A RETROSPECTIVE REAL-LIFE STUDY OF THE SAFETY, EFFICACY AND THE CONDITIONS OF USE OF COSMO PEEL 12% AND COSMO PEEL 15% MEDICAL DEVICES. C ϵ 0051

Cosmo Peel 12% and 15% are superficial chemical peels intended for the treatment of solar lentigines, superficial pigmented lesions and keratosis pilaris.

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BACKGROUND

TCA 12 and TCA 15 are superficial chemical peels developed by Dermaceutic, formulated respectively with 12% and 15% of trichloroacetic acid (TCA) to effectively address a variety of skin conditions. They are available each in a kit Cosmo Peel 12% and Cosmo Peel 15%. In alignment with Dermaceutic's ongoing commitment to advancing non-invasive dermatological solutions and improving patient care, a retrospective clinical study was conducted in collaboration with a French investigator to describe the performance and safety of Cosmo Peel 12% and Cosmo Peel 15%. By sharing real-world clinical outcomes, Dermaceutic continues to support evidence-based skincare practices, safe and effective use of those medical devices.

OBJECTIVE

Dermaceutic conducted a retrospective clinical study to gather historical data on patients previously treated with Cosmo Peel 12% and 15%, superficial chemical peels classified as medical devices in France. The goal was to describe the real-life safety and performance of both products. The Dermaceutic clinical team is pleased to share the study results, which contribute to advancing knowledge about superficial chemical peels as an alternative treatment for skin abnormalities. This clinical study is registered in the French public registry, Health Data Hub, under the title: "Étude en vie réelle des conditions d'utilisation, de l'efficacité et de la tolérance du Cosmo Peel 12% et 15%."

INTRODUCTION

Cosmo Peel 12% and 15% are manufactured in France under stringent quality control measures, adhering to the highest standards for medical devices (ISO 13485). The peels' main active ingredient is trichloroacetic acid, well-known keratolytic agent capable of penetrating the superficial layers of the skin. Cosmo Peel 12% and 15% are specifically designed to treat solar Lentigines, keratosis pilaris, superficial pigmented lesions, fine lines, dull complexion and skin irregularities. Cosmo Peel 12% and 15% are performed as part of a full treatment with several sessions of peeling. This study was conducted as part of Dermaceutic's post-market surveillance of those medical devices.

MATERIALS / METHODS

The study was conducted in France based on the historical data retrieved from 20 patients treated with Cosmo Peel 12% and 15% from December 2023 to December 2024 by Dr F. Bedar. The data included demographic characteristics, skin phototypes, indications for use of Cosmo Peel 12% and 15%, adverse events and follow-up visits. Efficacy was assessed as variation in the severity grade of each indication of use before and after the treatment. The IGA scale (Investigator Global Assessment) was used as reference. Adverse events were compared with skin reactions described in the literature. Data were captured and analyzed using EasyMedStat software.

RESILITS

SUMMARY OF PATIENT DEMOGRAPHIC CHARACTERISTICS

All patients represented in this study were women.

Variable	N	Mean (SD)
Average age (range: 30-56 years old)	20	42.05 (8.37)
Treated with Cosmo Peel 12% (range: 30-56 years old)	9	42.32 (8.21)
Treated with Cosmo Peel 15% (range: 30-53 years old)	11	41.84 (8.49)
Skin Phototype	20	
IV		14 (70%)
II		2 (10%)
III		2 (10%)
1		1 (5%)

EFFICACY OF COSMO PEEL 12% AND 15%

Cosmo Peel 12% and Cosmo Peel 15% reduced the severity grades of various skin conditions. While both TCA concentrations demonstrated efficacy in improving skin conditions and texture, TCA 15% produced a greater mean reduction in severity grades, indicating enhanced clinical performance. These findings also highlight that even the lower TCA concentration (12%) exerts significant exfoliative and regenerative effects on the skin. Overall, the results confirm that both TCA 12% and TCA 15% are effective in addressing pigmentary and structural skin concerns.

Skin condition	Average variation of severity grade after Cosmo Peel 12%	Average variation of severity grade after Cosmo Peel 15%	Average variation of severity grade after Cosmo Peel 12% and 15%
Solar Lentigines	-0.33	-1.33	-0.83
Superficial Pigmented Lesions	-0.60	-1.00	-0.82
Fine lines	-0.50	-0.67	-0.62
Dull complexion	-1.67	-1.40	-1.53
Skin irregularities	-1.11	-1.33	-1.22

BEFORE AND AFTER

Superficial pigmented lesions









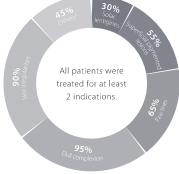


SAFETY OF COSMO PEEL 12% AND 15%

No serious adverse events related to the treatment peels.

As expected, adverse events such as erythema, burning sensation, and white frosting were observed during the peel application.

Desquamation occurred as part of the normal healing process, typically resolving within 72 hours.



CONDITIONS OF USE

- 100 % of participants were treated on the full-face area.
- 100% of participants were treated with Cosmo Peel 12% and 15% for at least two skin indications simultaneously.
- Dermaceutic products used before, during and after Cosmo Peel 12% and 15%:

Protocol	Dermaceutic Products
Pre-treatment	Hyal Ceutic, Foamer 5-15, C25 Cream, one peel of Milk Peel, Actibiome (old formula of current Activabiome), Tri Vita C30
Treatment	With Cosmo Peel 12%, at least 2 sessions With Cosmo Peel 15% between 2-3 sessions
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(*) acne, post-inflammatory hyperpigmentation scars and melasma.

CONCLUSION

The retrospective and observational study on Cosmo Peel 12% and Cosmo Peel 15% as Class IIa medical devices, shows that they are effective in treating solar lentigines and superficial pigmented lesions, as well as in improving the appearance of fine lines, dull complexion and skin irregularities.

As expected with chemical peels, adverse events such as erythema, burning sensation, white frosting, and desquamation were observed during the procedure and throughout the post-treatment healing process.

Cosmo Peel 12% and 15% have shown a favorable safety and efficacy profile enabling professionals healthcare to customize treatments according to each patient's clinical indications and skin needs.



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