

A Non-Invasive Skin Treatment Combining LED with Pharmacologic and Ultrasonic Technologies for Facial Rejuvenation

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Abstract

Background: Non-invasive facial treatments have the ability to rejuvenate the facial profile when specific pharmacologic agents and modalities are prescribed and used in combination taking into consideration each patient's unique skin type and condition. RATIONALE Epinova is a non-invasive skin treatment that combines the correct concentrations and combinations of topicals and modalities to elicit facial rejuvenation with no down-time or side effects. **Purpose:** This paper focuses on facial rejuvenation improvements combining the RATIONALE Essential Six skincare system (RATIONALE, Victoria, Australia) to protect and repair the skin with the RATIONALE Epinova facial treatment every 4 - 6 weeks—which uses non-invasive technologies and professional strength active ingredients to deliver visible changes to skin tone and texture. **Methods:** Subjects underwent a RATIONALE consultation, including taking a skin history and skin imaging, followed by a data analysis and diagnosis of skin condition and prescription of a customized RATIONALE treatment (Epinova), including appropriate pharmacologic agents and treatment with personalized photo/sono therapeutic devices. **Results:** Subjects reported increased skin hydration, tactile improvements, skin firmness and visible radiance following the RATIONALE Epinova treatment. Further investigations will be initiated to explore the potential for longer term improvements, including connective tissue deposition, reduction of erythema etc. Treatments should be performed every 4 - 6 weeks for patients under 40 and every 3 - 4 weeks for patients over 40, to support cell differentiation, migration and desquamation to achieve non-invasive facial rejuvenation. **Conclusion:** This study demonstrated that the synergy of pharmacologic, LED light therapy and ultrasonic technologies when prescribed and administered by a trained skin therapist, can lead to a visible improvement

in the signs of facial ageing and photodamage, restoring the appearance of healthy, radiant skin.

Keywords

LED, Non-Invasive Skin Treatment, Pharmacologic Agents, Rejuvenation, Ultrasonic Technology

1. Introduction

Epinova (RATIONALE, Australia) is a non-invasive facial treatment combining phototherapy (Light Emitting Diode/LED) and ultrasound modalities with various pharmacologic agents to refine skin tone, texture and support, resulting in a rejuvenated, more luminous facial profile.

Light Emitting Diode (LED) therapy has established a wide variety of medical and cosmetic applications. This form of phototherapy is a promising modality for skin photorejuvenation as it is safe, noninvasive, accessible and easily combined with other treatment modalities. LED irradiation treatments enhance intrinsic cellular activity via absorption by wavelength specific chromophores located throughout the skin, resulting in desirable photorejuvenation effects.

The energy of ultrasound is used to enhance transport of molecules across the stratum corneum barrier to deeper layers of the skin. The acoustic cavitation generated by ultrasonic devices and the subsequent collapse of microbubbles on the skin's surface leads to enhanced permeability which is thought to play an essential role in ultrasound-assisted delivery of active ingredients to target tissues and cells. This form of therapy is less invasive and less painful than other forms of delivery including microneedling and injection.

The Epinova treatment is customisable based on consultation and analysis of each patient's unique skin type, underlying conditions and desired results.

The pharmacologic agents applied topically include hydroxy acids, masks and vitamins infusions which are manually and ultrasonically infused. The specific active ingredients used are based on the skin therapist's analysis of the patient's skin.

This facial treatment achieves clinical results without downtime and incorporates lifting massage techniques to reap the health benefits of relaxation and massage. Clinical facial treatments such as laser may not be pleasant to experience whereas beauty treatments may not yield long-term results for skin health. The Epinova encompasses both to achieve your skin goals.

2. Materials and Methods

2.1. The Epinova Procedure

The procedure begins with consultation and diagnosis. Treatment incorporates a

deep cleanse with barrier lipid enriched cleanser, application of alpha/beta hydroxy acid solution, infusion of vitamins and antioxidants using an ultrasound device and LED treatment with 415 nm or 830 nm light.

2.2. Consultations and Diagnosis

Identification of facial skin concerns is the primary objective of the skincare consultation process. This provides a deep understanding of the patient's priorities and allows therapists to select the most appropriate treatment [1].

Facial imaging, using VISIA (Canfield, NJ, USA) **Figure 1** deploys polarised light capture to provide invaluable data at multiple levels in the skin, identifying inflammatory, vascular, pigmentary, sebaceous, and textural anomalies that may need to be addressed to bring about visible skin rejuvenation [2]. Imaging data provides the therapist with visible tools that can be used to explain various skin conditions and proposed pathways of therapeutic options to patients.

The consultation must also include in-depth questions designed to elicit knowledge of the patient's medical skin history, pre-existing skin conditions, medications prescribed and home-use skincare regimens.

The insights gained via a combination of imaging data and verbal consultation will ensure accord between patient and therapist regarding the patient's state of skin health, desired outcomes and treatments/products recommended.

2.3. Contraindications

All facial rejuvenation treatments possess an array of contraindications or precautions, which the therapist must understand prior to the application of modalities and pharmacologic agents. Whilst many of the precautions are general, some are more specific to the modality selected. See **Table 1**.



Figure 1. Visia skin analysis system (Canfield, NJ, USA).

Table 1. Contraindications to RATIONALE Epinova.

General Precautions:	LED Specific Contraindications:	Ultrasound Specific Contraindications:
Active herpes infection (cold sores)	Photosensitising medications	Diabetes, impaired sensation
Injury/broken skin	Isotretinoin medication	Metal implants, braces, plates, pins
Recent hair removal treatments	Oral or topical antibiotics	Heart conditions
Resurfacing laser, IPL, or electrical treatments	Anticoagulant medications	Pacemaker
Abrasive microdermabrasion or ablative skin treatments	Immunosuppressant medications	Epilepsy
Chemical peels	Topical benzoyl peroxide	Chemotherapy/radiation
Dermal fillers and botulinum toxin injections	Topical corticosteroids	Migraines
Pregnancy and breastfeeding	Overactive or underactive thyroid	Autoimmune disease
Topical or oral prescription Vitamin A (tretinoin/isotretinoin)	Hormone replacement therapy medication	
Facial surgery	Active cancer	
Allergies	Albinism	
	Autoimmune disease, <i>i.e.</i> , lupus	

2.4. Pharmacological Agents

To achieve optimal skin rejuvenation, the pH of the stratum corneum (SC) should be in the healthy acidic range of 4.5 - 5.5 [3]. When SC conditions are too alkaline, a variety of pathologies, lack of resilience and susceptibility to premature ageing may manifest.

Under acidic conditions, the skin's connective tissue synthesizing enzymes function optimally. Connective tissue stimulating hydroxylases are upregulated, resulting in firmer, more resilient skin, while collagen and elastin degrading matrix metalloproteinases (MMP's) are downregulated. Conversely, when the SC becomes more alkaline as a result of photodamage, MMP's are upregulated and hydroxylases downregulated, leading to skin laxness, wrinkles and sagging [4].

In addition, acidic SC pH ensures optimal cellular resurfacing for improved skin tone and texture. This process can be stimulated through the precise application of hydroxy acids, (also described as enzyme reactivators), including lactic acid (LA), pyruvic acid (PA) and salicylic acid (SA). During the diagnostic process the skin therapist determines which of these pharmacological agents is most suited to their patient's skin type, existing conditions and desired outcomes. The improvement in SC superstructure and integrity elicited by acidic pH adequately prepares the skin for the application of further pharmacological agents, ultrasound, and LED therapy [5].

Prior to the application of the prescribed hydroxyacid solution, a preparatory lactic acid solution is applied in firm, outward motions to remove excess sebum,

dirt or debris and ensure adequate penetration of the hydroxyacid solution. To follow, a protective lipid-rich balm is applied to the delicate tissues of the lips, nostrils and periorbital zone.

LA is an alpha hydroxy acid (AHA) well suited to resilient skin types. LA boosts SC hydration by upregulating natural moisturising factors (NMF), also stabilising the skin's microbiome as the SC microbiota are supported by the NMF system. LA hosts its own form of bacteria, lactobacillus, which is also found in the skin microbiome. The topical application of LA also increases ceramide production, fortifies barrier function, fades hyperpigmentation, and stimulates collagen production.

By acidifying the SC, lactic acid induces desquamation of surface corneocytes by upregulating various proteases that break down desmosome bonds between mature and deeper corneocytes. This process resurfaces the skin, allowing for optimal penetration of pharmacologic agents with ultrasound and LED.

PA is a metabolic alpha-keto acid (AKA) that has a high affinity for phospholipid cell membranes. As a major metabolite in the Krebs cycle, PA provides cellular energy through adenosine triphosphate (ATP), making it suitable for all skin types and conditions. Its strengthening properties and skin-compatible biochemistry make it suitable for sensitive skin and safe for all Fitzpatrick skin types. PA produces less sensation during treatment and has no downtime.

In contrast to LA and PA, SA is a beta hydroxy acid (BHA). Its lipid-soluble nature normalises sebaceous activity and clears pilosebaceous cellular debris, making it an appropriate treatment for oily skin and acne-prone patients.

By prepping the skin with pharmacological agents such as LA, PA, SA, the penetration of further skincare actives and effectiveness of modalities to follow is enhanced. To obtain visible and long-term skin rejuvenation, the therapist must ensure that the skin is prepped and stimulated at all stages in a controlled and precise manner. The application of orthomolecular mask formulations containing B-group vitamins, water-soluble hyaluronic acid, magnesium, copper and zinc will deliver hydration, strengthen barrier function, reduce redness and restore skin resilience. Such formulations should be applied with upwards strokes and slight pressure to stimulate circulation and promote blood flow. Once the mask has been applied for the optimal time frame of 20 minutes it must be removed, ready for the application of phototherapy in the form of LED, to promote ultimate skin rejuvenation.

2.5. Modalities

Non-invasive skin rejuvenation involves the stimulation of connective tissue (collagen and elastin) synthesis, optimal cellular differentiation and desquamation, even melanin distribution and surface hydration. The result is a firmer facial profile and a smoother, clearer, more youthful and luminous complexion.

Two well established and researched modalities; ultrasound and LED, are helpful in this type of skin rejuvenation. An example of a suitable ultrasound de-

vice is ELEGANS “Ultrasonic Sonophoresis” (Figure 2), which can be used to infuse orthomolecular active ingredients through the stratum corneum to reach deeper keratinocytes, melanocytes and even dermal fibroblasts. Skin ultrasound devices operate at frequencies ranging from 1 - 3 Megahertz. Sonic waves of this magnitude disrupt intercellular lipids and cell membranes, allowing for enhanced penetration and oxygenation of skin tissues and cells [6].

Ultrasound also generates thermal effects throughout the epidermis and dermis, promoting blood flow and stimulating collagen production [7].

For optimal efficiency of ultrasound, the skin should be well hydrated. A lack of moisture impedes sound transfer [8]. A tailored water-based mask infusion is applied prior to ultrasound in an uplifting application technique to hydrate the skin’s surface prior to treatment. This medium is used to aid the delivery of ultrasound energy towards the dermal tissues to stimulate collagen production for a more youthful skin appearance. In addition, ultrasound enhances penetration of the active ingredients in the hydrating mask solution to improve skin concerns. Niacinamide, hyaluronic acid or L-ascorbic acid solutions can all be delivered in this manner, depending on the condition being treated. The infusion of hydrating ingredients such as hyaluronic acid has been shown to decrease transepidermal water loss (TWEL) [9].

The second form of non-invasive skin rejuvenation modality deployed in the RATIONALE Epinova treatment is LED Light Therapy using the Healite II (Lutronic, South Korea) (Figure 3) a form of phototherapy which translates as “*light healing*” [10]. The Healite II can deliver energy at four different skin depths; 415 nm, 590 nm, 633 nm and 83 nm to initiate skin rejuvenation without causing thermal damage. Four possible physical interactions of Low-Level Light Therapy (LLLT) on the skin exist; reflection, transmission, scattering and absorption. Light that is not immediately reflected passes through the stratum corneum, via transmission through the epidermis to the dermis, where the energy form can then either scatter throughout the dermis and/or be absorbed by skin cells as a source of cellular energy. Near-Infrared energy (NIR) and blue light (BL) can both be delivered to the skin using Healite II by Lutronic.

NIR is most commonly used for skin rejuvenation as it accelerates healing and promotes healthy cellular function through a reduction of inflammation and optimization of skin immune responses [10] [11]. BL is an effective adjunct in the



Figure 2. Elegans Ultrasonic Sonophoresis.



Figure 3. Healite II (Lutronic, South Korea).

treatment of acne due to its ability to normalise skin microbiota, particularly the pathogenic over-colonisation of *C. acne* [12].

For LED skin rejuvenation treatment to be effective, multiple parameters must be considered, including: wavelength of light, intensity of photons to be delivered, length of the treatment and distance from the light source to the skin. 830 nm is considered the most efficacious wavelength for this purpose as it provides a superior penetrative depth and can photo-activate a larger number of cells (See **Figure 4**) [10]. To prepare skin for LED light therapy, an array of pharmacological agents can be applied to help rebalance, stabilise, and remove excess sebum and corneocyte build-up from the stratum corneum.

2.6. Post-Treatment Care and Maintenance

After the application of facial rejuvenation formulations and modalities, the patient should apply barrier-restoring products containing ceramides and intercellular lipids, such as cleansers and Crème's, whilst using SPF50+ every day. The patient should cease use of hydroxy acids and retinoids for up to 72 hours post-treatment to reduce additional skin resurfacing, erythema or skin irritation. To maintain the skin's health after 72 hrs and see maximum benefit from their treatment, the patient should incorporate all the vital nutrients for skin health

and facial rejuvenation such as: B-group vitamins (including niacinamide), skin identical antioxidants (vitamin C, vitamin D, vitamin E) and zinc oxide SPF 50+ by day, as well as, ceramides and intercellular lipids, hydroxy acids, and retinoids each night.

In two separate studies, Tanaka reports 2-D and 3-D improvements in skin tone, texture and volume following this regimen (The RATIONALE Essential Six, **Figure 5**) [2] [13]. Tanaka, Parker and Aganahi were also able to validate the broad spectrum (UV, Visible light, NIR) efficacy of the RATIONALE #3 Tinted Serum SPF50+ Zinc-Fusion Superfluid optically [14] [15] [16] and substantiate epigenetic upregulation of genes responsible for immune, antioxidant and solar

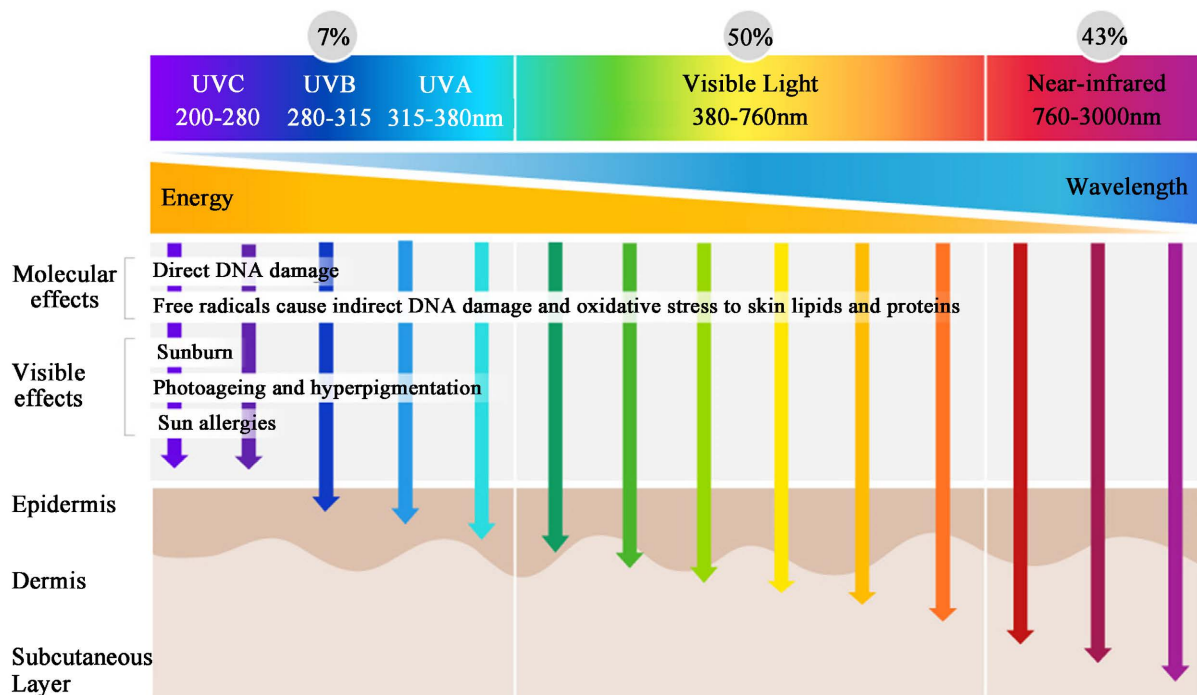


Figure 4. Skin penetration of electromagnetic radiation.



Figure 5. The RATIONALE Essential Six (RATIONALE, Victoria, Australia).

protection in addition to barrier repair, pH repair and DNA repair in a 3-D reconstructed human skin model treated with The RATIONALE Essential Six [17].

3. Results

To promote facial rejuvenation, the combination of LED with pharmacologic and ultrasonic technologies should be performed in line with the skin's natural cell cycle. New cells are formed at the base of the epidermis, and take approximately 28 - 40 days to mature and migrate upward to form the outermost layer of the epidermis (the stratum corneum). These surface cells, known as corneocytes, are then required to desquamate to enable new, healthy cells to form the next iteration of the stratum corneum skin barrier, ensuring a more resilient, youthful skin tone and texture. In general, for patients under 40, rejuvenating treatments should be performed every 4 - 6 weeks, while patients over 40 should undergo treatment every 3 - 4 weeks to overcome the natural retardation of the cell cycle turnover that occurs with age. By supporting and optimising the skin's natural rhythm of differentiation, migration and desquamation through the treatment techniques discussed here at the required frequency and intensity, non-invasive facial rejuvenation can be achieved.

4. Discussion

To be truly classified as non-invasive, rejuvenating skin treatments must visibly improve skin tone, texture and radiance without trauma. This eliminates treatments that cause inflammation, including lasers, radio-frequency, skin needling and injectables. Non-invasive treatments should simultaneously bring about a reduction in inflammation and erythema while boosting skin barrier function, resilience and hydration.

The RATIONALE Epinova treatment synergy of diagnostic, pharmacologic phototherapeutic and sonotherapeutic modalities, combined with daily use of a solar-specific daily skin protection and nightly repair topical regimen results in visible and measurable improvements in skin quality and appearance [2] [13]. Further studies are required to determine the effect of the regular in-clinic, non-invasive treatments to determine genetic and histological changes.

Imaging technologies improve the detection and diagnosis of skin concerns, including solar-induced pigmentation and erythema. This tool provides invaluable, visible data during the consultation to assist practitioner and client in understanding the client's current skin status and possible treatment pathways, greatly enhancing accuracy and outcomes. Patients reported greater satisfaction with results when diagnostic imaging formed part of the consultation process [1].

To avoid adverse reactions or diminish results, strict adherence to exclusion criteria (contraindications) is necessary. Patients should not undergo Epinova treatment if they have recently used irritating medications or treatments that

cause inflammation. The aim is rejuvenation of facial tissues without trauma. The treatment commences with a barrier-lipid rich cleanser to remove makeup and excess lipids without stripping or irritating the skin. Replenishment of barrier lipids prior to treatment enhances uptake of pharmacologic agents to be subsequently applied.

Selection of the correct hydroxy acid to re-acidify the stratum corneum depends on skin fragility, resilience and seborrheic tendency. Application of the appropriate hydroxy acid immediately lowers skin pH, initiating the upregulation of enzymes responsible for connective tissue synthesis, optimal differentiation and hydration while downregulating inflammatory agents and connective tissue degrading matrix metalloproteinases [4]. Skin reactions should be carefully monitored, but the lower-strength hydroxy acids used in the Epinova Treatment do not require neutralization. Likewise, “second pass” applications are not required or recommended.

Following SC re-acidification, the therapist is able to administer a customized “cocktail” of skin identical vitamins, minerals, antioxidants and lipids, depending on skin condition and desired outcomes. To deliver these actives to target tissues and cells, sonophoresis is deployed. By temporarily altering the physiology of intercellular lipids, sonophoresis allows larger molecules including proteins and antioxidants to cross the stratum corneum barrier [3]. Evidence also suggests that ultrasonic wave energy, in itself, contributes to facial rejuvenation and “lifting” effects, possibly by improving muscle tone or stimulating connective tissue synthesis [6] [7] [8].

Next, LED light is administered to the desired facial field to bring about therapeutic endpoints, for example a reduction in inflammation, edema or erythema. Such endpoints require specific LED wavelengths, requiring experience and knowledge on the part of therapists to make the correct wavelength selection.

Ultimately, long-term results of Epinova treatment depend largely on the disciplined adherence to a daily skincare regimen encompassing solar protection by day and solar repair at night, *i.e.* the RATIONALE Essential Six.

5. Conclusion

The tone and texture of photoaged skin can be rejuvenated by combining a daily solar protection and repair skincare regimen with regular in-clinic treatments employing pharmacologic, LED and ultrasound technologies.

Limitations

Inclusion of a control group and a comparison between dosage strengths and frequencies would enhance the significance of our findings.

Disclosure

The authors disclose that this study was entirely funded by RATIONALE Skincare Pty Ltd., Victoria, Australia. Author 1 are paid employees of RATIONALE.

Author 2 is a paid consultant plastic surgeon for RATIONALE.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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