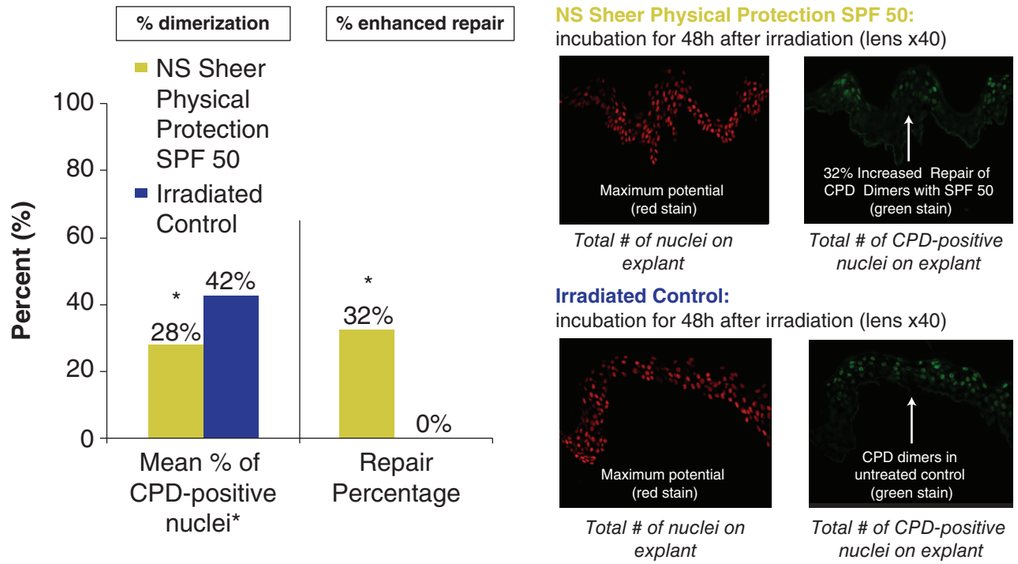
➢ NeoStrata Sheer Physical Protection SPF 50 **enhances natural DNA repair by 32%** versus the irradiated control (Figure 6).

Figure 6. DNA Repair



*Significantly fewer DNA CPD dimers and increased repair following SPF 50 treatment, $P<0.05$

Conclusions

NeoStrata Sheer Physical Protection SPF 50 is an elegant, mineral-based sunscreen in a serum-solution vehicle for everyday use that:

- ✓ **Provides broad spectrum protection against UV and visible light**
- ✓ **Delivers the highest rating for UVA protection: PA++++ and critical wavelength >370nm**
- ✓ **Provides DNA protection & enhanced repair of CPDs (DNA dimers) that form when exposed to UV light**
- ✓ **Is formulated with complementary antioxidant and antiaging ingredients**
- ✓ **Contains a universal tint (iron oxides), suitable for all skin types and may be used on melasma-prone skin due to protection in UV and visible light ranges**

References

1. Liebel F, Kaur S, Ruvolo E, et al. Irradiation of skin with visible light induces reactive oxygen species and matrix-degrading enzymes. *J Invest Dermatol*. 2012;132(7):1901-1907.
2. Zastrow L, Groth N, Klein F, et al. The missing link--light-induced (280-1, 600 nm) free radical formation in human skin. *Skin Pharmacol & Phys*. 2009; 22(1):31-44.
3. Castanedo-Cazares JP, Hernandez-Blanco D, Carlos-Ortega B, et al. Near-visible light and UV photoprotection in the treatment of melasma: a double-blind randomized trial. *Photodermatology, Photoimmunology & Photomedicine*. 2013;30(1):35-42.
4. Dayan N, Ballantyne A, Ngo T, et al. A melanin derivative to shield the skin from high energy visible light. *Cosmetics & Toiletries.* 2011;126(3):186-194.
5. Emanuele E, Spencer JM, Braun M. An experimental double-blind irradiation study of a novel topical product (TPF 50) compared to other topical products with DNA repair enzymes, antioxidants, and growth factors with sunscreens: implications for preventing skin aging and cancer. *J Drugs Dermatol*. 2014;13(3): 309-14.

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A Sheer, Inorganic, Broad-Spectrum Sunscreen With Antioxidants Provides Protection Against UV-Induced Cellular DNA Damage (CPD Dimers), Enhances DNA Repair and Covers the Visible Light Spectrum

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Introduction

When skin is exposed to solar radiation, reactive oxygen species are generated causing cellular DNA damage, activation of skin degrading MMP enzymes and upregulation of pro-inflammatory mediators. Moreover, UVA and UVB radiation directly damages cellular DNA.[1] In addition to damage caused by UV light, visible light generates 50% of the oxidative stress endured by skin.[2] A multi-functional sunscreen, covering both UV and visible light wavelengths, offers protection against photoaging and may provide enhanced benefits for melasma.[3]

A novel, inorganic SPF 50 sunscreen was formulated to deliver strong protection against UVA (PA++++), UVB and visible light in an aesthetically-pleasing and well-tolerated serum vehicle. The formulation was augmented with potent antioxidants including purified EGCG extracted from green tea plus vitamin E. In addition, a 4% blend of gluconolactone and lactobionic acid (PHA/Bionic Acids) was included for complementary protective and antiaging effects including, metal chelation, MMP inhibition, anti-glycation, moisturization and skin barrier conditioning and smoothing effects. Iron oxides provide a universal light tint to mitigate whitening caused by the inorganic sunscreens. Refer to Figures 1, 2 and Table 1.

Research Objectives

1. An *in vitro* study was performed on human skin explants to evaluate the ability of the new sunscreen formulation to protect cellular DNA from exposure to solar-simulated UVB + UVA irradiation, as well as enhance DNA repair post-exposure.
2. A visible light absorbance spectrum was measured to evaluate photo protection in the visible light range.

Figure 1. Virtually Invisible Universal Tint Enhances and Helps Even Skin Tone With No White Residue

Without SPF 50 **With SPF 50**

Figure 2. UV Filter Photograph Demonstrates Protection From UV Light

Without SPF 50 **With SPF 50**

Test Product

Table 1. Summary of Key Benefit Ingredients in NeoStrata® Sheer Physical Protection SPF 50

Ingredient		Classification		Effect
Titanium Dioxide 7%, Zinc Oxide 6%		Mineral sunscreen		Photostable, broad spectrum UVA/UVB sunscreen
Gluconolactone	4% PHA/Bionic	PHA	Multi antioxidant formula	Preserves skin matrix (anti-glycation), antioxidant/chelator, provides antiaging, skin smoothing benefits
Lactobionic Acid		Patented Bionic Acid		Preserves skin matrix (MMP inhibitor, anti-glycation), antioxidant/chelator, provides antiaging, skin smoothing benefits
EGCG Green Tea Extract Vitamin E		Potent antioxidant Vitamin antioxidant		Antioxidant that has been shown to help protect cellular DNA (stabilized with sodium bisulfite) Helps protect against oxidative damage
Tinted Vehicle (Iron oxides: red, yellow, black)		Ultrafine transparent solution/serum		Sheer, mattifying, complexion-evening solution. Paraben free, fragrance free, oil free. Packaged in bottle with shaker beads to distribute the formulation (shake well)
Product Claims				Non-irritating, non-sensitizing. Non-comedogenic, non-acnegenic. Can be used post-procedurally.

Aesthetics & Tolerability

- Daily use of the test sunscreen demonstrated positive aesthetics with consumers. (Table 2)
- The test sunscreen was applied post-procedurally in a dermatologist's office and was found to be well-tolerated across a range of procedures. Self-assessment supported the results. (Table 3)

Table 2. Consumer Evaluation

After 4 Weeks of Once Daily Use (n=30)	% Observed
Easy to apply, gentle & non-irritating	100%
Evens skin color & tone Does not rub off	97%
Gives ultra-sheer coverage, non-whitening Overall positive rating	93%
Favorable consistency	90%
Skin texture is smoother, is natural looking	87%

Table 3. Post-Procedure Case Studies

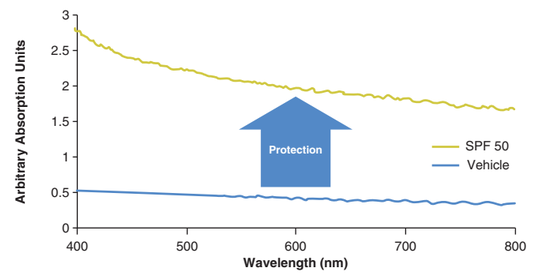
Sheer Physical Protection SPF 50 was applied post-procedurally to dry skin after cool compresses, before patient left the dermatologist's office.
✓ Fractional laser *(Palomar 1440/1540)* ✓ IPL
✓ Laser hair removal ✓ Microneedling ✓ Injectables

Self-Assessment (n=14) (microneedling was not part of self-assessment)	Positive Feedback
Comfortable on skin immediately post-procedure	93%
Is not irritating	100%
Is gentle	100%
Evens skin tone	100%

Solar Protection in the Visible Light Range

- The absorbance spectrum of the test sunscreen demonstrates protection across the visible light range vs. vehicle control (no sunscreens, no iron oxides) (Figure 3).

Figure 3. Visible Light Absorption Spectrum

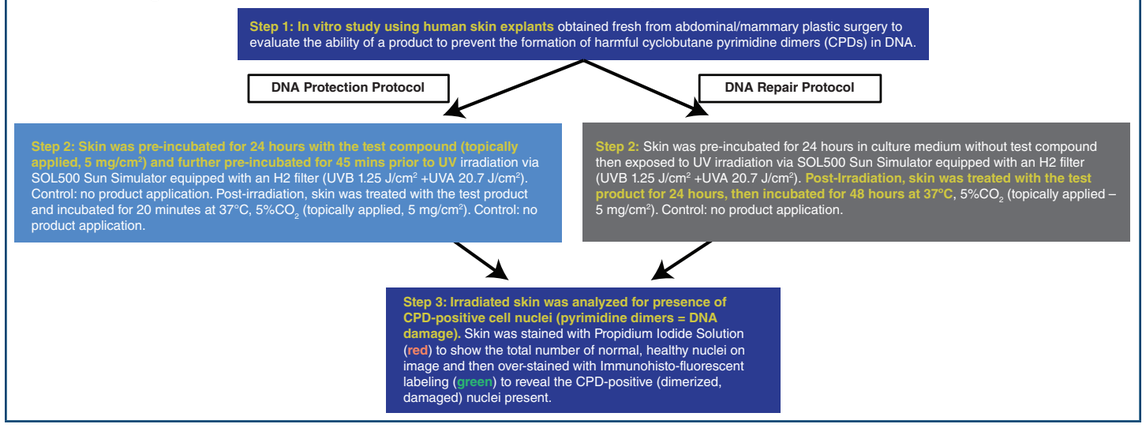


Evaluation of DNA Damage via Formation of Cyclobutane Pyrimidine Dimers (CPDs) to Evaluate DNA Protection and Repair

UV light induces the production of covalent double bonds (C=C) between DNA pyrimidine bases causing photoproducts known as CPDs. CPDs modify DNA structure, disturb polymerase actions and stop DNA replication. If left unrepaired, the CPDs can be mutagenic and cause photoaging and tumorigenesis.[5]

An experiment was conducted to evaluate the ability of the test sunscreen to protect skin from DNA damage and, separately, to determine whether the antioxidant-containing formulation encourages DNA repair (Figure 4).

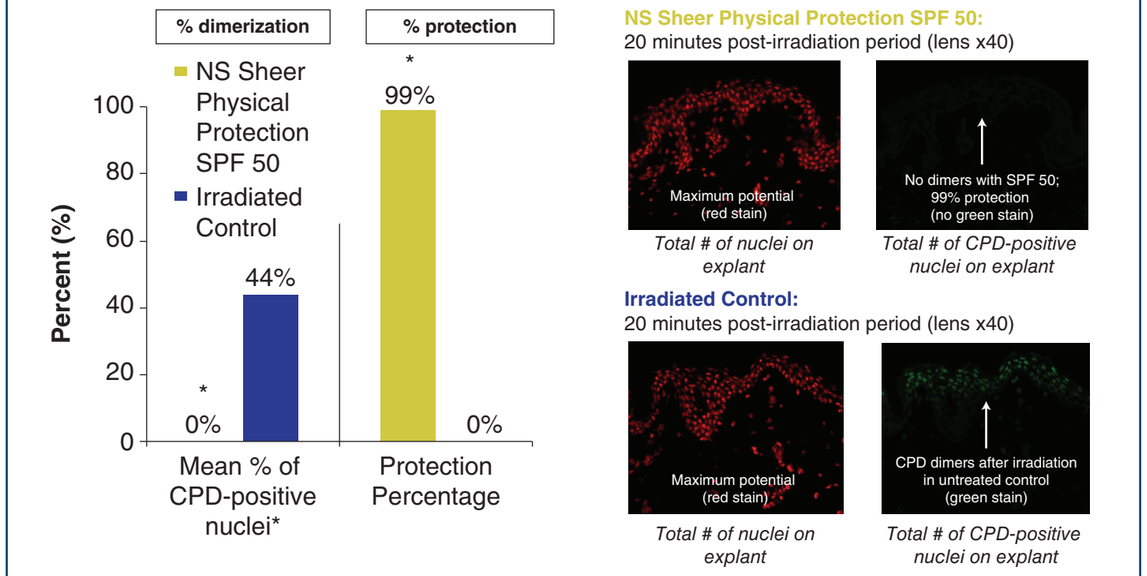
Figure 4. Method to Evaluate DNA Protection and Repair Effects of the SPF 50 Sunscreen



Results

- NeoStrata Sheer Physical Protection SPF 50 provides **99% protection of cellular DNA** versus the irradiated control (Figure 5).

Figure 5: DNA Protection



*Significantly fewer DNA CPD dimers and increased protection following SPF 50 treatment, $P<0.001$