

Lytic Products Visibly Reduce Actinic and Senile Comedones

Clinical Assessment Results

ABSTRACT

Actinic and senile comedones occur in individuals exposed primarily to extreme weather. In a 16-week blinded, prospective, controlled clinical study, Epionce® Lytic Tx and Lite Lytic Tx eliminated 56.2% of the visible comedones and reduced the severity by 53.6%, both highly statistically significant ($p=0.0001$). Similar significant changes were also observed at 8 weeks. No panelists developed irritant reactions or symptoms with the test products.

INTRODUCTION

A clinical characteristic of extrinsic aging, which is often a challenge to treat, is actinic/senile comedones (ASC). These comedones may progress to follicular cysts and yellowish nodules usually distributed on the lateral and inferior aspects of the periorbital area. The constellation of nodules, cysts and comedones is known as Favre-Racouchot (FR) disease. It is reported to afflict 6% of people 50 years and older, predominately Caucasians with outdoor lifestyles and/or occupations.¹ Other than destructive procedures such as curettage, acne surgery and excision, topical tretinoin and systemic isotretinoin are the only medications reported to effectively treat FR and ASC.² Yet these two treatments are limited by adverse reactions especially in atopic, sensitive and elderly skin.

A blinded, prospective controlled clinical study was performed to assess effectiveness of two cosmeceutical products in visibly reducing the number and severity of ASC in 20 panelists. These botanical based products have keratolytic activity and prevent the release and activation of proinflammatory factors. The extracts are formulated in an emollient base that contains delivery systems to maximize efficacy and minimize the risk of adverse reactions.

PATIENTS

Twenty Caucasian panelists ages 62-85 signed an informed consent document. All panelists were Fitzpatrick photo skin types I-III. Individuals with adult acne and rosacea were excluded. Treatment consisted of a morning application of Lite Lytic Tx and an evening application of Lytic Tx for a period of 16 weeks. No sunscreens or moisturizers were allowed during the treatment period. In addition, no systemic retinoids, antiandrogens, estrogens, phytoestrogens or prolonged use of antibiotics were allowed during the trial.

METHOD

Board certified dermatologist investigators assessed the number and severity of facial open and closed comedones. Assessments were made at 0, 8 and 16 weeks. The clinical severity of the lesions were graded using a scale where 0 = none and 10 = severe. The mean value of severity of the lesions were graded using a scale where 0 = none and 10 = severe. The mean value of severity of the lesions and the number of lesions were statistically compared to baseline using a paired t-test with significance level of $p \leq 0.05$. After cleansing the face with a non-medicated cleanser, a dime-sized amount of the test material was applied over the entire face, avoiding the upper eyelid.

RESULTS

Visible actinic comedones resolved by 56.6% and severity of the lesions was reduced by 53.6% after 16 weeks of the test regimen. Both results are highly statistically significant with $p=0.0001$. The results at 8 weeks were similar statistically, but with lower raw scores, as shown in Table 1.

Table 1 - Clinical Grading and Lesion Count

	Baseline	Week 8		Week 16	
		%Δ	p value	%Δ	p value
Lesion Count	15.1	-31.6	0.0005	-56.6	0.0001
Severity	4.61	-28.0	0.0006	-53.6	0.0001

DISCUSSION

Actinic and senile comedones (ASC) and Favre-Racouchot (FR) syndrome both result from the loss of dermal connective tissue, particularly elastin with diskeratinization of the pilosebaceous follicle resulting in sebum retention.³ These abnormalities result from prolonged exposure to radiation, both ultraviolet and x-ray, as well as other physical climate agents on predisposed skin.⁴ These lesions have been observed in people as young as their late twenties with extensive exposure to the environment.⁵ Treatment for ASC and FR with traditional acne peeling is generally disappointing due to the depth and large size of the comedones.⁶ Dermabrasion, extraction, curettage and excision, topical tretinoin and oral isotretinoin have all been reported to have variable success. A combined approach with excision, dermabrasion and topical tretinoin appears to produce the best temporary results.⁷

Unfortunately, a major limiting factor for therapeutic success is the difficulty of minimizing tissue destruction in the atrophic skin, which results in slower healing time and less desirable cosmetic appearance. Poor patient compliance with the topical retinoids is another limiting factor since the afflicted, more mature population suffers from a higher incidence of irritant reactions and/or symptoms after application. Retinoid irritation approaches 30% in sensitive skin people.⁸ Dermatologists can expect similar irritation rates in atrophic and elderly skin. Moreover, there is a paucity of topical therapies with documented effectiveness for ASC and FR despite these conditions afflicting a significant number of people.

The test regimen consists of two novel cosmeceutical lotions. These products consist of blends of novel botanical extracts, including lipids and keratolytics combined with a naturally derived modified salicylate, in an emollient base that prevents release and activation of proinflammatory factors. The unique delivery systems in these products enhance delivery and maximize activity while reducing the risk of irritation.

These statistically significant trial results suggest these botanical extracts may have previously unreported phytoestrogenic or antiandrogenic activity. These botanical based products do not include teas, soy, vitamins, retinoids, alpha hydroxy acids and traditional

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antioxidants. Epionce cosmeceuticals are formulated for elderly, infant, atopic and sensitive skin, people with outdoor lifestyles and occupations and those who live in harsh environments and climates. All 20 patients tolerated these proprietary products without visible irritation or symptoms of itching, burning or sensitivity.

Epionce Lite Lytic Tx and Lytic Tx appear to be a significant advancement in apparently relieving people of a cutaneous nuisance.

REFERENCES

1. Friedman SJ, Su WPD. Favre Racouchet syndrome associated with radiation therapy. *Cutis*. 1983; 31:306-10.
2. Jansen T, Plewig G. Favre Racouchot disease In: Demis DJ (ed) *Clinical Dermatology*. Philadelphia: Lippincott-Raven. 1997; (1) 4-44: 1-4.
3. Izumi AK, Marples RR, Klingman AM. Senile solar comedones. *J Invest Dermatol*. 1973; 61: 46-50.
4. Schultz Larsen F, Heydenreich G, Christiansen JV. Comedone formation following cobalt irradiation. *Dermatologica*. 1979; 158: 287-92.
5. Cuce LC, Paschoal LHC, Curban GV. Cutaneous modular elastoidosis with cysts and comedones: cases in women. *Arch Dermatol*. 1964; 89:798-862.
6. Ogawa CM. Degenerative skin disorders. Toll of age and sun. *Geriatrics*. 1975; 30: 65-9.
7. Sharkey MJ, Keller RA, Grabski WJ, et al. Favre-Rocouchot Syndrome: A combined therapeutic approach. *Arch Dermatol*. 1992; 128: 615-6.
8. Leyden JJ, Grove GL. Randomized facial tolerability studies comparing gel formulations of retinoids used to treat acne vulgaris. *Cutis*. 2001; 67 (6 supp): 17-27.

