Effectiveness of SHEALD[™] RECOVERY BALM Plus CLEANSING COMPLEX

After Fractionated Laser Procedures

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STUDY OBJECTIVE

Fractionated laser treatment as well as other cosmetic procedures aim to deliver desirable cosmetic results with restoration of a healthy more youthful skin surface. Patients strongly desire less downtime and fewer complications. This study was performed to determine if using iS CLINICAL®'s SHEALD™ RECOVERY BALM and CLEANSING COMPLEX immediately following fractionated laser treatments furthered these goals of both physician and patient.

STUDY DESIGN

Plastic surgeons and aesthetic dermatologists were asked to evaluate SHEALD[™] RECOVERY BALM in combination with CLEANSING COMPLEX when used immediately after fractional laser treatments. SHEALD[™] RECOVERY BALM was applied to the treated area every 2-3 hours in a thin layer. A thicker layer was applied at the patient's discretion based on level of discomfort. CLEANSING COMPLEX was used to gently cleanse the treated area 3 times daily after which SHEALD[™] RECOVERY BALM was immediately reapplied. Physicians were asked to use this regimen instead of their previously preferred wound care products and evaluate results in these parameters: 1) peeling/flaking; 2) occurrence of milia; 3) speed of re-epithelialization.

SIGNIFICANCE OF STUDY

Both physicians and patients continually search for products and procedures that decrease the rate of complications, improve post-procedure results, lessen downtime, and minimize patient discomfort. The parameters evaluated during this study are of primary importance in achieving favorable post-fractional laser results. PERCENTAGE IMPROVEMENT with SHEALD™ RECOVERY BALM + CLEANSING COMPLEX Post-Laser



Figure 1. Percentage of parameter improvement using SHEALD[™] RECOVERY BALM in conjunction with CLEANSING COMPLEX. Patient improvement reported by physician survey utilizing a ranking poll.

RESULTS AND CONCLUSIONS

<u>Milia</u>

Milia are small white bumps occurring during the initial days after laser treatments and are caused by micro-disruptions in the hair follicle. They consist of tiny cysts filled with keratin debris. Milia are temporary but patients often find them distressing, resulting in scratching or popping of the milia unit. Complications such as infections or scarring may then ensue. Practitioners often remove milia in the office although this may extend procedure recovery time. The incidence of milia reported by various authors following fractional laser treatments is in the range of 14-15 percent and sometimes as high as 19 percent¹ of all patients having the procedure. With combined use of SHEALD™ RECOVERY BALM and CLEANSING COMPLEX, the incidence of milia decreased 85 percent compared to the usual frequency; in other words, the occurrence of milia dropped to 2-2.8 percent of all patients. Such a dramatic reduction in occurrence of milia directly supports the effectiveness of CLEANSING COMPLEX's mechanism of gentle cleansing within the follicular unit, as well as SHEALD[™] RECOVERY BALM's mechanism for rapid re-epithelialization and healing. Results indicate SHEALD[™] RECOVERY BALM and CLEANSING COMPLEX markedly reduce the occurrence of post-procedural milia.

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¹ TS Alster, Al Metelitsa. 2010. Fractionated Laser Skin Resurfacing Treatment Complications: A Review. Dermatologic Surgery 36(3):299-306.



Peeling and/or Flaking

Peeling and/or flaking are common side effects of laser treatments that increase down time and are often uncomfortable. Fractionated laser treatments aim to reduce the occurrence of peeling or flaking in comparison to previous laser treatments. Peeling and flaking reduce the advantages of newer fractionated laser treatments. The use of SHEALD[™] RECOVERY BALM and CLEANSING COMPLEX improved peeling and flaking by 41 percent and therefore significantly reduced downtime.

Re-Epithelialization

Re-epithelialization is a key aspect of a successful outcome following fractionated laser treatments. Restoration of healthy skin is the goal of laser treatment. Re-epithelialization was measured by a 54 percent improvement in rapidity of growth of new overlying epithelium in the treatment area, following the use of SHEALD[™] RECOVERY BALM and CLEANSING COMPLEX. An increased rate of healing significantly improved downtime with this protocol. SHEALD[™] RECOVERY BALM and CLEANSING COMPLEX would therefore be expected to decrease the risk of adverse reactions by accelerating healing of the treatment area, maximizing a successful outcome.

No Adverse Effects

No adverse effects including redness, irritation, stinging, burning or itching were reported when SHEALD[™] RECOVERY BALM was placed on open skin (ablative procedures). SHEALD[™] RECOVERY BALM was found to be safe and effective for both ablative and non-ablative procedure types.

SUMMARY

Physicians reported improved results in the successful healing of treatment areas using SHEALD[™] RECOVERY BALM and CLEANSING COMPLEX as post-procedural care products. The use of SHEALD[™] RECOVERY BALM plus CLEANSING COMPLEX decreased the occurrence of milia and peeling and induced more rapid re-epithelialization in fractionated laser patients.

REFERENCES

- N Abbasi, KA Arndt, JS Dover, MA Durfee, MS Kaminer, BC Latowsky, JL Macgregor, TE Rohrer, SR Tahan, NO Wesley. 2012. A Randomized Controlled Trial of Four Ablative Fractionated Lasers for Photoaging: A Quadrant Study. Dermatologic Surgery 38(9):1477-89.
- PA Adamson, E Brunner, DA Ellis, JN Harlock, J Otolaryngol. 2000. Laser Facial Resurfacing: Patient Survey of Recovery and Results. 29(6):377-81.
- TS Alster, EM Graber, EL Tanzi. 2008. Side Effects and Complications of Fractional Laser Photothermolysis: Experience with 961 Treatments. Dermatologic Surgery 34(3):301-7.
- TS Alster, Al Metelitsa. 2010. Fractionated Laser Skin Resurfacing Treatment Complications: A Review. Dermatologic Surgery 36(3):299-306.
- TS Alster, M Lazarus, EL Tanzi. 2007. The Use of Fractional Laser Photothermolysis for the Treatment of Atrophic Scars. Dermatologic Surgery 33(3):295-9.
- TS Alster, EL Tanzi. 2003. Side Effects and Complications of Variable-Pulsed Erbium: Yttrium-Aluminum-Garnet Laser Skin Resurfacing: Extended Experience with 50 Patients. Plastic Reconstructive Surgery 111(4):1524.
- J Drugs, CW Hanke, EP Tierney. 2010. Treatment of CO2 Laser Induced Hypopigmentation with Ablative Fractionated Laser Resurfacing. Dermatology Case Report and Review of Literature 9(11):1420-6.
- DJ Goldberg, J Man. 2012. Safety and Efficacy of Fractionated Bipolar Radiofrequency Treatment in Fitzpatrick Skin Types V-VI. Cosmetic Laser Therapy 14(4):179-83.
- MP Goldman, JD Peterson, O Shamsaldeen. 2001. The Adverse Events of Deep Fractional CO(2): A Retrospective Study of 490 Treatments in 374 Patients. Lasers and Surgical Medicine 43(6):453-6.vv

INNOVATIVE SKINCARE®

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SHEALD[™] RECOVERY BALM

5.5 pH +/- 0.5 60ml £48



PROTECTIVE | SOOTHING | POST PROCEDURE

A powerful reparative formula, SHEALD[™] RECOVERY BALM is a gentle fortifying solution designed to address the special needs of postprocedure and compromised skin. SHEALD[™] RECOVERY BALM calms and encourages skin recovery while immersing severely dry skin in deep, healthy hydration. Antimicrobial and fragrance-free, this ultra-soothing balm helps to prevent the appearance of scarring and maximize your results.

BENEFITS

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- Stimulates human keratinocyte differentiation while decreasing inflammation
- Reduces irritation & discomfort with a thick antimicrobial environmental barrier
- Encourages collagen synthesis
- Softens & hydrates raw, dry, sensitive skin
- · Prevents scabbing & relieved itching or tightness
- Antioxidant rich formula minimizes scars
 - Faster healing in all types of wounds

KEY INGREDIENTS	INGREDIENT BENEFITS
CERAMIDE NP, CERAMIDE AP, CERAMIDE EOP, CHOLESTEROL, PHYTOSPHINGOSINE, ZEA MAYS (CORN) KERNAL EXTRACT (hyaluronic acid-botanically derived) 5.0%	A group of lipid molecules bioidentical to those synthesized by the stratum corneum. Necessary for healthy barrier function. Antimicrobial. Important for apoptosis and signaling of functional epithelium. Includes a botanical source (Zea mays) of Vitamin E. Temporarily assumes and augments skin functions prior to re-epithelialization.
SODIUM HYALURONATE (hyaluronic acid-botanically derived) 10.0%	Humectant; demonstrates hydrophilic properties – attracts and binds up to 1800 times its molecular weight in water.
GLYCERIN 8.0%	Necessary for proper barrier function and protection during the healing process. Gives softness and smoothness to counteract dryness and irritation from procedures.
TOCOPHEROL (Vitamin E) 3.0%	Potent antioxident that inhibits DNA damage, thymine dimer formation, inflammation and oxidative damage. Protects against UV-induced (photo) damage.
PANTHENOL (Vitamin B5) 1.0%	Essential element required for enzymatic functions within all cells. Enables the metabolism of carbohydrates, proteins, and lipids, increasing cellular integrity and efficiency.
AHNFELTIA COCINNA EXTRACT 2.0%	An intertidal seaweed algae extract from the Rhodophyta group containing proteoglycans, peptides, polypeptides and glycans. Contains high amounts of 4-hydroxproline, an unusual amino acid found only in collagen, which triggers the epidermis to begin the collagen repair process.
AVENA SATIVA (OAT) KERNAL EXTRACT 3.0%	Biomodulator of inflammatory processes, it soothes and calms irritation and redness. Fortifies epithelial structural elements.
PIPER METHYSTICUM LEAF/ROOT/STEM EXTRACT (Kava kava) 2.0%	Controls pain due to local anaesthetic effects and limits itch caused by nerve root stimulation during the healing process.

less peeling

85%

CLINICAL STUDY

RESULTS

41%

54% more rapid re-epithelialization





CLEANSING COMPLEX

5.6 pH +/-.25 60ml £16.00 180ml £34.00

RESURFACING I ANTI-ACNEIC I DEEP CLEANSING

This clear, lightweight cleansing gel is powerful - yet gentle enough for hypersensitive skin. Formulated with a balance of bionutrients, antioxidants and mild resurfacing ingredients that thoroughly cleanse without stripping essential natural oils. Skin benefits include the vitamin anti-oxidant blend encapsulated in a liposome for ease of penetration, combined with centella asiatica which stimulates collagen synthesis, promotes healing and the reduction of scar tissue.

BENEFITS

- · Deep cleans surface skin & pores without drying
- Gently resurfaces & removes dead skin cells
- · Helps to control acne & breakouts
- Prepares skin for treatment products
- Effectively removes makeup

PRODUCT HIGHLIGHTS

Excellent for all skin types and all ages, this product even helps control acne. CLEANSING COMPLEX is excellent as a treatment step in professional facials and is very effective for removing makeup.

KEY INGREDIENTS	INGREDIENT BENEFITS
0.5% SALIX ALBA (WHITE WILLOW BARK) EXTRACT (Source of salicylic acid)	Encourages desquamation by "dissolving" intracellular "cement" with no inflammatory effects. Also deep-cleans the pore and removes debris within follicles.
0.43% SACCHARUM OFFICINARUM (SUGAR CANE) EXTRACT (source of glycolic acid)	Desquamation agent; encourages the exfoliation of the stratum corneum.
0.2% CHAMOMILA RECUTITA (MATRICARIA) EXTRACT (chamomile)	Potent antioxidant that posses anti-irritant, antiviral and photo-protective properties
0.1% ASIATICOSIDE, ASIATIC ACID, MADECASSIC ACID (centella asiatica)	Potent antioxidant that stimulates collagen synthesis and improves microcirculation, capillary flow and vascular tone. Promotes wound healing and reduction of scar tissue.
0.025% RETINYL PALMITATE (vitamin A) 0.004% TOCOPHEROL ACETATE (vitamin E) 0.001% ASCORBYL PALMITATE (Vitamin C)	Powerful vitamin antioxidant blend encapsulated in a liposome for ease of penetration.