Episciences, Inc. Clinical Study

Epionce Lytic Lotion and Lite Lytic Lotion Help Visibly Reduce Sebaceous Hyperplasia

Abstract

Sebaceous hyperplasia lesions are visibly annoying to a significant number of middle aged, elderly and acne prone people. Two novel marketed cosmeceutical products, each used once daily for 16 weeks, produced highly statistically significant 43.6% reduction in the number and 51.5% reduction in the severity of sebaceous hyperplasia lesions. No panelist developed irritant reactions or symptoms with the test products.

Introduction

Sebaceous hyperplasia is a hypertrophy of the entire sebaceous gland developing into distinct visible benign neoplasms. The lesions are characterized by yellowish centrally umbilicated papules and less frequently, nodules on the forehead, nose and cheeks of usually middle aged and elderly people. These neoplasms often have telangiectasias, thus, may resemble basal cell carcinoma, intradermal nevi, trichoepitheliomas and xanthomas.[1] Other than destructive procedures, only systemic and topical retinoids are reported to somewhat effectively treat these lesions.[2,3]

This brief article summarizes a prospective controlled clinical study in which sebaceous hyperplasia lesions were visibly improved or resolved with topical application two novel cosmeceuticals: Epionce®Lytic and Lite Lytic Lotions. These botanical-based products have keratolytic activity and prevent the release and activation of proinflammatory factors in the skin. The extracts are formulated in an emollient base containing delivery systems to maximize efficacy and minimize the risk of adverse effects. Episciences, Inc. of Boise, Idaho, who generated safety and stability data to support these products, exclusively distributes these marketed, nonprescription lotions.

Patients

Seventeen Caucasian male and female panelists with Fitzpatrick photo skin types I -III ages 56-73 signed the informed consent. Panelists did not apply sunscreen or topical "antiaging" or acne therapeutic products during the treatment period. Systemic retinoids, antiandrogens, estrogens, phytoestrogens and prolonged use of antibiotics were prohibited during the trial. The test regimen consisted of Epionce Lite Lytic Lotion each morning and Epionce Lytic Lotion each evening, for 16 weeks.

Method

Board certified dermatologist investigators assessed the number and severity of facial sebaceous hyperplasia lesions at time 0, weeks 8 and 16. The clinical severity of the lesions were graded using a scale of 0=none to 10=severe. The mean values of clinical severity of the lesions and the number of lesions were statistically compared to baseline using a paired t-test with the significance level of p 0.05. After cleansing the face with a non-medicated cleanser, a dime-sized amount of the test material was applied gently over the entire face, avoiding the upper eyelid. These novel cosmeceuticals reduced the number of visible lesions by 43.6% and reduced the severity of the lesions by 51.5%, both highly statistically significant with $p<0.0001$. Similar statistically significant changes, but with lower raw scores, were also observed after only 8 weeks of therapy, as demonstrated in Table 1.

Discussion

Sebaceous hyperplasia, or senile sebaceous hyperplasia, commonly accompanies intrinsic aging. It may also occur in younger people with acne prone skin and individuals of any age suffering from seborrhea. These lesions have been a therapeutic conundrum as evidenced by the paucity of published reports of effective topical medicaments.[4]

This blinded, prospective, controlled clinical study documents visible resolution and reduction in severity of facial sebaceous hyperplasia lesions to a highly statistically significant degree by the 8 week visit. The test regimen consists of two novel cosmeceutical lotions distributed by Episciences, Inc.

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 study 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 or traditional antioxidants. Epionce cosmeceuticals are formulated for elderly, infant, atopic and sensitive skin, individuals with outdoor lifestyle and occupations, including those living in harsh environments and climates. All 17 patients tolerated these proprietary products without visible irritation or symptoms of itching, burning or sensitivity. The Epionce Lite Lytic and Lytic Lotions appear to be a significant advancement in apparently relieving people of a cutaneous nuisance.

References

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2. Burton CS, Sawchuk WS. Premature sebaceous gland hyperplasia: Successful treatment with isotretinoin. *J Am Acad Dermatol.* 1985; 12:182-4.
3. McCalmont TH Adnexal Neoplasms. In: Bolognia JL, Jorizzo JL, Rapini RP (eds) Dermatology. London: Mosby 2003; 112:1743.
4. Prioleau PG, Santa Cruz DJ. Sebaceous gland neoplasia. *J. Cutan Pathol.* 1984; 11:396-414.

Table 1 - Clinical Grading and Lesion Count

	Baseline	8 weeks		12 weeks	
		%Δ	p value	%Δ	p value
Lesion Count	5.18	-23.9	0.002	-43.6	<0.0001
Severity	4.31	-30.7	0.0001	-51.5	<0.0001