged three subcutaneous deliveries of the Class III CE-marked medical device PLINEST based on PN HPT™ (20 mg/mL as gel in 2-mL prefilled sterile syringes; Mastelli S.r.l., Sanremo, Italy) at T0 (baseline assessment and first treatment session), T1 (second injection session four weeks after T0), and T2 (third injection session eight weeks after T0), with efficacy and safety evaluations at T1, T2, T3 (first follow-up session four months after T0) and T4 (second follow-up session six months after T0) [1]. At T4, the mean Investigator GAIS scores were 3.33 out of 5.0 for the "Skin Tone Evenness" skin quality perceptual category, 3.46 for the "Skin Surface Evenness" perceptual category, 3.61 for "Skin Firmness", and 3.45 per for the radiance determinant of the "Skin Glow" perceptual category. The skin quality benefits, reached with no early- or late-onset adverse events, persisted for up to six months in all subjects. Most treated subjects rated the procedures they underwent as "comfortable" and "very comfortable" at T1 (26% and 42%, respectively) and T4 (42% and 32%, respectively). [1].

This Research Letter aims to complement the available study report with a more in-depth critical focus on iconography and the benefits of a tridimensional (3D) stereophotogrammetry system in clinical studies and everyday aesthetic medicine clinical practice.

Quantitative Tridimensional Skin Quality Analysis

A proprietary portable, tridimensional (3D) stereophotogrammetry technology (QuantifiCare, www.quantificare.com/clinical-trials-photography) allowed the reconstruction of the standardised and comparable-over-time 3D facial images [1]. The 3D image

reconstruction and analysis are based on artificial intelligence.

The device's dual beam pointers adjust the system to the distance between the camera and the subject (in the original study, about 80 cm); shutter regulations are also automatic, and the double flashes consistently equalise the environmental lighting conditions. The technological concept is analogous to 3D computed tomography imaging. The stereophotogrammetry algorithm reconstructs the final 3D images from plain bidimensional photographs. The system allows visualising facial shapes and volumes, augmented by anatomical reference points, with appropriate angle, length, and width measurements from any angle. The quantitative scoring of the standardised, anatomically-referenced 3D pictures taken over time and throughout multiple visits allows a precise evaluation of skin quality changes compared to baseline in treated subjects.

In the original study, scoring was based on the validated GAIS investigator's rating scale that classifies the global aesthetic improvement in facial appearance compared to the baseline in five categories—worse, no change, improved, much improved, and very much improved [1,6].

The trained assistants, who took the primary plain photographs of the representative sample of thirty Asian subjects (mean age 40.2 ± 11.4 years old, median 38, range 25 to 67) before and after three and six months of intradermal PN HPT™ treatment, acted independently from the investigator pool. In the following step, the investigators were responsible for blindly and independently scoring the digitally constructed 3D images for efficacy on the four emergent perceptual skin quality categories — "Skin Tone Evenness", "Skin Surface Evenness", "Skin Firmness", and "Skin Glow" — at each assessment visit [1]. The current supplementary report illustrates the outcomes compared with the baseline at the second final follow-up visit (T4), focusing on the benefits of 3D documentation.

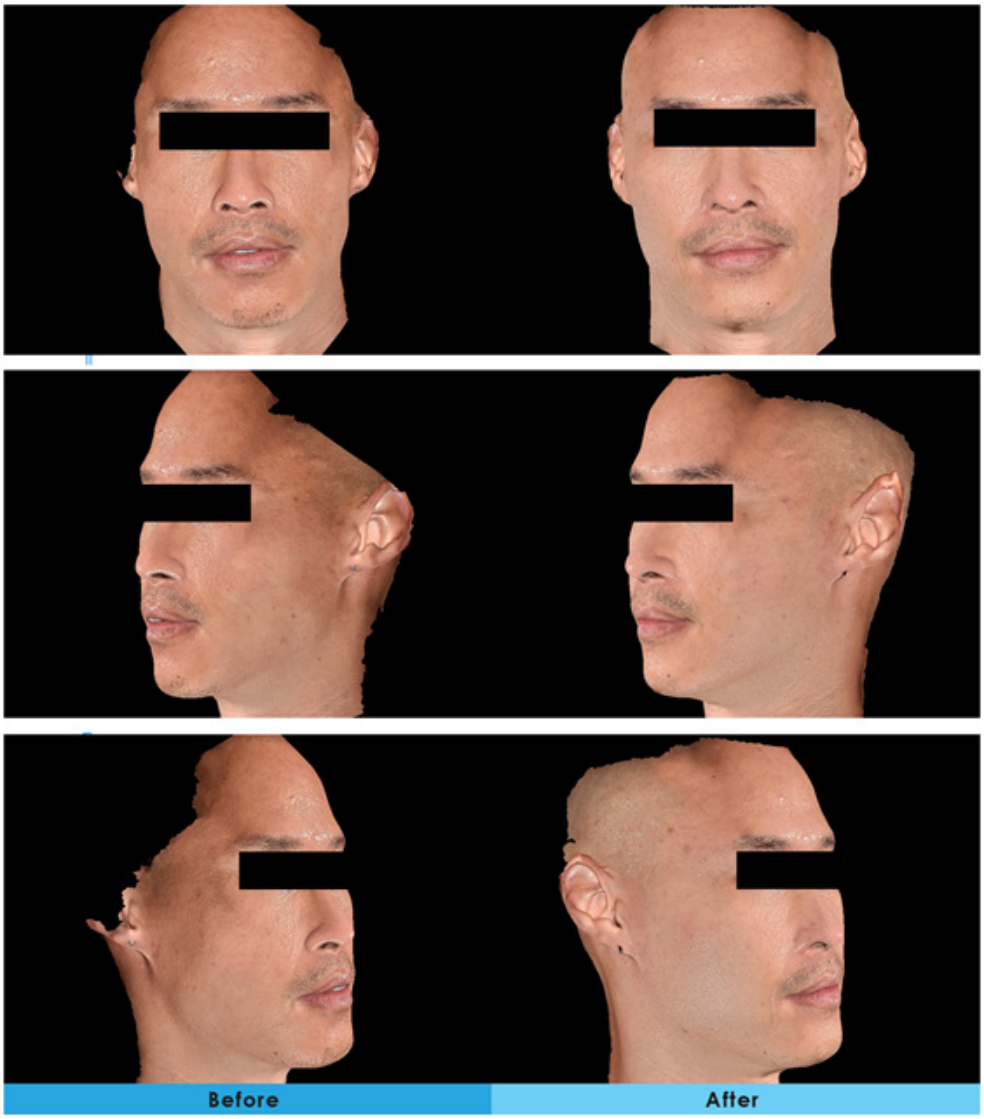

Figure 1: Reconstructed 3D examples of the aesthetic benefits of PN HPT™ in a male subject in his early thirties with dull skin, mild sagging, enlarged pores, and generally sensitive, erythematous and uneven-toned skin—individual photographs: courtesy of Clique Clinic, published with the subject's written agreement.

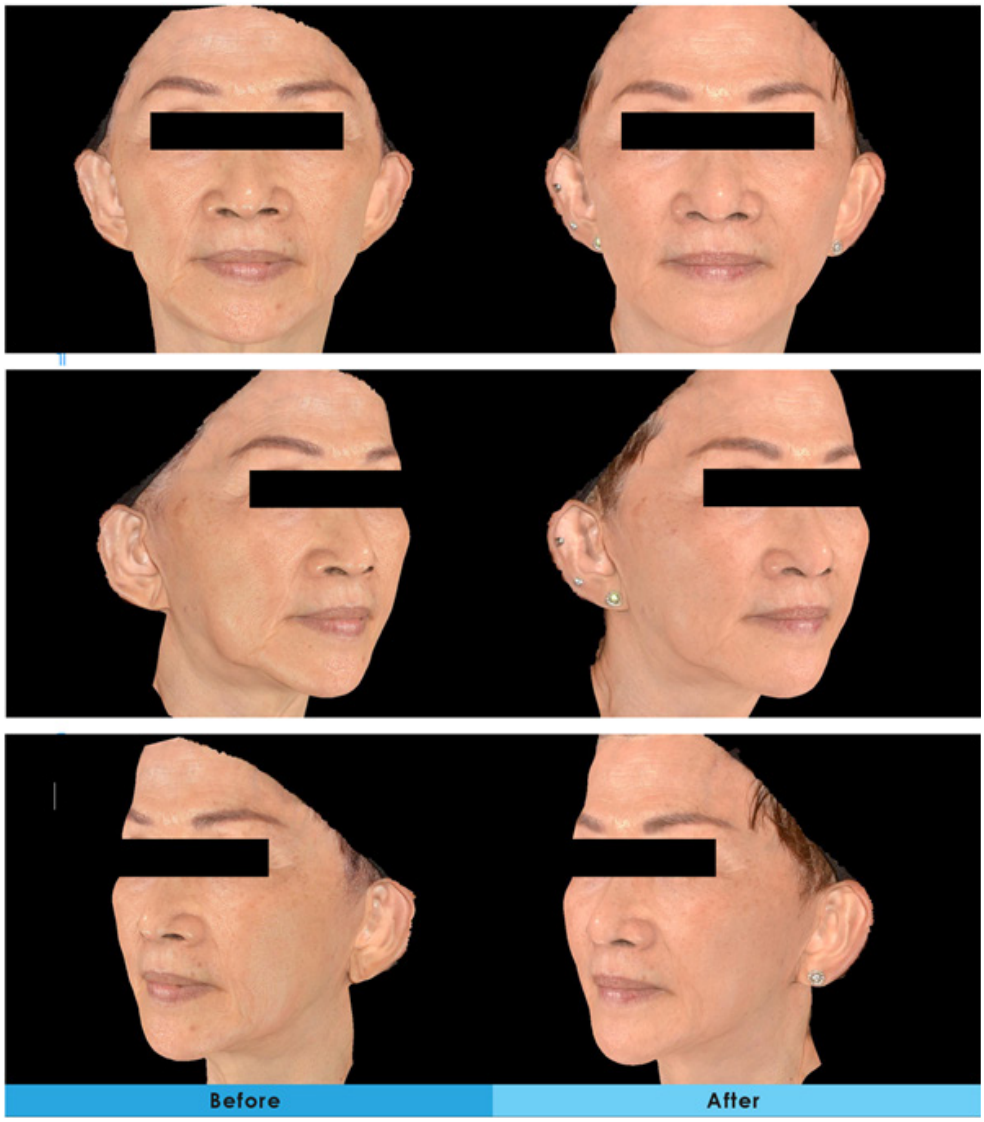

Figure 2: Reconstructed 3D examples of the aesthetic benefits of PN HPT™ in a late middle-aged woman with uneven skin tone, sagging skin with deep wrinkles, nasolabial folds and jowls. Individual photographs: courtesy of Clique Clinic, published with the subject's written agreement.

Discussion

The previous report confirmed the remarkable performance of the intradermal PN HPT™-based medical device, with a consistently upward trend of the Investigator GAIS score from visit T1 to T4 for each of the four perceptual skin quality categories [1]. The satisfaction and comfort of treated subjects were high as early as the first visit T1, with all subjects satisfied with outcomes at the end of the sixth-month follow-up period. The outcomes appeared solid; however, the non-randomised cohort design of the original study and the need for a control group are liabilities that only the properly designed and statistically robust randomised studies currently launched will overcome [1].

Regarding the study design and the six-month follow-up period, it supported the long-term, in-depth skin rejuvenation linked to the passive PN HPT™ replenishing of the dermal pools of critical precursors. The long-term PN HPT™ benefits follow the short-term volume enhancement associated with the PN HPT™ hydrophilic nature [1]. Unlike fillers, PN HPT™ are not burdened by the typical adverse effects of fillers like the disturbing bluish skin hue known as the Tyndall effect and clumping in the tear trough area when smiling of hyaluronic acid fillers and the fibroplasia and nodules of poly-L-lactic acid fillers. Because of that double, temporally spaced activity without filler-like side effects, the authors labelled PN HPT™ as belonging to a class different from fillers [1]. The reconstructed 3D images offer a detailed account of how the skin quality determinants change and improve over time after three sessions of intradermal PN HPT™. Figures 1 and 2 demonstrate the recovery of the gentle transition of lower eyelids into the cheek, sometimes lost even in young subjects due to the downward sliding of soft tissues between the medial and lateral canthus. Similar improvements, demonstrated by 3D images in malar areas, regard the attenuated dark shadows and concavities due to the soft tissue loss over the zygomatic arch and tethering tensions by the orbital ligament, McGregor's patch, and malar septum [7]. Even in young subjects and even more in elderly

subjects, the deep nasolabial folds, anatomically associated with the loss of bone tissue and the recession of the canine fossa, appear counteracted by the subcutaneous deposition of new soft tissue. The fuller appearance in the malar septal area after the first signs of depression due to wasted soft tissue, even in young subjects, will reproduce the youthful convex cheek [7]. Several follow-up 3D photographs show the new highlights of those areas. The photographs also show how the PN HPT™ treatment of the upper-third facial area has a persistent augmentation effect on depressed forehead areas.

The original study's non-randomised cohort design and the need for a control group are liabilities. Only the currently launched, adequately designed, statistically robust randomised studies will overcome such liabilities.

Conclusion

An eight-week treatment with a PN HPT™-based intradermal device led to a clinically meaningful improvement in skin quality in all its declinations, skin surface, firmness, pigmentation, and radiance, with no immediate or late-onset adverse events and high patient satisfaction. The skin quality benefits persisted for up to six months in all subjects, as demonstrated by the highly informative tridimensional images algorithmically constructed with stereophotogrammetry technology.

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